

# Summary of Product Characteristics



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. See Section 4.8 for how to report adverse reactions.

## 1 NAME OF THE MEDICINAL PRODUCT

Efluelda Tetra, suspension for injection in pre-filled syringe

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains\*:

A/Victoria/4897/2022 (H1N1)pdm09-like strain  
(A/Victoria/4897/2022, IVR-238).....60 micrograms HA\*\*

A/Darwin/9/2021 (H3N2)-like strain  
(A/Darwin/9/2021, SAN-010).....60 micrograms HA\*\*

B/Austria/1359417/2021-like strain  
(B/Michigan/01/2021, wild type)..... 60 micrograms HA\*\*

B/Phuket/3073/2013-like strain  
(B/Phuket/3073/2013, wild type) ..... 60 micrograms HA\*\*

Per 0.7 ml dose

\* propagated in embryonated chicken eggs

\*\* haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2023/2024 season.

Efluelda Tetra may contain traces of eggs, such as ovalbumin, formaldehyde which are used during the manufacturing process (see Section 4.3).

For the full list of excipients, see Section 6.1.

## 3 PHARMACEUTICAL FORM

Suspension for injection, in a pre-filled syringe  
Efluelda Tetra, after shaking gently, is a colourless opalescent liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Efluelda Tetra is indicated for active immunisation in adults 60 years of age and older for the prevention of influenza disease. The use of Efluelda Tetra should be based in accordance with official recommendations on vaccination against influenza.

### 4.2 Posology and method of administration

#### Posology

In adults 60 years of age and older: one dose of 0.7 ml.

#### *Paediatric population*

The safety and effectiveness of Efluelda Tetra in children less than 18 years of age have not been established.

#### Method of administration

The preferred route of administration for this vaccine is intramuscular although it may also be given subcutaneously.

The recommended site for intramuscular injection is the deltoid region. The vaccine should not be injected into the gluteal region, or into areas where there may be a major nerve trunk.

For instructions on preparation of the medicinal product before administration, see Section 6.6.

### **4.3 Contraindications**

Hypersensitivity to the active substances or to any of the excipients listed in Section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins) and formaldehyde.

### **4.4 Special warnings and precautions for use**

#### *Traceability*

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Efluelda Tetra should under no circumstances be administered intravascularly.

Vaccination should be postponed in patients with acute febrile illness until the fever is resolved.

If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of any previous influenza vaccination, the decision to give Efluelda Tetra should be based on careful consideration of the potential benefits and risks.

As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

As with any vaccine, a protective response may not be elicited in all vaccine recipients.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

### **4.5 Interaction with other medicinal products and other forms of interaction**

Co-administration of Efluelda Tetra with an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified/elasomeran) has been evaluated in a limited number of participants in a descriptive clinical study (see sections 4.8 and 5.1).

If Efluelda Tetra needs to be given at the same time as another injectable vaccine(s), immunisation should be carried out on separate limbs.

It should be noted that the adverse reactions may be intensified by any co-administration.

The immunological response may be reduced if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been reported. An appropriate Western Blot test should be used to confirm or

disprove the results of the ELISA test. The transient false positive reactions could be due to a non-specific IgM response induced by influenza vaccine.

#### 4.6 Fertility, pregnancy and lactation

Eflueldais Tetra only indicated for use in adults aged 60 years and older.

Efluelda Tetra has not been clinically evaluated in pregnant and breast-feeding women.

##### Pregnancy

Inactivated influenza standard dose vaccines (15 micrograms haemagglutinin of each virus strain per dose) can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester. Data from worldwide use of inactivated influenza standard dose vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. However, data on the use of influenza vaccines containing 60 micrograms haemagglutinin of each virus strain per dose in pregnant women are limited.

##### Breastfeeding

Efluelda Tetra may be used during breast-feeding. Based on experience with standard dose vaccines, no effects on the breast-fed infant are anticipated.

##### Fertility

Efluelda Tetra has not been evaluated for possible effects on human fertility.

#### 4.7 Effects on ability to drive and use machines

Efluelda Tetra has no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

##### a. Summary of the safety profile

Adverse event information is based on data coming from two clinical trials with Efluelda Tetra and on the clinical and post-marketing experience of Trivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose (TIV-HD).

The safety of Efluelda Tetra was assessed in a pooled analysis of two clinical trials (QHD00013 and QHD00011) in which 2549 adults from 60 years of age and older (378 adults from 60 to 64 years of age and 2171 adults 65 years of age and older) received Efluelda Tetra.

