For use in Ireland

Tyenne®
tocilizumab

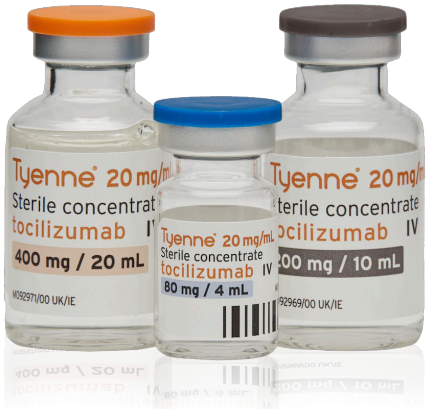
TYENNE Dosing Guide

TYENNE intravenous (IV) and subcutaneous (SC) formulations

A guide to assist healthcare professionals with the dose preparation and administration of TYENNE therapy in patients with:

- Rheumatoid Arthritis [Intravenous or subcutaneous]
- Giant Cell Arteritis [Subcutaneous]
- Polyarticular Juvenile Idiopathic Arthritis (also referred to as Juvenile Idiopathic Polyarthritis) [Intravenous or subcutaneous]
- Systemic Juvenile Idiopathic Arthritis [Intravenous or subcutaneous]
- Tyenne is indicated for the treatment of chimeric antigen receptor (CAR) T-cell induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older [Intravenous]
- Tyenne is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation [Intravenous]

This Tyenne Dosing Guide is additional risk minimisation material and is provided by Fresenius Kabi (Ireland) Limited as a condition of the Tyenne marketing authorisation. It contains important safety information that you need to be aware of when administering Tyenne. This Tyenne Dosing Guide must be read together with the Tyenne Healthcare Professional and Patient Brochures (available online at www.hpra.ie), the Tyenne Summary of Product Characteristics and the Package Leaflet that comes with Tyenne (and is also available on www.medicines.ie) as it contains important information about Tyenne. Please read this information carefully



TYENNE
20mg/ml concentrate solution for infusion

TYENNE
162mg/ml solution for injection prefilled syringe (PFS)

TYENNE
162 mg solution for injection in prefilled pen.

This educational material is provided by Fresenius Kabi and is mandatory as a condition of the Marketing Authorisation in order to minimize important selected risks. Full prescribing information can be found in the TYENNE® Summary of Product Characteristics (SmPC): www.medicines.ie (Ireland)

FRESENIUS KABI
caring for life

Indications and Usage
TYENNE Intravenous

TYENNE 20 mg/ml concentrate for solution for infusion

TYENNE, in combination with methotrexate (MTX), is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, TYENNE can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

TYENNE has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX.

TYENNE is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Tyenne can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

TYENNE in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Tyenne can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

TYENNE is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life threatening cytokine release syndrome in adults and paediatric patients 2 years of age and older.

TYENNE is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation [Intravenous].

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TYENNE Subcutaneous

TYENNE 162 mg solution for injection in pre-filled syringe (PFS)

TYENNE, in combination with methotrexate (MTX), is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- The treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Tyenne can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Tyenne has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX.

TYENNE is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

TYENNE is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Tyenne can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

TYENNE in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Tyenne can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

TYENNE 162 mg solution for injection in pre-filled pen

TYENNE, in combination with (MTX), is indicated for:

- The treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, Tyenne can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

TYENNE has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX.

TYENNE is indicated for the treatment of active sJIA in patients 12 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids.

TYENNE can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

TYENNE in combination with MTX is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 12 years of age and older, who have responded inadequately to previous therapy with MTX).

TYENNE can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

TYENNE is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

General information

Tocilizumab SC formulation is administered with a single-use pre-filled pen. Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, sJIA, pJIA and/or GCA. The pre-filled pen should not be used to treat paediatric patients < 12 years of age since there is a potential risk of intramuscular injection due to thinner subcutaneous tissue layer. The first injection should be performed under the supervision of a qualified health care professional. A patient or parent/guardian can inject TYENNE only if the physician determines that it is appropriate and the patient or parent/guardian agrees to medical follow-up as necessary and has been trained in proper injection technique. Patients who transition from tocilizumab IV therapy to SC administration should administer the first SC dose at the time of the next scheduled IV dose under the supervision of a qualified healthcare professional. All patients treated with TYENNE should be given the Patient Alert Card. Suitability of the patient or parent/guardian for subcutaneous home use should be assessed.

Prior to starting treatment with TYENNE

It is important that you review the baseline checklist found under section "General Recommendations" in the Tyenne Healthcare Professional Brochure with your patient, the patient's parents/guardians, or both. These documents contain valuable information that will help your patients fully understand what they may expect from their treatment.

Allow ample time to discuss any questions your patient, the patient's parents/guardians, or both may have.

It is important that you review the information contained within the TYENNE Healthcare Professional (HCP) Brochure for TYENNE® (tocilizumab) intravenous (IV) and subcutaneous (SC) formulations and the TYENNE Patient Brochure with your patient, the patient's parents/guardians, or both. These will help them understand what they may expect from the treatment of the patient's condition with TYENNE

- For full information, see the Summary of Product Characteristics (SmPC) and the Package Leaflet, which can be found on www.medicines.ie (Ireland)
- TYENNE Patient Alert Cards and other information can be requested from your sales representative or Medical Information. If you have questions or concerns, please email Medical.information-UK@fresenius-kabi.com or call +44 1928 533 575

Part I: Intravenous (IV) administration of TYENNE by infusion

This section will walk you through the TYENNE infusion process in 6 steps

1. Weigh patient and calculate TYENNE dose based on indication

TYENNE dosing is calculated based on each patient's weight and the indication for which they are treated. The treatment frequency varies by indication. Verify the patient's weight and indication, then locate it on the charts (included on the following pages) to find the corresponding dose and recommended vial combination. If the patient's dose has been calculated prior to the infusion date, take his or her weight to ensure that it has not changed from the time of the original calculation necessitating a change in dose. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the relevant chart to check whether a dosing adjustment is necessary. Once the dose is calculated, choose the vial combination of TYENNE that best matches the patient's needs.

RA: Dosing Preparation and Administration Guide with TYENNE IV

TYENNE dosing is calculated based on each patient's weight as follows:

For the 8 mg/kg dose:
Patient weight (kg) x 8 mg/kg
= TYENNE dose

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended.

Dosing should take place at 4-week intervals.

Once the dose is calculated, choose the vial combination of TYENNE that best matches the patient's needs.

TYENNE is available in three different dosing vials:

400 mg (20 ml) vials

200 mg (10 ml) vials

80 mg (4 ml) vials

Parenteral medicinal products should be inspected visually for particulate matter or discolouration prior to administration. Only solutions which are clear and colourless to pale yellow and practically free of visible particles should be diluted. Use a sterile needle and syringe to prepare TYENNE.

Doses above 1.2 g have not been evaluated in clinical studies.

Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
50	110.0	400	20.0	1 × 400 mg
52	114.4	416	20.8	1 × 400 mg + 1 × 80 mg
54	118.8	432	21.6	1 × 400 mg + 1 × 80 mg
56	123.2	448	22.4	1 × 400 mg + 1 × 80 mg
58	127.6	464	23.2	1 × 400 mg + 1 × 80 mg
60	132.0	480	24.0	1 × 400 mg + 1 × 80 mg
62	136.4	496	24.8	1 × 200 mg + 4 × 80 mg
64	140.8	512	25.6	1 × 200 mg + 4 × 80 mg
66	145.2	528	26.4	1 × 400 mg + 1 × 80 mg
68	149.6	544	27.2	1 × 400 mg + 1 × 80 mg
70	154.0	560	28.0	1 × 400 mg + 1 × 80 mg
72	158.4	576	28.8	1 × 400 mg + 1 × 200 mg
74	162.8	592	29.6	1 × 400 mg + 1 × 200 mg
76	167.2	608	30.4	1 × 400 mg + 3 × 80 mg
78	171.6	624	31.2	1 × 400 mg + 3 × 80 mg
80	176.0	640	32.0	1 × 400 mg + 3 × 80 mg
82	180.4	656	32.8	1 × 400 mg + 1 × 200 mg + 1 × 80 mg
84	184.8	672	33.6	1 × 400 mg + 1 × 200 mg + 1 × 80 mg
86	189.2	688	34.4	1 × 400 mg + 1 × 200 mg + 4 × 80 mg
88	193.6	704	35.2	1 × 400 mg + 1 × 200 mg + 4 × 80 mg
90	198.0	720	36.0	1 × 400 mg + 1 × 200 mg + 4 × 80 mg
92	202.4	736	36.8	1 × 400 mg + 1 × 200 mg + 2 × 80 mg
94	206.8	752	37.6	1 × 400 mg + 1 × 200 mg + 2 × 80 mg
96	211.2	768	38.4	2 × 400 mg
98	215.6	784	39.2	2 × 400 mg
≥100	≥220.0	800	40.0	2 × 400 mg

pJIA: Dosing Preparation and Administration Guide with TYENNE IV

Dosing should take place at 4-week intervals. The dose should be calculated based on the patient's body weight at each administration. If the patient's dose has been calculated prior to the infusion date, take his or her weight to make sure that it has not changed from the time of the original calculation to require a change in dose. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. A change in dose of 8 mg/kg or 10 mg/kg should only be based on a consistent change in the patient's body weight over time. Refer to the charts to check whether a dosing adjustment is necessary.