The most frequently reported adverse reaction after vaccination was injection site pain reported by 42.6% of study participants followed by myalgia (23.8%), headache (17.3%) and malaise (15.6%). Most of these reactions occurred and resolved within three days of vaccination. The intensity of most of these reactions was mild to moderate.

Overall, adverse reactions were generally less frequent in participants aged 65 years and older than in participants aged 60 to 64 years.

Reactogenicity of Efluelda Tetra was slightly increased as compared to the standard dose vaccine, but no major difference in intensity was observed.

The safety of Efluelda Tetra (QIV-HD) was evaluated in a descriptive study (QHD00028) in which subjects received QIV-HD together with an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) (n=100), QIV-HD only (n=92) or an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) only (n=104). The frequency and severity of local and systemic adverse reactions was similar in subjects who were co-administered with QIV-HD and licensed COVID-19 mRNA vaccine and subjects administered with a booster dose of licensed COVID-19 mRNA vaccine.

##### b Tabulated list of adverse reactions

The data below summarizes the frequencies of adverse reactions that were recorded following vaccination with Efluelda Tetra and adverse reactions reported during clinical development and post-marketing experience with TIV-HD (marked with \* in the table below).

Adverse events are ranked under headings of frequency using the following convention:

Very common ( $\geq 1/10$ );

Common ( $\geq 1/100$  to  $< 1/10$ );

Uncommon ( $\geq 1/1,000$  to  $< 1/100$ );

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ );

Very rare ( $< 1/10,000$ );

Not known (cannot be estimated from available data).

ADVERSE REACTIONS	FREQUENCY
<b>General Disorders and Administration Site Conditions</b>	
Injection site pain, injection site erythema, malaise	Very common
Injection site swelling, injection site induration, injection site bruising, fever ( $> 37.5^{\circ}\text{C}$ ), shivering	Common
Injection site pruritis, fatigue	Uncommon
Asthenia	Rare
Chest pain	Not known*
<b>Musculoskeletal and Connective Tissue Disorders</b>	
Myalgia	Very common
Muscle weakness <sup>a</sup>	Uncommon
Arthralgia, pain in extremities	Rare
<b>Nervous System Disorders</b>	
Headache	Very common
Lethargy <sup>a</sup>	Uncommon
Dizziness, paraesthesia	Rare
Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination)	Not known*
<b>Blood and Lymphatic System Disorders</b>	
Thrombocytopenia, lymphadenopathy	Not known*
<b>Respiratory, Thoracic and Mediastinal Disorders</b>	
Cough, oropharyngeal pain	Uncommon
Rhinorrhea	Rare
Dyspnea, wheezing, throat tightness	Not known*
<b>Gastrointestinal Disorders</b>	
Nausea, vomiting, dyspepsia <sup>a</sup> , diarrhoea	Uncommon
<b>Immune System Disorders</b>	
Pruritus, urticaria, night sweats, rash	Rare
Anaphylaxis, other allergic/hypersensitivity reactions (including angioedema)	Not known*
<b>Vascular Disorders</b>	
Flushing	Rare
Vasculitis, vasodilatation	Not known*
<b>Ear and Labyrinth Disorders</b>	
Vertigo	Rare
<b>Eye Disorders</b>	
Ocular hyperemia	Rare

<sup>a</sup>Dyspepsia, lethargy, and muscular weakness were observed with TIV-HD in the QHD00013 trial.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**4.9 Overdose**

Cases of administration of more than the recommended dose have been reported with TIV-HD associated with inadvertent use in the population below 60 years of age due to medication error. When adverse reactions were reported, the information was consistent with the known safety profile of TIV-HD.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02.

Annual influenza vaccination is recommended because immunity during the year after vaccination declines and because circulating strains of influenza virus change from year to year.

Pharmacodynamic effects

Immunogenicity - QHD00013

A randomized, active-controlled, modified double-blind Phase III clinical trial was conducted in the US in adults 65 years and older.

The objective was to demonstrate the noninferiority of Efluelda Tetra over TIV-HD, as assessed by HAI (hemagglutinin inhibition) Geometric mean antibody titers (GMTs) at Day 28 and seroconversion rates.

A total of 2670 adults from 65 years of age were randomized to receive either one dose of Efluelda Tetra or one dose of TIV-HD (one of two formulations of comparator vaccine [TIV-HD1 or TIV-HD2]); each TIV HD formulation contained a B strain that corresponds to one of the two B strains in Efluelda Tetra (either a B strain of the Yamagata lineage or a B strain of the Victoria lineage).

The immunogenicity results are summarized below in **Table 1**.

**Table 1: Study 1<sup>a</sup>: Analyses of Noninferiority of Efluelda Tetra (QIV-HD) Relative to TIV-HD by Post-Vaccination HAI Antibody GMTs and Seroconversion Rates in Adults 65 Years of Age and Older, Per-Protocol Analysis Set**

Influenza Strain	GMT			GMT Ratio	Seroconversion Rate (Percentage) <sup>b</sup>			Difference of Seroconversion Rates	Met Pre-defined Noninferiority Criteria <sup>f</sup>
	QIV-HD N <sup>c</sup> = 1679 -1680 (95% CI)	TIV-HD1 <sup>d</sup> (B1 Victoria) N <sup>c</sup> =423 (95% CI)	TIV-HD2 <sup>e</sup> (B2 Yamagata) N <sup>c</sup> =430 (95% CI)		QIV-HD over TIV-HD (95% CI)	QIV-HD N <sup>c</sup> = 1668 -1669 (95% CI)	TIV-HD1 <sup>d</sup> (B1 Victoria) N <sup>c</sup> =420-421 (95% CI)		
<b>A (H1N1) <sup>g</sup></b>	312 (292; 332)	374 (341; 411)		0.83 (0.744; 0.932)	50.4 (48.0; 52.8)	53.7 (50.2; 57.1)		-3.27 (-7.37; 0.86)	Yes
<b>A (H3N2) <sup>g</sup></b>	563 (525; 603)	594 (540; 648)		0.95 (0.842; 1.058)	49.8 (47.3; 52.2)	50.5 (47.1; 53.9)		-0.71 (-4.8; 3.38)	Yes

		653)		1.066)		53.9)		3; 3.42)	
<b>B1 (Victoria)</b>	516 (488; 545)	476 (426; 532)	--	1.08 (0.958; 1.224)	36.5 (34.2; 38.9)	39.0 (34.3; 43.8)	--	-2.41 (-7.6 6; 2.70)	Yes
<b>B2 (Yamagata)</b>	578 (547; 612)	--	580 (519; 649)	1.00 (0.881; 1.129)	46.6 (44.2; 49.0)	--	48.4 (43.5; 53.2)	-1.75 (-7.0 4; 3.53)	Yes

<sup>a</sup> NCT03282240

<sup>b</sup> Seroconversion Rates: For subjects with a pre-vaccination titer <10 (1/dil), proportion of subjects with a post-vaccination titer ≥40 (1/dil) and for subjects with a pre-vaccination titer ≥10 (1/dil), proportion of subjects with a ≥four-fold increase from pre- to post-vaccination titer.

<sup>c</sup> N is the number of vaccinated participants with available data for the immunologic endpoint listed

<sup>d</sup> TIV-HD1 contained A/Michigan/45/2015 (H1N1), A/Hong Kong/4801/2014 (H3N2), and B/Brisbane/60/2008 (B1, Victoria lineage).

<sup>e</sup> TIV-HD2 contained A/Michigan/45/2015 (H1N1), A/Hong Kong/4801/2014 (H3N2), and B/Phuket/3073/2013 (B2, Yamagata lineage).

<sup>f</sup> Predefined noninferiority criterion for seroconversion rates: the lower limit of the two-sided 95% CI of the difference of the seroconversion rates (Efluelda Tetra minus TIV-HD) is >-10%. Predefined noninferiority criterion for the GMT ratio: the lower limit of the 95% CI of the GMT ratio (Efluelda Tetra divided by TIV-HD) is >0.667.

<sup>g</sup> For the A strain comparison, TIV-HD1 and TIV-HD2 were pooled into a TIV-HD group for comparison with Efluelda Tetra.

Efluelda Tetra was as immunogenic as TIV-HD for GMTs and seroconversion rates for the common influenza strains. Moreover, Efluelda Tetra induced a superior immune response with respect to the additional B strain than the immune response induced by TIV-HD that does not contain the corresponding B.

The efficacy and effectiveness results of TIV-HD are thus inferred to Efluelda Tetra given the demonstration of statistically comparable immunogenicity between TIV-HD and Efluelda Tetra.

#### QHD00011

A randomized, active-controlled, modified double-blind, Phase III clinical trial conducted in Europe in adults 60 years and older to demonstrate the superiority of Efluelda Tetra over QIV-SD for all strains, as assessed by HAI (hemagglutinin inhibition) geometric mean antibody titers (GMTs) at Day 28 in adults 60 to 64 years of age and in adults 65 years of age and older.