TYENNE IV dosing in pJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg:
Patient's weight (kg) x 10 mg/kg
= TYENNE dose

For patients weighing ≥30 kg:
Patient's weight (kg) x 8 mg/kg
= TYENNE dose

Once the dose is calculated, choose the vial combination of TYENNE that best matches the patient's needs. TYENNE is available in three different dosing vials:


400 mg (20 ml) vials


200 mg (10 ml) vials


80 mg (4 ml) vials

Parenteral medicinal products should be inspected visually for particulate matter or discolouration prior to administration. Only solutions which are clear and colourless to pale yellow and practically free of visible particles should be diluted. Use a sterile needle and syringe to prepare TYENNE.

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
10 mg/kg	10	22.0	100	5.0	80 mg + 80 mg
	12	26.4	120	6.0	80 mg + 80 mg
	14	30.8	140	7.0	80 mg + 80 mg
	16	35.2	160	8.0	80 mg + 80 mg
	18	39.6	180	9.0	200 mg
	20	44.0	200	10.0	200 mg
	22	48.4	220	11.0	80 mg + 80 mg + 80 mg
	24	52.8	240	12.0	80 mg + 80 mg + 80 mg
	26	57.2	260	13.0	200 mg + 80 mg
	28	61.6	280	14.0	200 mg + 80 mg
8 mg/kg	30	66.0	240	12.0	80 mg + 80 mg + 80 mg
	32	70.4	256	12.8	200 mg + 80 mg
	34	74.8	272	13.6	200 mg + 80 mg
	36	79.2	288	14.4	80 mg + 80 mg + 80 mg + 80 mg
	38	83.6	304	15.2	80 mg + 80 mg + 80 mg + 80 mg
	40	88.0	320	16.0	80 mg + 80 mg + 80 mg + 80 mg
	42	92.4	336	16.8	200 mg + 80 mg + 80 mg
	44	96.8	352	17.6	200 mg + 80 mg + 80 mg
	46	101.2	368	18.4	400 mg
	48	105.6	384	19.2	400 mg
	50	110.0	400	20.0	400 mg
	52	114.4	416	20.8	200 mg + 80 mg + 80 mg + 80 mg
	54	118.8	432	21.6	200 mg + 80 mg + 80 mg + 80 mg
	56	123.2	448	22.4	400 mg + 200 mg
	58	127.6	464	23.2	400 mg + 200 mg
	60	132.0	480	24.0	400 mg + 200 mg
	62	136.4	496	24.8	200 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	64	140.8	512	25.6	200 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	66	145.2	528	26.4	400 mg + 80 mg + 80 mg
	68	149.6	544	27.2	400 mg + 80 mg + 80 mg
	70	154.0	560	28.0	400 mg + 80 mg + 80 mg
	72	158.4	576	28.8	400 mg + 200 mg
	74	162.8	592	29.6	400 mg + 200 mg
	76	167.2	608	30.4	400 mg + 80 mg + 80 mg + 80 mg
	78	171.6	624	31.2	400 mg + 80 mg + 80 mg + 80 mg
	80	176.0	640	32.0	400 mg + 80 mg + 80 mg + 80 mg
	82	180.4	656	32.8	400 mg + 200 mg + 80 mg
	84	184.8	672	33.6	400 mg + 200 mg + 80 mg
	86	189.2	688	34.4	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	88	193.6	704	35.2	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	90	198.0	720	36.0	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	92	202.4	736	36.8	400 mg + 200 mg + 80 mg + 80 mg
	94	206.8	752	37.6	400 mg + 200 mg + 80 mg + 80 mg
	96	211.2	768	38.4	400 mg + 400 mg
	98	215.6	784	39.2	400 mg + 400 mg
	≥100	≥220.0	800	40.0	400 mg + 400 mg

sJIA: Dosing Preparation and Administration Guide with TYENNE IV

400 mg (20 ml) vials

200 mg (10 ml) vials

80 mg (4 ml) vials

Dosing should take place at 2-week intervals. A change in dose of 8 mg/kg or 12 mg/kg should only be based on a consistent change in the patient's body weight over time. If the patient's weight has changed, contact the prescriber to discuss whether a dosing change is needed. Refer to the chart to check whether a dosing adjustment is necessary.

TYENNE dosing in sJIA patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg:
Patient's weight (kg) x 12 mg/kg
= TYENNE dose

For patients weighing ≥30 kg:
Patient's weight (kg) x 8 mg/kg
= TYENNE dose

Once the dose is calculated, choose the vial combination of TYENNE that best matches the patient's needs. TYENNE is available in three different dosing vials:

	Weight (kg)	Weight (lbs)	Dose (mg)	Dose (ml)	Vial combinations
12 mg/kg	10	22.0	120	6.0	80 mg + 80 mg
	12	26.4	144	7.2	80 mg + 80 mg
	14	30.8	168	8.4	200 mg
	16	35.2	192	9.6	200 mg
	18	39.6	216	10.8	80 mg + 80 mg + 80 mg
	20	44.0	240	12.0	80 mg + 80 mg + 80 mg
	22	48.4	264	13.2	200 mg + 80 mg
	24	52.8	288	14.4	80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	26	57.2	312	15.6	80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	28	61.6	336	16.8	200 mg + 80 mg + 80 mg
8 mg/kg	30	66.0	240	12.0	80 mg + 80 mg + 80 mg
	32	70.4	256	12.8	200 mg + 80 mg
	34	74.8	272	13.6	200 mg + 80 mg
	36	79.2	288	14.4	80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	38	83.6	304	15.2	80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	40	88.0	320	16.0	80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	42	92.4	336	16.8	200 mg + 80 mg + 80 mg + 80 mg
	44	96.8	352	17.6	200 mg + 80 mg + 80 mg + 80 mg
	46	101.2	368	18.4	400 mg
	48	105.6	384	19.2	400 mg
	50	110.0	400	20.0	400 mg
	52	114.4	416	20.8	200 mg + 80 mg + 80 mg + 80 mg + 80 mg
	54	118.8	432	21.6	200 mg + 80 mg + 80 mg + 80 mg + 80 mg
	56	123.2	448	22.4	400 mg + 200 mg
	58	127.6	464	23.2	400 mg + 200 mg
	60	132.0	480	24.0	400 mg + 200 mg
	62	136.4	496	24.8	200 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	64	140.8	512	25.6	200 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	66	145.2	528	26.4	400 mg + 80 mg + 80 mg + 80 mg
	68	149.6	544	27.2	400 mg + 80 mg + 80 mg + 80 mg
	70	154.0	560	28.0	400 mg + 80 mg + 80 mg + 80 mg
	72	158.4	576	28.8	400 mg + 200 mg
	74	162.8	592	29.6	400 mg + 200 mg
	76	167.2	608	30.4	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	78	171.6	624	31.2	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	80	176.0	640	32.0	400 mg + 80 mg + 80 mg + 80 mg + 80 mg
	82	180.4	656	32.8	400 mg + 200 mg + 80 mg + 80 mg
	84	184.8	672	33.6	400 mg + 200 mg + 80 mg + 80 mg
	86	189.2	688	34.4	400 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	88	193.6	704	35.2	400 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	90	198.0	720	36.0	400 mg + 80 mg + 80 mg + 80 mg + 80 mg + 80 mg
	92	202.4	736	36.8	400 mg + 200 mg + 80 mg + 80 mg + 80 mg
	94	206.8	752	37.6	400 mg + 200 mg + 80 mg + 80 mg + 80 mg
	96	211.2	768	38.4	400 mg + 400 mg
	98	215.6	784	39.2	400 mg + 400 mg
	≥100	≥220.0	800	40.0	400 mg + 400 mg

Parenteral medicinal products should be inspected visually for particulate matter or discolouration prior to administration. Only solutions which are clear and colourless to pale yellow and practically free of visible particles should be diluted. Use a sterile needle and syringe to prepare TYENNE.

CRS: Dosing Preparation and Administration Guide with TYENNE IV

TYENNE dosing in CRS patients is calculated based on each patient's weight as follows:

For patients weighing <30 kg: Patient's weight (kg) x 12 mg/kg = TYENNE dose

For patients weighing ≥30 kg: Patient's weight (kg) x 8 mg/kg = TYENNE dose

If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of TYENNE may be administered. The interval between consecutive doses should be at least 8 hours. Doses exceeding 800 mg per infusion are not recommended in CRS patients.

Subcutaneous administration is not approved

Covid-19: Dosing Preparation and Administration Guide with TYENNE IV

The recommended posology for treatment of COVID-19 is a single 60-minute intravenous infusion of 8 mg/kg in patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation, see section 5.1 of the TYENNE 20 mg/mL concentrate for solution for infusion Summary of Product Characteristics (SmPC). If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of TYENNE 8 mg/kg may be administered. The interval between the two infusions should be at least 8 hours.

For individuals whose body weight is more than 100 kg, doses exceeding 800 mg per infusion are not recommended (see section 5.2 of the SmPC).

Administration of TYENNE is not recommended in patients with COVID-19 who have any of the following laboratory abnormalities:

Laboratory test type	Laboratory value	Action
Liver enzyme	>5 x ULN	Administration of Tyenne is not recommended
Absolute neutrophil count	< 1 x 10^9 /L	
Platelet count	< 50 x 10^3 /μL	

2. Gather all necessary supplies

You will need:

- TYENNE at room temperature
- Syringes and large-bore needles
- One primary infusion set
- One 100 ml bag of 0.9% (9 mg/mL) or 0.45% (4.5 mg/mL) sterile, non-pyrogenic sodium chloride solution for injection for patients ≥30 kg OR one 50 ml bag of 0.9% (9 mg/mL) or 0.45% (4.5 mg/mL) sterile, non-pyrogenic sodium chloride solution for injection for patients <30 kg
- One intravenous (IV) catheter
- Gauze
- Tourniquet
- Gloves
- Alcohol/cleansing wipes
- Appropriate treatment to manage an anaphylactic reaction

3. Take baseline assessments

Take baseline assessments to ensure the patient is healthy enough to receive the infusion.

Vital signs may include:

- Blood pressure
- Temperature
- Pulse

Follow the recommended baseline patient questions as described in the TYENNE Healthcare Professional Brochure (Section 13 – General Recommendations) as well as the Summary of Product Characteristics (Section 4.4 – Warnings and Precautions).

4. Prepare the patient for the infusion

Review the TYENNE Patient Brochure with the patient. Answer any questions he or she might have. TYENNE does not require premedication.

5. Prepare the TYENNE infusion

TYENNE is a ready-mix solution and requires no reconstitution. The expiry date should always be checked before use. The Tyenne concentrate for IV infusion should be diluted by a healthcare professional using aseptic technique.

- TYENNE should be refrigerated for storage. However, the diluted TYENNE solution should be allowed to reach room temperature before it is infused.
- The diluted TYENNE solution for infusion is physically and chemically stable in sodium chloride 9 mg/mL (0.9%) or 4.5 mg/mL (0.45%) solution for injection at 30°C for 24 hours. From a microbiological point of view, the prepared solution for infusion should be used immediately.
- If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C and up to 8 hours at 30°C, unless dilution has taken place in controlled and validated aseptic conditions.
- Tyenne is for single-use only. Any unused product or waste material should be disposed of in accordance with local requirements.

▶ **For RA, CRS (≥30 kg), sJIA (≥30 kg), COVID-19 (≥30 kg) and pJIA (≥30 kg):**

From a 100 ml infusion bag withdraw a volume of 0.9 % (9 mg/ml) or 0.45% (4.5 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the TYENE solution required for the patient's dose.

Withdraw the required amount of TYENNE concentrate (**0.4 mL/kg**) from the vial and place in the 100 mL infusion bag. This should be a final volume of 100 mL. To mix the solution, gently invert the infusion bag to avoid foaming

For COVID-19 patients

- TYENNE should not be infused concomitantly in the same IV line with other medications. No physical or biochemical compatibility studies have been conducted to evaluate the co-administration of TYENNE with other medications.
- Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. Only solutions which are clear to opalescent, colourless to pale yellow and free of visible particles should be diluted.
- Dispose of needle and syringe in accordance with local requirements when finished.

▶ **sJIA and CRS Patients < 30 kg**

- From a 50 ml infusion bag withdraw a volume of 0.9 % (9 mg/ml) or 0.45% (4.5 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the TYENNE solution required for the patient's dose.

  Withdraw the required amount of TYENNE concentrate (**0.6 mL/kg**) from the vial and place in the 50 mL infusion bag. This should be a final volume of 50 mL. To mix the solution, gently invert the infusion bag to avoid foaming.

▶ **pJIA Patients < 30 kg**

- From a 50 ml infusion bag withdraw a volume of 0.9 % (9 mg/ml) or 0.45% (4.5 mg/ml) sterile, non-pyrogenic sodium chloride solution for injection equal to the volume of the TYENNE solution required for the patient's dose.

  Withdraw the required amount of TYENNE concentrate (**0.5 mL/kg**) from the vial and place in the 50 mL infusion bag. This should be a final volume of 50 mL. To mix the solution, gently invert the infusion bag to avoid foaming.

If an anaphylactic reaction or other serious hypersensitivity / serious infusion related reaction occurs, administration of TYENNE should be stopped immediately and TYENNE should be permanently discontinued.

6. Begin the TYENNE infusion

After dilution, Tyenne for RA, sJIA, pJIA, CRS and COVID-19 patients should be administered as an intravenous infusion over 1 hour. It must be administered with an infusion set and should never be administered as an IV push or bolus.

Monitor the patient for infusion related reactions.

Once the infusion is completed, remove the catheter and dispose of all supplies in accordance with local requirements, clean and bandage the infusion site and check the patient's vital signs.

Part II: SC administration of TYENNE by injection using either the PFS or pre-filled pen

The pre-filled syringe is used in RA (162 mg once per week), GCA (162 mg once every week in combination with a tapering course of glucocorticoids), pJIA (162 mg once every 2 weeks in patients weighing ≥30 kg or once every 3 weeks in patients weighing <30 kg), and sJIA (162 mg once every week in patients weighing ≥30 kg or 162 mg once every 2 weeks in patients <30 kg) indications only.

The pre-filled pen is used in the following indications only:

- RA (162 mg once per week)
- GCA (162 mg once every week in combination with a tapering course of glucocorticoids)
- In patients 12 years of age and older for the treatment of active systemic juvenile idiopathic arthritis (sJIA) (162 mg subcutaneously once every week in patients weighing greater than or equal to 30 kg or 162 mg subcutaneously once every 2 weeks in patients weighing less than 30 kg)
- In patients 12 years of age and older for the treatment of juvenile idiopathic polyarthritis (pJIA, rheumatoid factor positive or negative and extended oligoarthritis) (162 mg subcutaneously once every 2 weeks in patients weighing greater than or equal to 30 kg or 162 mg subcutaneously once every 3 weeks in patients weighing less than 30 kg).

Patients must have a minimum body weight of 10 kg when receiving Tyenne subcutaneously.

The pre-filled pen should not be used to treat paediatric patients < 12 years of age since there is a potential risk of intramuscular injection due to thinner subcutaneous tissue layer.

Instructions apply to both devices.

Monitor the patient for injection related reactions.

This section will walk you through the injection process for both subcutaneous devices

1. Gather all necessary supplies

You will need:

- 1 TYENNE PFS OR pre-filled pen at room temperature
- 1 alcohol swab to clean the site before injection
- 1 sterile cotton ball or gauze to use after the injection
- 1 sharps disposal container for safe disposal of needle cap and used syringe
- A well-lit, clean, flat surface
- Clock or watch

2. Take baseline assessments

The first injection using the TYENNE device should be performed under the supervision of a qualified healthcare professional.

The healthcare professional should take baseline assessments to ensure the patient is healthy enough to receive the injection.

Vital signs may include:

- Blood pressure
- Temperature
- Pulse

Follow the recommended baseline patient questions as described in the TYENNE Healthcare Professional Brochure (Section 13 – General Recommendations) as well as the Summary of Product Characteristics (Section 4.4 – Warnings and Precautions).

3. Preparation for injection

- Store TYENNE device in its original carton in a refrigerator between 2 °C and 8 °C. Do not freeze.
- After removing the TYENNE SC device from the refrigerator, it should be allowed to reach room temperature (18°C to 28°C)
- **Do not** speed up the warming process in any way, such as in a microwave, hot water, or direct sunlight.
- **Do not** shake the device.
- **Do not** reuse the device.
- **Do not** try to take apart the device at any time.
- **Do not** use the device through clothing.
- Keep out of the reach of children.
- If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, administration of TYENNE should be stopped immediately and TYENNE should be permanently discontinued.
- **Before every use:**
  - Check the TYENNE device to make sure it is not cracked or damaged. Do not use it if it shows signs of damage or if it has been dropped.
  - **Do not** use the device if the sealed plastic tray or carton are open or damaged.
  - Check the expiration date on device. Do not use the TYENNE SC device if the expiration date has passed because it may not be safe. If the expiration date has passed, safely dispose of the device in a sharps container.
  - Inspect the TYENNE SC device visually for particulate matter and discolouration prior to administration. Do not use if the medicine is cloudy or contains particles, is any colour besides colourless to pale yellow, or any part of the device appears to be damaged.
  - If you are opening the box for the first time, check to make sure that it is properly sealed.
  - **Do not** use the device if the box looks like it has already been opened.

Do not leave the TYENNE device unattended. Stop administration of Tyenne immediately if an anaphylactic reaction or other serious hypersensitivity reaction occurs. Initiate appropriate therapy and permanently discontinue TYENNE.

Injection Preparation: TYENNE PFS

Tyenne is supplied as a 0.9 mL pre-filled syringe containing 162 mg tocilizumab solution for injection.

Each pack contains 1, 4 or 12 pre-filled syringes. Not all pack sizes may be marketed.

- Store the pre-filled syringe in its original carton in a refrigerator between 2 °C and 8 °C.
- Keep the pre-filled syringe in the original carton to protect from light.
- Keep the pre-filled syringe out of the reach and sight of children.
- Let the PFS in its sealed plastic tray sit at room temperature for at least 30 minutes before use to allow the medicine to reach room temperature.
- Prepare and check your records of previous injection sites. This will help you choose the appropriate injection site for this injection.