A total of 1539 adults (760 adults 60 to 64 years of age and 779 adults 65 years of age and older) were randomized to receive either one dose of Efluelda Tetra or one dose of QIV-SD.

**Table 2: Study 2<sup>a</sup>: Analyses of Superiority of Efluelda Tetra to QIV-SD by Post-Vaccination HAI Antibody GMTs in Adults 60-64 Years of Age and 65 Years of Age and Older, Full Analysis Set**

Influenza Strain	Adults 60 to 64 Years of Age			Met Pre-defined Superiority Criteria <sup>c</sup>	Adults 65 years of Age and Older			Met Pre-defined Superiority Criteria <sup>c</sup>
	GMT		GMT Ratio		GMT		GMT Ratio	
	<b>Efluelda Tetra</b> N <sup>b</sup> =376-377 7 (95% CI)	<b>QIV-SD</b> N <sup>b</sup> =377 (95% CI)	<b>Efluelda Tetra over QIV-SD</b> (95% CI)		<b>Efluelda Tetra</b> N <sup>b</sup> =392 (95% CI)	<b>QIV-SD</b> N <sup>b</sup> =381 (95% CI)	<b>Efluelda Tetra over QIV-SD</b> (95% CI)	
<b>A (H1N1)</b>	471 (416 ; 533)	248 (217 ; 283)	1.90 (1.58 ; 2.28)	Yes	286 (250 ; 326)	162 (139 ; 190)	1.76 (1.44 ; 2.15)	Yes

<b>A (H3N2)</b>	303 (262 ; 350)	178 (154 ; 206)	1.70 (1.38 ; 2.08)	Yes	324 (281 ; 374)	151 (129 ; 176)	2.15 (1.74 ; 2.65)	Yes
<b>B1 (Victoria)</b>	497 (450 ; 548)	330 (297 ; 367)	1.51 (1.30 ; 1.74)	Yes	405 (366 ; 447)	262 (236 ; 291)	1.55 (1.34 ; 1.79)	Yes
<b>B2 (Yamagata)</b>	766 (690 ; 849)	433 (391 ; 480)	1.77 (1.53 ; 2.04)	Yes	536 (485 ; 592)	305 (274 ; 340)	1.76 (1.52 ; 2.03)	Yes

<sup>a</sup> NCT04024228

<sup>b</sup> N is the number of participants with available data for the considered endpoint

<sup>c</sup> Superiority was concluded if the lower limit of the two-sided 95% CI of the ratio of GMTs between groups (QIV-HD/QIV-SD) was > 1 for each strain and in each age group

The efficacy and effectiveness results of TIV-HD are thus inferred to Efluelda Tetra, given the demonstration of statistically comparable immunogenicity between TIV-HD and Efluelda Tetra in adults 65 years of age and older (QHD00013) and similar immune responses observed in adults 60 to 64 years of age and in adults 65 years of age and older (QHD00011).

In addition, Efluelda Tetra induced an immune response that was superior to the responses induced by QIV-SD for all 4 virus strains 28 days post-vaccination in adults 60 to 64 years of age and in adults 65 years of age and older.

#### Pivotal Clinical Efficacy (FIM12)

FIM12 was a multi-centre, double-blind efficacy trial conducted in the US and Canada in which adults 65 years of age and older were randomised (1:1) to receive the TIV-HD or a standard dose vaccine. The study was conducted over two influenza seasons (2011-2012 and 2012-2013) to assess the occurrence of laboratory-confirmed influenza caused by any influenza viral type/subtype, in association with influenza-like illness (ILI) as the primary endpoint.

Participants were monitored for the occurrence of a respiratory illness by both active and passive surveillance, starting 2 weeks post-vaccination for approximately 7 months. After an episode of respiratory illness, nasopharyngeal swab samples were collected for analysis; attack rates and vaccine efficacy were calculated. The pre-specified statistical superiority criterion for the primary endpoint (lower limit of the 2-sided 95% CI of the vaccine efficacy for the TIV-HD relative to standard dose vaccine > 9.1%) was met.