Injection Preparation: TYENNE pre-filled pen

- Do not remove the pre-filled pen cap until you are ready to inject TYENNE.
- Remove the carton containing the pre-filled pen from the refrigerator.
- Remove the sealed tray from the carton.
- Let the sealed tray sit on the prepared surface for 45 minutes before use to allow the medicine in the pre-filled pen to reach room temperature.

4. Choose and prepare an injection site

- Wash your hands well with soap and water and dry them with a clean towel.
- Wipe the skin where you want to inject with an alcohol swab to clean it. Let the skin dry. Do not blow or touch the injection site after cleaning.
- If it is a self-injection or a caregiver is giving the injection, use the front of your upper thigh or abdomen, except for within 5cm of the belly button (navel). (see **Figure A**).
- If a caregiver is giving the injection, they can use the outer area of the upper arm (see **Figure B**).

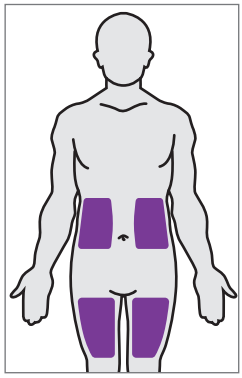


Figure A.

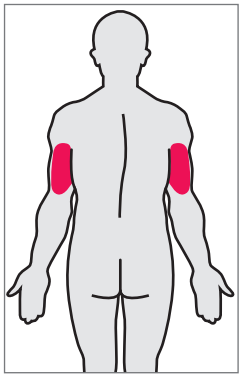


Figure B.

- **Rotate Injection Site**
  - Choose a different injection site for each new injection, at least:
  - PFS: 3 cm from the area you used for your previous injection Pre-filled pen: 2.5 cm from the last area you injected
  - Do not inject into skin that is sore (tender), bruised, red, hard, scaly, or has lesions, moles, scars, or stretch marks or tattoos.

Key:

Self or Caregiver

Caregiver ONLY

What you need to know to use the TYENNE PFS safely

- Read this Instruction for Use before using your TYENNE pre-filled syringe and each time you get a prescription refill
- Store the pre-filled syringe in its original carton in a refrigerator between 2 °C and 8 °C. Keep the pre-filled syringe in the original carton to protect from light. Keep the pre-filled syringe out of the reach and sight of children. Do not use the pre-filled syringe if the sealed plastic tray or carton are open or damaged.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break.
- **Do not** remove the needle cap from the prefilled syringe until you are ready to inject.
- **Do not** try to reuse the pre-filled syringe because it could lead to an infection.

Your TYENNE pre-filled syringe

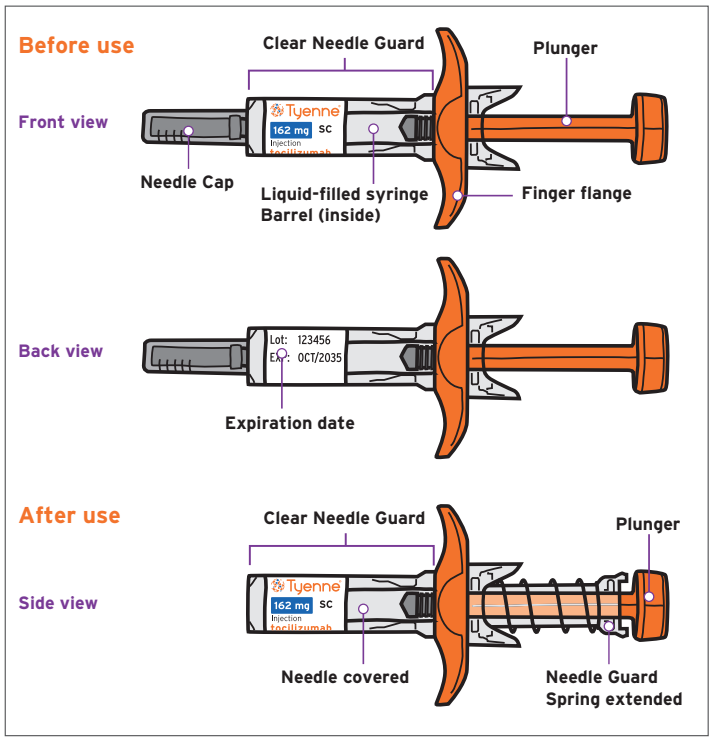


Figure C.

5a. Administering the injection with the PFS for RA, GCA, pJIA and sJIA

Administration: TYENNE Pre-filled Syringe

Do not shake the pre-filled syringe. Hold the needle-shield of the syringe firmly with one hand and pull off the needle-cap with the other. Do not pull or press the plunger. Do not touch the needle or let it touch any surface. After removing the needle-cap, the injection must be started within 5 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of removing the cap, you must dispose of it in a puncture resistant container and use a new pre-filled syringe. Never re-attach the needle-cap after removal.

Step 1 – Prepare for your Injection

1.1 Prepare a clean, flat surface, such as a table or counter top, in a well-lit area

1.2 Supplies needed (see **Figure A**): 1 alcohol swab to clean the site before injection 1 sterile cotton ball or gauze to use after the injection 1 sharps disposal container for safe disposal of needle cap and used syringe (see Step 7 "Throw away your syringe").

1.3 Take the TYENNE carton out of the refrigerator and open it (see **Figure B**).

1.4 Remove TYENNE sealed plastic tray out of the carton: Put the sealed plastic tray with the PFS on a clean flat surface. Let the PFS in its sealed plastic tray sit at room temperature for at least 30 minutes before use to allow the medicine to reach room temperature (see **Figure C**). Injecting cold medicine can cause your injection to feel uncomfortable and make it difficult to push the plunger in.

1.5 Prepare and check your records of previous injection sites. This will help you choose the appropriate injection site for this injection (see Step 8 "Record your injection").

- Do not try to activate the clear needle guard before injecting.
- Do not speed up the warming process in any way, such as in a microwave, or placing the syringe in hot water, or direct sunlight.
- Do not remove the needle cap while allowing your TYENNE PFS to reach room temperature.

Figure A.

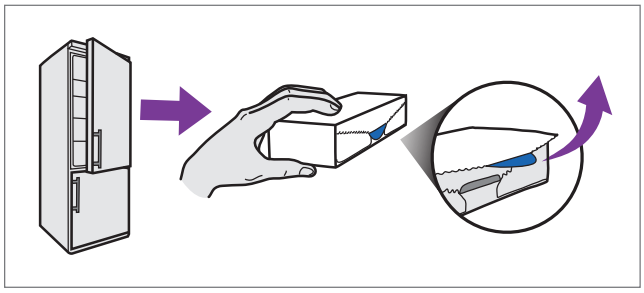


Figure B.

Figure C.

Step 2 - Wash your hands

2.1 Wash your hands well with soap and water and dry them with a clean towel (see **Figure D**).

Figure D.

Step 3 - Check the syringe

Remove TYENNE PFS from the sealed plastic tray

- Peel off the seal from the sealed plastic tray.
- Place two fingers on either side, in the middle of the clear needle guard.
- Pull the PFS straight up and out of the tray (see **Figure E**).

- **Do not** pick up the PFS by the plunger or the needle cap. Doing so could damage the PFS or activate the clear needle guard.

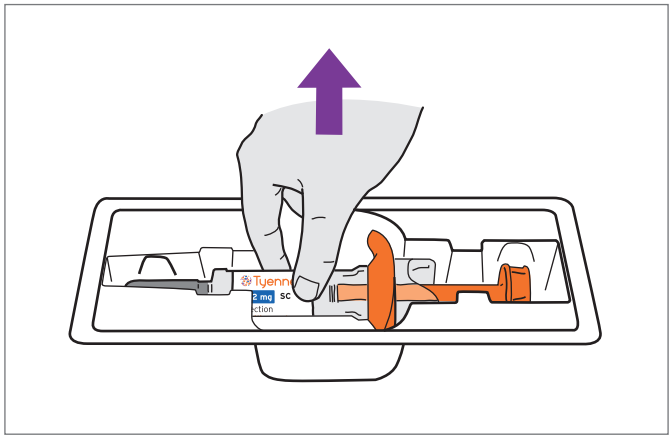


Figure E.

Step 3 – Check the syringe

3.1 Check the PFS to make sure that:

- The PFS, the clear needle guard, and the needle cap are not cracked or damaged (see **Figure F**).
- The needle cap is securely attached (see **Figure G**).
- The needle guard spring is not extended (see **Figure H**)

3.2 Check the liquid through the clear window of the syringe to make sure that:

- The liquid is clear and colorless to pale yellow, and free of particles and flakes (see **Figure I**)

3.3 Check the label on the PFS to make sure that:

- The name on the PFS says TYENNE (see **Figure J**).
- The expiration date (EXP:) on the PFS has not passed (see **Figure J**).

- **Do not** use the syringe if it shows any sign of damage. If damaged, call your doctor or pharmacist right away and throw away the syringe in your sharps disposal container (see Step 7 "Throw away your syringe").
- **Do not** use the PFS if the liquid is cloudy, discolored, contains particles or flakes, or shows any sign of damage. If the liquid is cloudy, discolored, contains particles or flakes, call your doctor or pharmacist right away and throw away the syringe in your sharps disposal container (see Step 7 "Throw away your syringe").
- **Do not** use the PFS if:
  - The name on the PFS is not TYENNE.
  - The expiration date on the PFS has passed.
- If the label does not have TYENNE on it or the expiration date has passed contact your doctor or pharmacist right away and throw away the PFS in your sharps disposal container (see Step 7 "Throw away your syringe").

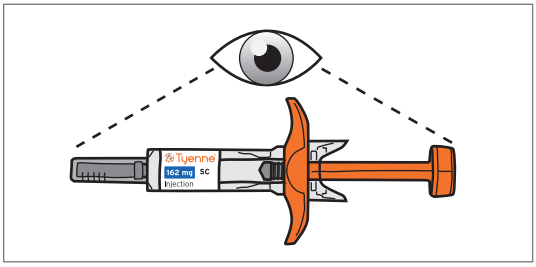


Figure F.

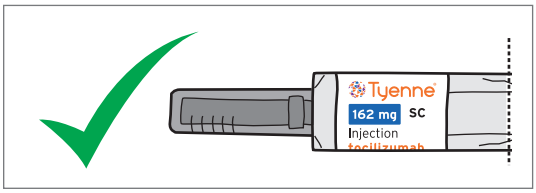


Figure G.

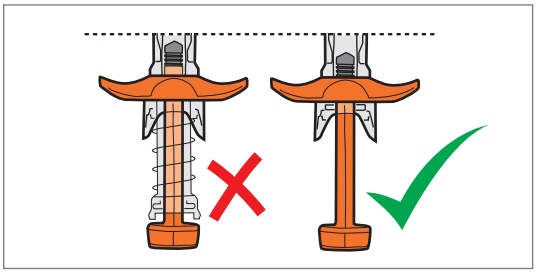


Figure H.

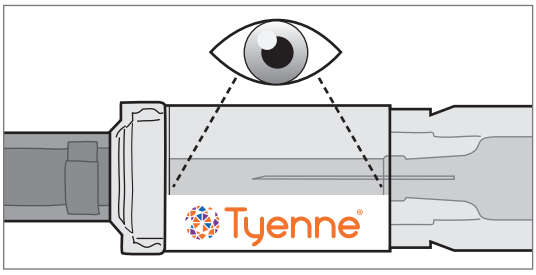


Figure I.

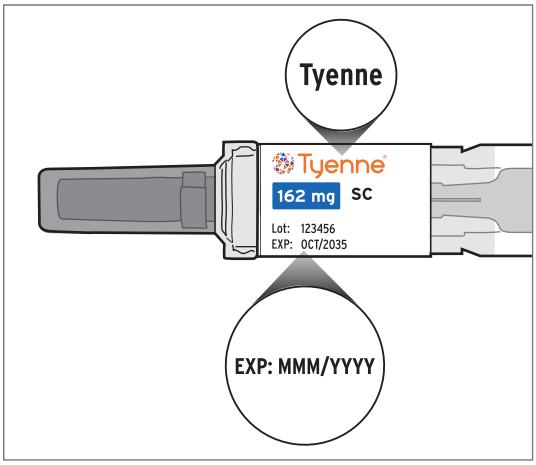


Figure J.

Step 4 - Choose the injection site

4.1 Choose an injection site (see **Figure K**):

- The front of the thighs, or stomach area (lower abdomen), except for 5 cm around the navel (belly button)
- If you are injecting someone else, you may use the back of the arm (see **Figure L**)

4.2 Choose a different injection site (at least 3 cm from the last area you injected) for each new injection to reduce redness, irritation or other skin problems.

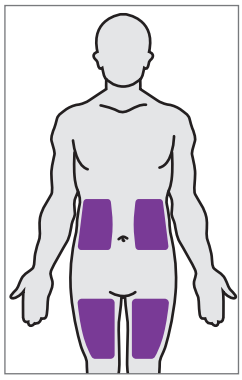


Figure K.

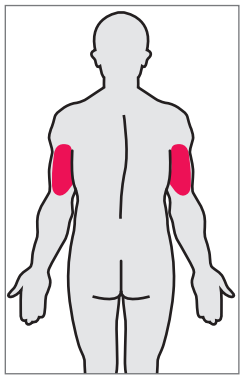


Figure L.

Key:

Self or Caregiver

Caregiver ONLY

- **Do not** attempt to use the upper arm area by yourself. Only inject into the sites shown.
- **Do not** inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks, moles or tattoos.
- If you have psoriasis, do not inject into any lesions or red, thick, raised or scaly patches.

Step 5 - Clean the injection site

5.1 Wipe the skin of your injection site with an alcohol swab in a circular motion to clean it (see **Figure M**). Let the skin dry before injecting.

- **Do not** blow or touch the injection site after cleaning.

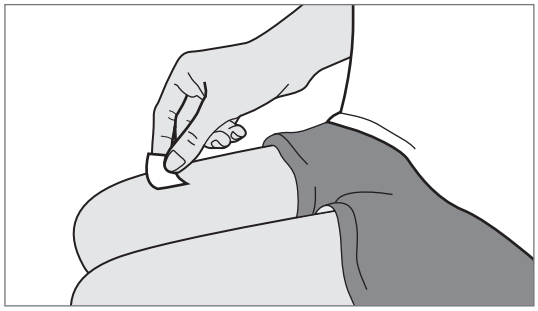


Figure M.

Step 6 – Give your injection

6.1 Remove the needle cap

- Hold the PFS by the clear needle guard in one hand(see **Figure N**)
- Use your other hand to remove the needle cap by pulling the cap straight off (see **Figure N**)
- After removing the needle-cap, the injection must be started within 5 minutes to prevent the medicine from drying out and blocking the needle. If the pre-filled syringe is not used within 5 minutes of removing the cap, you must dispose of it in a puncture resistant container and use a new pre-filled syringe.

If you cannot remove the needle cap, you should ask a caregiver for help or contact your doctor.

- Throw away the needle cap in your sharps container

You may see drops of liquid at the needle tip. This is normal and will not affect your dose.

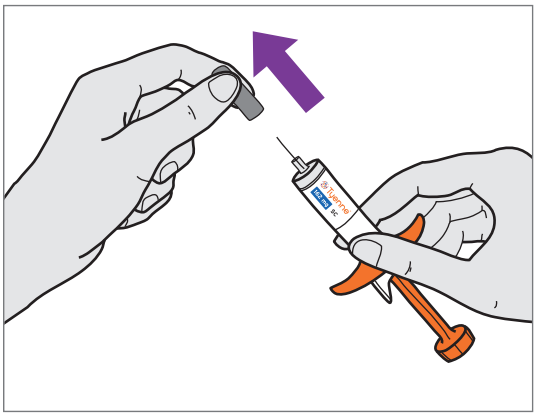


Figure N.

- **Do not** hold the plunger while you remove the needle cap.
- **Do not** touch the needle or let it touch any surface after removing the needle cap, because this might cause an accidental needle stick.

6.2 Pinch the skin

- With your free hand, gently pinch around the area where you plan to inject (without squeezing or touching the cleaned area) and hold it firmly to avoid injecting into muscle (see **Figure O**). Injection into muscle could cause the injection to feel uncomfortable

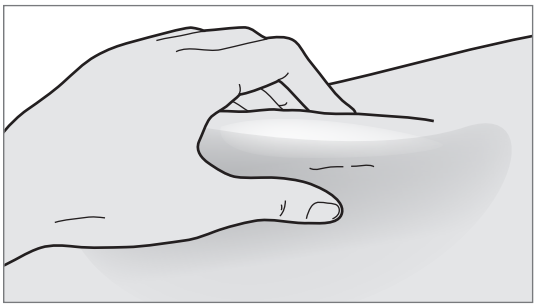


Figure O.

6.3 Insert the needle. Hold the PFS like a pencil.

- With a quick, short motion, insert the needle all the way into the pinched skin at an angle between 45° to 90° (see **Figure P**). Give the injection at the angle your doctor instructed you to use

It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful, and the medicine may not work.

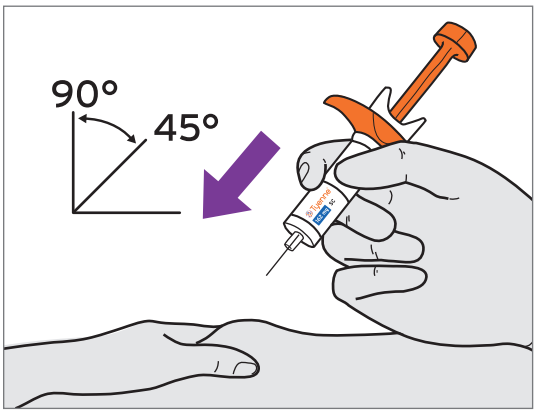


Figure P.

6.4 Inject

- Use your thumb to gently push the plunger all the way down (see **Figure Q**)
- Keep pressing down on the plunger to deliver the full dose until you cannot press any more (see **Figure R**).

▶ **Do not** pull the needle out of the skin when the plunger is pushed all the way down.

- Hold the syringe firmly without moving it, at the same angle as inserted.
- Slowly release your thumb off the plunger. The plunger will move up. The safety system will remove the needle from the skin and cover the needle (see **Figure S**).
- Release the pinched skin.