**Table 3: Relative vaccine efficacy to prevent influenza-like illness<sup>a</sup> in adults ≥ 65 years**

	<b>High Dose vaccine</b> <b>N<sup>b</sup> = 15892</b> <b>n<sup>c</sup> (%)</b>	<b>Standard dose vaccine</b> <b>N<sup>b</sup> = 15911</b> <b>n<sup>c</sup> (%)</b>	<b>Relative Efficacy</b> <b>% (95% CI)</b>
Laboratory-confirmed influenza <sup>d</sup> caused by:			
• <b>Any type/subtype<sup>e</sup></b>	227 (1.43)	300 (1.89)	24.2 (9.7; 36.5)
• <b>Viral strains similar to those contained in the vaccine</b>	73 (0.46)	113 (0.71)	35.3 (12.4; 52.5)

<sup>a</sup> Occurrence of at least one of the following respiratory symptoms: sore throat, cough, sputum production, wheezing, or difficulty breathing; concurrent with at least one of the following systemic signs or symptoms: temperature >37.2°C, chills, tiredness, headaches or myalgia

<sup>b</sup> N is the number of vaccinated participants in the per-protocol analysis set for efficacy assessments

<sup>c</sup> n is the number of participants with protocol-defined influenza-like illness with laboratory confirmation

<sup>d</sup> Laboratory-confirmed: culture- or polymerase-chain-reaction-confirmed

<sup>e</sup> Primary endpoint

#### Effectiveness Studies

##### Randomized Clinical Trials

A cluster-randomized, controlled clinical trial in United States nursing homes assessed the relative effect of TIV-HD versus a standard dose of influenza vaccine in hospitalizations among 53008 individuals during the 2013-2014 influenza season.

During the 2013-2014 season, the incidence of respiratory-related hospital admissions (primary objective) was significantly reduced in facilities where residents received TIV-HD compared with those that received standard-dose influenza vaccines by 12.7% (adjusted risk ratio [ARR] 0.873, 95% CI 0.776 to 0.982,  $p=0.023$ ). Moreover, with respect to secondary endpoints, TIV-HD reduced hospital admissions for pneumonia by 20.9% (ARR 0.791, 95% CI: 0.267 to 0.953,  $p=0.013$ ) and all-cause hospital admissions by 8% (ARR 0.915, 95% CI: 0.863 to 0.970,  $p=0.0028$ ).

### Observational Studies

Several retrospective studies, over 8 influenza seasons and in more than 24 million individuals 65 years of age and older, confirmed the superior protection offered by TIV-HD compared to standard-dose influenza vaccines against complications of influenza such as pneumonia and influenza hospitalization (13.4% (95%CI: 7.3% to 19.2%,  $p<0.001$ )), cardio-respiratory hospitalizations 17.9% (95%CI :14.9% to 20.9%,  $p<0.001$ ) and all –cause hospitalization 8.1% (95%CI: 5.9% to 10.3%,  $p<0.001$ ) ; although the impact may vary per season.

### Concomitant Administration with COVID-19 mRNA Vaccine (nucleoside modified)

In a descriptive open-label clinical study (NCT04969276), healthy adults aged 65 years and older were divided in three groups: Group 1 received Efluelda Tetra alone (N=92), Group 2 (N=100) received Efluelda Tetra concomitantly with an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) at least 5 months after the second dose of the primary series, Group 3 (N=104) received only the investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) .

Co-administration resulted in no change to influenza vaccine immune responses as measured by hemagglutination inhibition (HAI) assay. Co-administration resulted in similar responses to COVID-19 mRNA vaccine, as assessed by an anti-spike IgG assay (see section 4.5 and 4.8).

## **5.2 Pharmacokinetic properties**

Not applicable.

## **5.3 Preclinical safety data**

Nonclinical data reveal no special hazards for humans based on conventional studies of local tolerance and repeated dose toxicity studies.

Efluelda Tetra has not been evaluated for carcinogenic or mutagenic potential nor for developmental and reproductive toxicity study.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

- Sodium phosphate-buffered isotonic sodium chloride solution
- Sodium chloride
- Monobasic sodium phosphate
- Dibasic sodium phosphate
- Water for injections
- Octoxinol-9

## **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## **6.3 Shelf life**

12 months



#### **6.4 Special precautions for storage**

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

#### **6.5 Nature and contents of container**

0.7 ml of suspension in pre-filled syringe (Type I glass) equipped with a plunger stopper (bromobutyl rubber) and a tip-cap.

Pack of 1, 5 or 10 pre-filled syringe(s) without needle(s).

Pack of 1, 5 or 10 pre-filled syringe(s) with separate needle(s) (stainless steel).

Pack of 1 or 10 pre-filled syringe(s) with separate needle(s) (stainless steel) with safety shield (polycarbonate).

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal and other handling**

The vaccine should be allowed to reach room temperature before use.