Important – Call your doctor right away if:

- The clear needle guard does not cover the needle after injecting. Injecting an incorrect amount of medicine could affect your treatment.

▶ **Do not** reuse a syringe even if all of the medicine was not injected.

▶ **Do not** try to recap the needle as it could lead to needle stick injury.

6.5 After Injection

- If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin (see **Figure T**). You may use an adhesive bandage if needed.

▶ **Do not** rub the injection site.

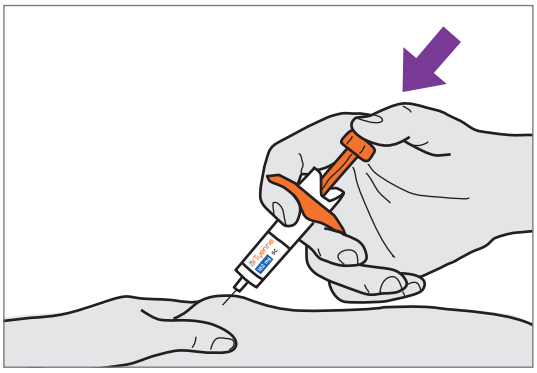


Figure Q.

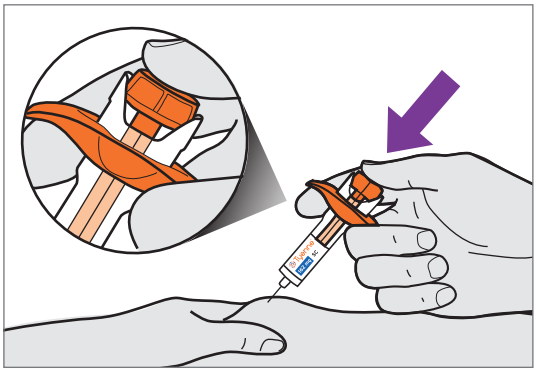


Figure R.

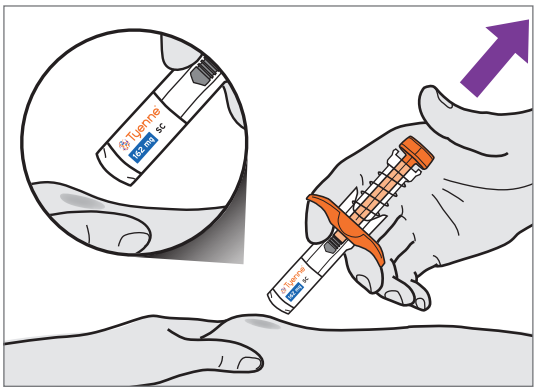


Figure S.

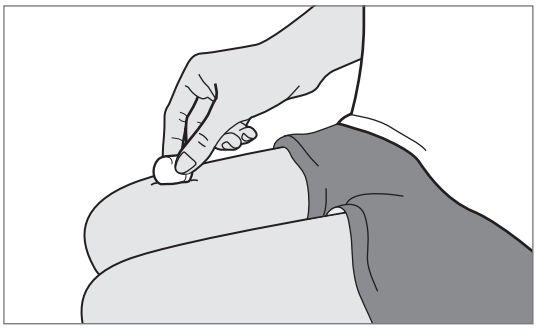


Figure T.

Step 7 – Throw away your PFS

7.1 Put your used pre-filled pen in a sharps disposal container right away after use (see **Figure U**).

If you do not have a sharps disposal container, you can use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, that will keep sharps from coming out
- upright and stable during use
- leak-resistant, and properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

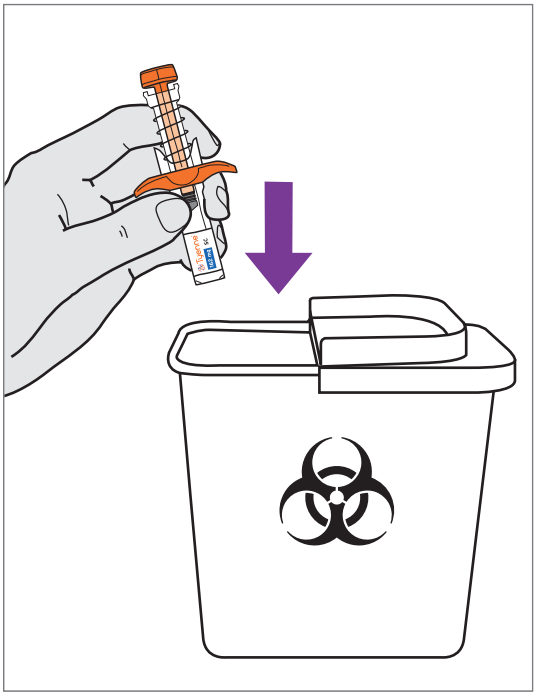


Figure U.

Keep Tyenne pre-filled syringes and disposal container out of the reach and sight of children.

- **Do not** throw away (dispose of) used syringes in your household trash.
- **Do not** throw away (dispose of) your used sharps disposal container in your household trash unless your local guidelines permit this.
- **Do not** recycle your used sharps disposal container.

Step 8 – Record your injection

8.1 To help you remember when and where to give your next injection, write the date, time, and specific part of your body where you injected yourself. (**Figure V**)

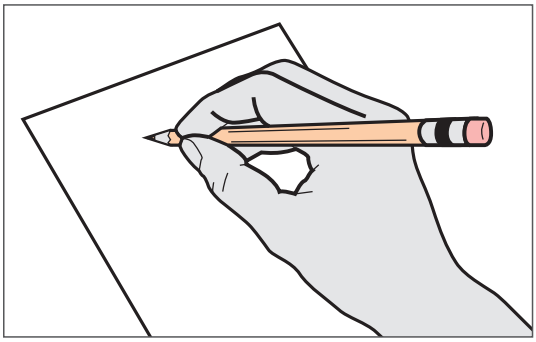


Figure V.

5b. Administering the injection with the pre-filled pen for RA, GCA and sJIA and pJIA patients over 12 years of age

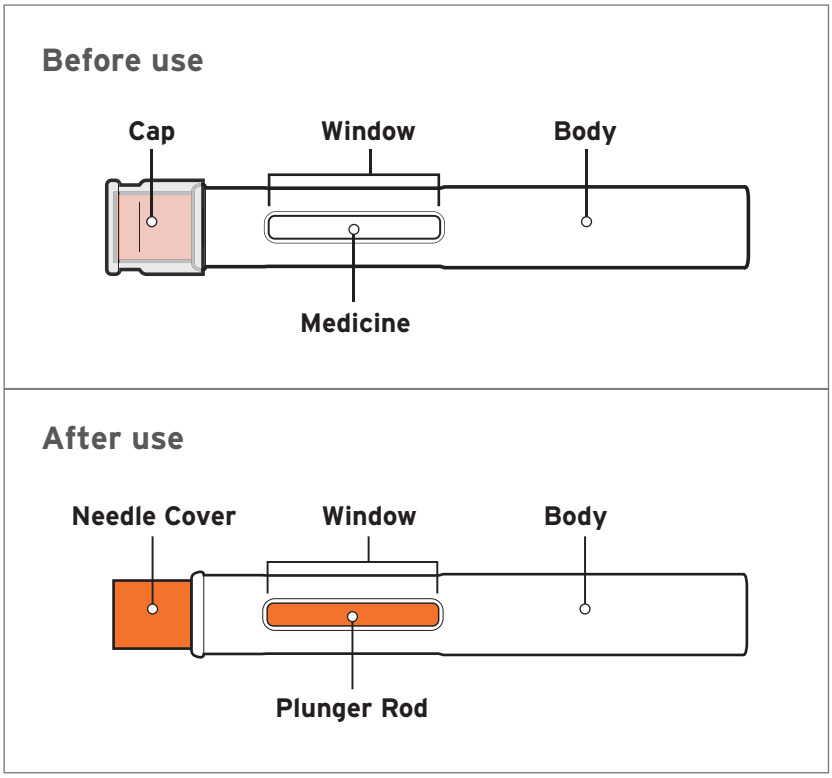
What you need to know to use the TYENNE pre-filled pen safely

Read and follow the Instructions for Use that come with your TYENNE pre-filled pen before you start using it and each time you get a refill. There may be new information. This information does not replace talking to your doctor about your medical condition or treatment.

Store Tyenne in the refrigerator between 2 °C to 8 °C. Store unused pre-filled pens in the original carton to protect from light. Do not freeze. If Tyenne freezes, throw it away in a sharp disposal container.

- **Do not** remove the pre-filled pen clear cap until you are ready to inject.
- **Do not** try to take apart the pre-filled pen at any time.
- **Do not** reuse the pre-filled pen. The pre-filled pen is for single-dose (1-time) use only.
- **Do not** use the pre-filled pen if it shows any signs of damage or if it has been dropped.
- Keep the pre-filled pen out of reach and sight of children.

Your TYENNE pre-filled pen



Step 1 – Preparing for for your injection

1.1 Prepare a clean, flat surface, such as a table or counter top, in a well-lit area

1.2 Gather the following supplies (not included) (see **Figure A**): A sterile cotton ball or gauze, an alcohol swab, a sharps disposal container

1.3 Remove the carton containing the pre-filled pen from the refrigerator. Do not keep your pre-filled pen out of the refrigerator for more than 14 days without use.

1.4 Check the expiration date on the carton to make sure the date has not passed (see **Figure B**). Do not use the pre-filled pen if the expiration date has passed.

1.5 Remove the sealed tray from the carton. Check the sealed tray for any signs of damage, and make sure the expiration date on the tray has not passed.

- **Do not** use the pre-filled pen if the expiration date has passed, because it may not be safe.
- **Do not** use the pre-filled pen if the tray looks damaged or like it has been opened.

Figure A.

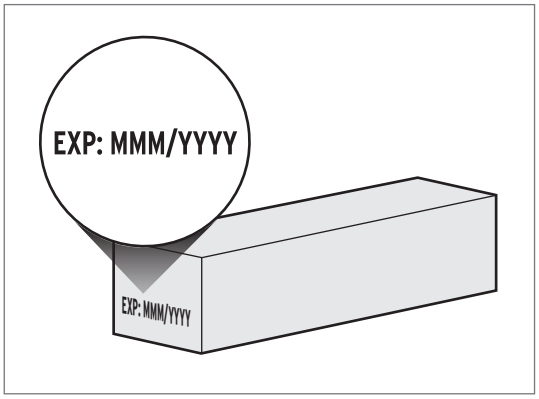


Figure B.

1.6 Let the sealed tray sit on the prepared surface for 45 minutes before use to allow the medicine in the pre-filled pen to reach room temperature (see **Figure C**).

Note: Not doing so could cause your injection to feel uncomfortable and it could take longer to inject.

- **Do not** warm in any other way, such as in a microwave, hot water, or direct sunlight.
- **Keep TYENNE out of the reach of children.**

1.7 Peel the seal off of the tray (see **Figure D**), and invert the tray to remove the single-use pre-filled pen (see **Figure E**).

- **Do not** remove the clear cap of the pre filled pen until you are ready to inject to avoid injury.

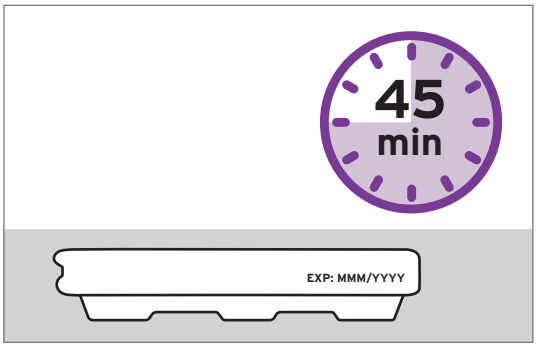


Figure C.

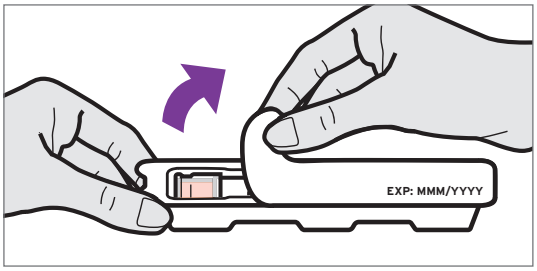


Figure D.

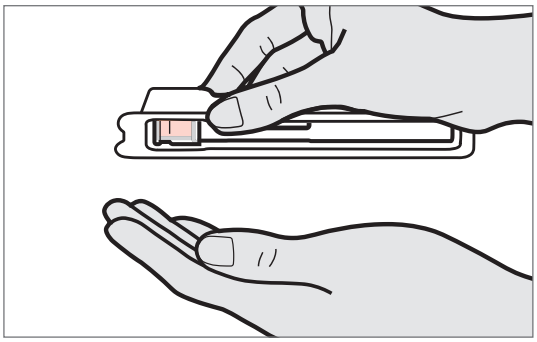


Figure E.

Step 2 - Check your pre-filled pen

2.1 Check the pre-filled pen to make sure it is not cracked or damaged (see **Figure F**).

2.2 Check the pre-filled pen label to make sure that: The name on the pre-filled pen says TYENNE The expiration date (EXP) on the prefilled pen has not passed (see **Figure G**).

2.3 Look at the medicine in the viewing window. Make sure it is clear and colorless to pale yellow and does not contain flakes or particles (see **Figure H**).

Note: Air bubbles in the medicine are normal

- **Do not** use if the pre-filled pen shows signs of damage or if it has been dropped.
- **Do not** use the pre-filled pen if the name on the label is not TYENNE or the expiration date on the label has passed.
- **Do not** inject if the liquid is cloudy, discolored, or has lumps or particles in it because it may not be safe to use.

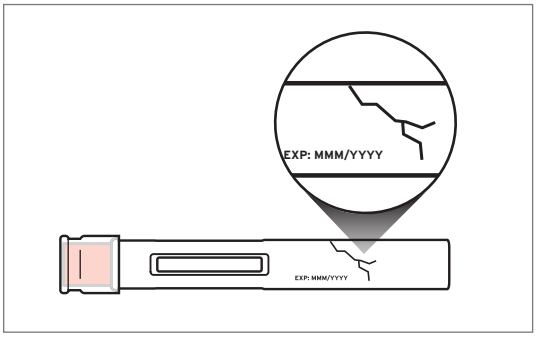


Figure F.

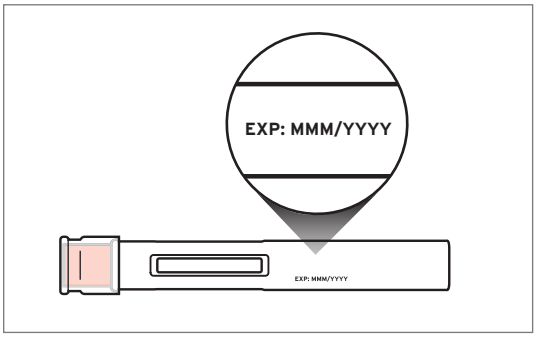


Figure G.

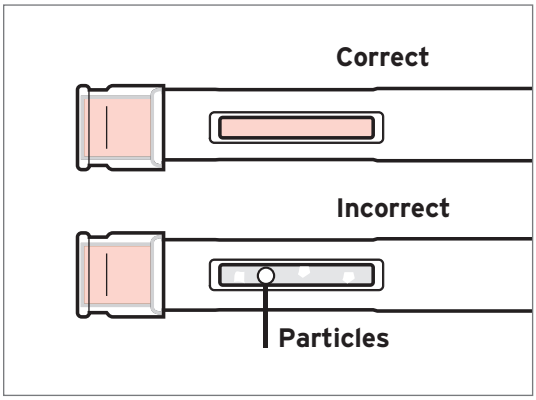


Figure H.

Step 3 - Wash your hands

3.1 Wash your hands well with soap and water, then dry them with a clean towel (see **Figure I**).

Figure I.

Step 4 - Choose the injection site

4.1 If you are giving yourself the injection, you can use:

- The front of your upper thigh
- The abdomen, except within 5 cm around the belly button (navel)
- If a caregiver is giving the injection, they can use the outer area of the upper arm (see **Figure J**).

Note: Choose a different site for each injection to reduce redness, irritation or other skin problems.

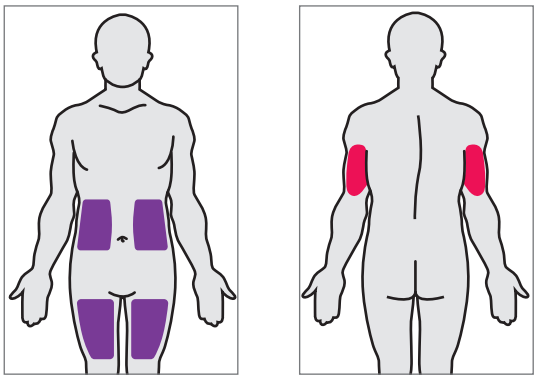


Figure J.

Key:

Self or Caregiver

Caregiver ONLY

- **Do not** inject into skin that is sore (tender), bruised, red, hard, scaly, or has lesions, moles, scars, or stretch marks or tattoos.
- **Do not** use the pre-filled pen through clothing.

Step 5 – Clean the injection site

5.1 Wipe the skin where you want to inject with an alcohol swab to clean it (see **Figure K**). Let the skin dry.

- **Do not** blow on or touch the site after cleaning.

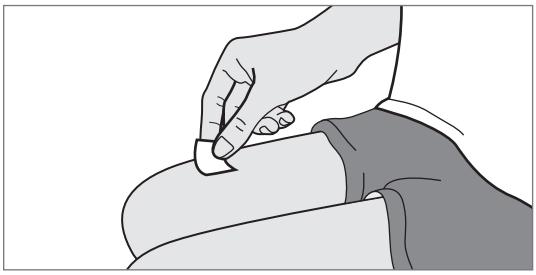


Figure K.

Step 6 – Give your injection

6.1 When you are ready to inject, hold the pre-filled pen in one hand with the clear cap on top, pointing straight up. Using your other hand, firmly pull the clear cap straight off without twisting (see **Figure L**).

Note: Use the pre-filled pen right away after removing the cap to avoid contamination.