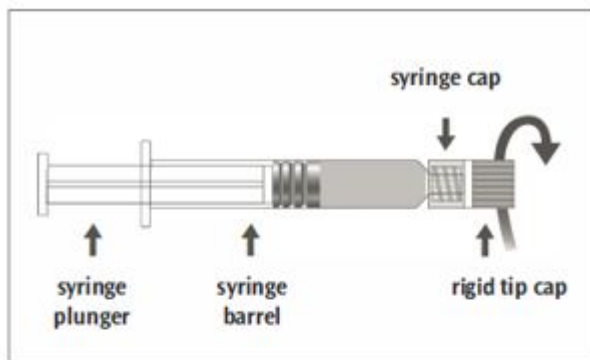
Shake before use.

The vaccine should be inspected visually for particulate matter and/or discoloration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

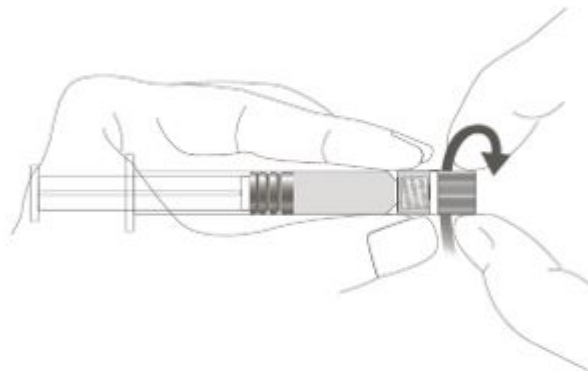
#### **Preparation for Administration**

The pre-filled syringe can be supplied with a Luer Lock with either Rigid Tip Cap (Picture A) or Soft Tip Cap (Picture B). The syringe with suspension for injection should be visually inspected prior to administration. In the event of any foreign particulate matter, leakage, premature activation of the plunger or faulty tip seal, discard the pre-filled syringe.

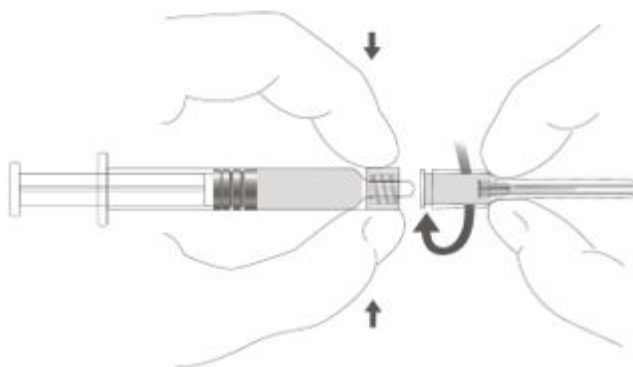
**Picture A: Luer Lock Syringe with Rigid Tip Cap**



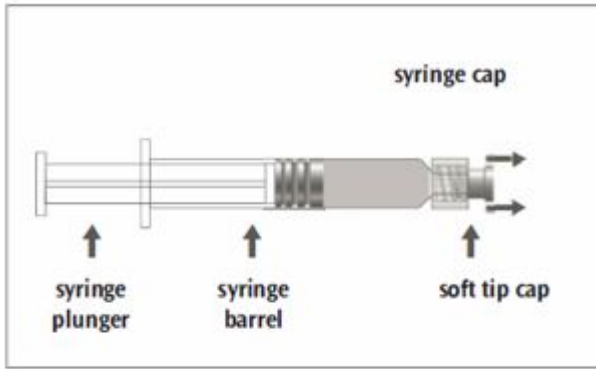
**Step 1:** Holding the syringe cap in one hand (avoid holding the syringe plunger or barrel), unscrew the tip cap by twisting it counterclockwise.



**Step 2:** To attach the needle to the syringe, gently twist the needle clockwise into the syringe until slight resistance is felt.



**Picture B: Luer Lock Syringe with Soft Tip Cap**



<p><b>Step 1:</b> Holding the syringe cap in one hand (avoid holding the syringe plunger or barrel), pull-off the tip cap.</p>	
<p><b>Step 2:</b> To attach the needle to the syringe, gently twist the needle clockwise into the syringe until slight resistance is felt.</p>	

The syringe is intended for single use only and must not be reused. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Sanofi Pasteur  
 14 Espace Henry Vallee  
 Lyon  
 69007  
 France

**8 MARKETING AUTHORISATION NUMBER**

PA2131/015/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24<sup>th</sup> April 2020

**10 DATE OF REVISION OF THE TEXT**

April 2024