6.2 Throw away the clear cap.

6.3 Rotate the pre-filled pen so that the orange needle cover points downwards.

6.4 Position your hand on the pre-filled pen so that you can see the window.

6.5 Place the pre-filled pen against your skin at a 90-degree (straight) angle (see **Figure M**).

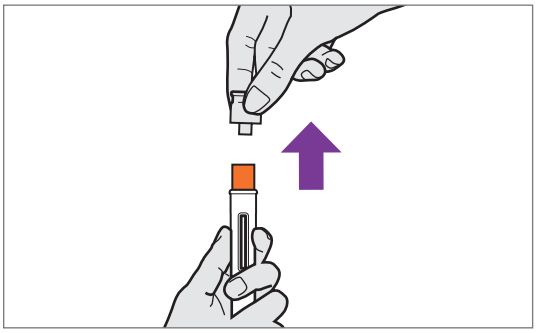


Figure L.

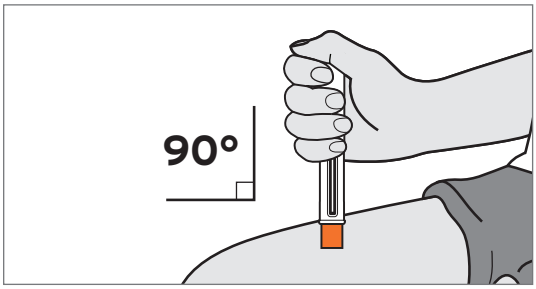


Figure M.

- **Do not** try to recap the needle at any time, even at the end of the injection.
- **Do not** touch the needle cover (the orange part located at the tip of the prefilled pen) because this might cause an accidental needle stick.

To make sure you inject under the skin (into fatty tissue), do not hold the pre-filled pen at an angle. You do not need to pinch your skin.

Note: You **do not** need to pinch your skin.

To make sure you inject the full dose, read all of the steps from 6.6 to 6.9 before you start:

6.6 In a single motion, push the pre-filled pen firmly against your skin until you hear a first click. The orange plunger rod will move through the window during the injection (this means the injection has started) (see **Figure N**).

6.7 WAIT and hold the pre-filled pen in place until you hear a second click. This may take up to 10 seconds. Continue to HOLD (see **Figure O**).

6.8 Wait and slowly count to 5 after you hear the second click. Continue to HOLD the pre-filled pen in place to make sure you inject a full dose (see **Figure P**).

- **Do not** lift the pre-filled pen until you are sure 5 seconds has passed, and the injection is complete.

6.9 While holding the pre-filled pen in place, check the window to make sure the orange plunger rod has fully appeared in the viewing window, and has stopped moving (see **Figure Q**).

Note: If the orange plunger rod did not come all the way down or you believe you did not get a full injection, call your doctor. Do not try to repeat the injection with a new pre-filled pen.

Figure N.

Figure O.

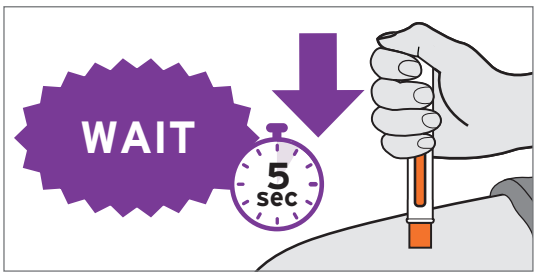


Figure P.

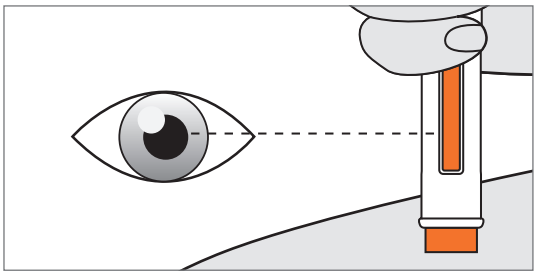


Figure Q.

Step 7 – Remove and check the pre-filled pen

7.1 When the injection is complete, lift the pre-filled pen straight away from your skin (see **Figure R**).

Note: The needle cover will slide down and cover the needle.

7.2 Check the window to make sure the orange plunger rod came all the way down (see **Figure S**).

Note: If the orange plunger rod did not come all the way down or you believe you did not get a full injection, call your doctor.

7.3 If you see blood on the injection site, press gauze or a cotton ball against the skin until the bleeding stops (see **Figure T**).

- **Do not** recap the pre-filled pen
- **Do not** try to repeat the injection with a new pre-filled pen.
- **Do not** rub the injection site

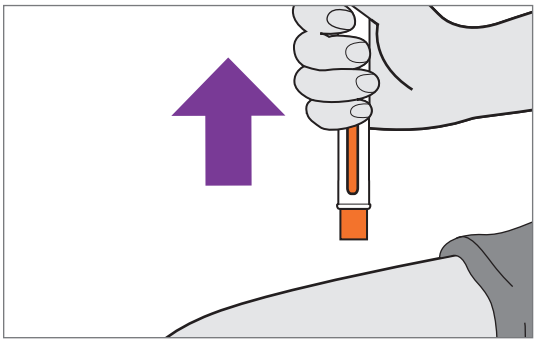


Figure R.

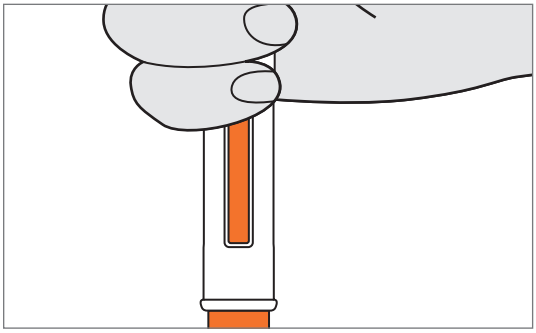


Figure S.

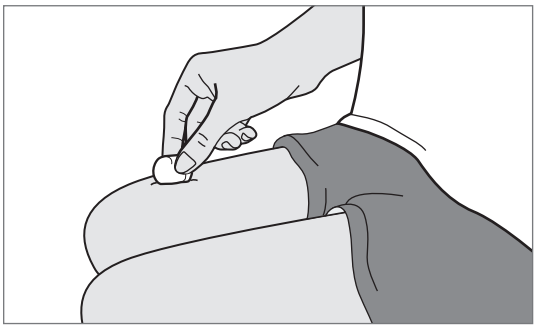


Figure T.

Step 8 – Throw away your pre-filled pen

8.1 Put your used pre-filled pen in a sharps disposal container right away after use (see **Figure U**).

If you do not have a sharps disposal container, you can use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant, and properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Figure U.

- **Always keep the sharps disposal container out of reach of children**
- **Do not** put the clear cap back on the pre-filled pen.
- **Do not** throw away (dispose of) your pre-filled pen in your household trash.
- **Do not** reuse the pre-filled pen.
- **Do not** throw away (dispose of) your used sharps disposal container in your household trash unless your local guidelines permit this.
- **Do not** recycle your used sharps disposal container.

Step 9 – Record your injection

5.1 Record your injection date and site (see **Figure V**).

- **Note:** This is to help you remember when and where to do your next injection.

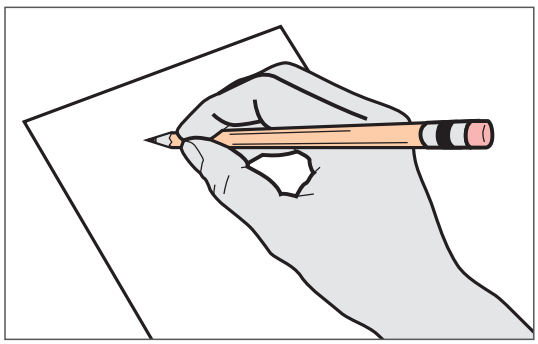


Figure V.

Product traceability

In order to improve the traceability of biological medicinal products, the tradename and batch number of the administered product should be clearly recorded (or stated) in the patient file.

If your patient would like more information about TYENNE, please direct them to the Patient Information Leaflet or contact Medical.Information-UK@fresenius-kabi.com or to call +44 1928 533 575.

For full information, see the Summary of Product Characteristics (SmPC) and the Package Leaflet, which can be found on medicines.ie (Ireland) website: www.medicines.ie

Product complaints: the patient should report any device issues to their pharmacy to arrange for a replacement and the return of the device.

Devices should be returned to your pharmacy and not disposed of in a sharps bin if faulty.

If there is an associated adverse event, the patient should report this.

Reporting of side effects - ▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

In the event of a suspected adverse reaction, please report it to by emailing pharmacovigilance.gb@fresenius-kabi.com or calling +441928 533 575.

Alternatively, suspected adverse reactions can be reported to HPRA Pharmacovigilance Website: www.hpra.ie

As TYENNE is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

Further Information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Tyenne' or 'tocilizumab' in the search box and click on 'EdM' next to any of the medicines that appear). **Alternatively if you would like hard copies**, please contact Fresenius Kabi Limited. Fresenius Kabi Ireland. Unit 3B Fingal Bay Business Park, Balbriggan, Co. Dublin, Ireland. Phone: +353 (0) 1 841 3030 Email: FK- enquiries.Ireland@fresenius-kabi.com. **For further information about this medicine**, please contact Medical Information at Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire WA7 1NT Email: Medical.Information-uk@fresenius-kabi.com tel: **+44 1928 533 575**

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