Package leaflet: Information for the user

Decapeptyl® 3-month
11.25 mg powder and solvent for suspension for injection
Triptorelin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Decapeptyl 3-month is and what it is used for

The active ingredient in Decapeptyl 3-month is triptorelin. Triptorelin belongs to a group of medicines called gonadotropin releasing hormone (GnRH) agonists. Triptorelin is similar to the gonadotropin releasing hormone which occurs naturally in your body.
In men, triptorelin lowers the levels of the hormone testosterone.
In women, it reduces oestrogen levels.

Decapeptyl 3-month has three different uses. It is used in men, women and children to treat completely different conditions.

This leaflet gives information for all three uses of Decapeptyl 3-month. Please read all the sections that are about you and your condition.

MEN
In men Decapeptyl 3-month is used to treat advanced Prostate Cancer.

WOMEN
In women Decapeptyl 3-month is used to treat Endometriosis - a condition in which the tissue that normally lines the uterus (endometrium) grows in other places.

CHILDREN

In children Decapeptyl 3-month is used to treat Puberty that occurs at a very young age, i.e., before 8 years in girls and 10 years in boys (Central Precocious Puberty). This is called 'early puberty' in the rest of this leaflet.

2. What you need to know before you use Decapeptyl 3-month

MEN

Do not use Decapeptyl 3-month:

- If you are allergic to triptorelin or similar types of drugs (other GnRH agonists) or any of the other ingredients of this medicine (listed in section 6).
- If your prostate cancer has spread to your spine or if the tumour is pressing on your spine.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Decapeptyl 3-month.

There have been reports of depression in patients taking Decapeptyl 3-month which may be severe. If you are taking Decapeptyl 3-month and develop depressed mood, **inform your doctor**. Your doctor may want to monitor your depression during treatment.

If you are using medicines for preventing your blood clotting, since you may experience bruising at the site of the intramuscular injection. The product could be administered by either the intramuscular or subcutaneous route.

In adults, triptorelin may cause thinning of the bones (osteoporosis) with an increased risk of bone fractures. You should therefore tell your doctor if you have any of the below risk factors as he/she might give you bisphosphonate (drugs used to treat weak bones) to treat bone loss. Risk factors may include:

- If you or any of your close family have thinning of the bones.
- If you drink excessive amounts of alcohol and/or smoke heavily.
- If you take medicines over a long period of time that may cause thinning of the bones, for example medicines for epilepsy or steroids (such as hydrocortisone or prednisolone).

When you first start treatment with Decapeptyl 3-month it actually **increases** the level of your hormones for a short time. This means that you may feel worse to begin with (see section 4 'Possible side effects' for more information). The doctor may give you some medicine (an anti-androgen) to prevent your symptoms from getting worse. After a short time the amount of hormone will drop and your symptoms will get better.

If you suffer from urinary obstruction or spinal cord (nerves in your backbone) compression due to your prostate cancer spreading, your doctor will supervise you closely for the first few weeks of treatment. If you experience difficulty passing urine, bone pain, weakness of lower limbs or pins and needles sensation, contact your doctor immediately, who will assess and treat you appropriately.

Tell your doctor if you have diabetes.

Tell your doctor if you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Decapeptyl 3-month.

Testosterone decreasing agents may cause changes in ECG associated with heart rhythm abnormalitites (QT prolongation).

If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment. Symptoms include sudden headache, problems with eyesight and paralysis of the eyes.

After surgical castration triptorelin does not induce any further decrease in serum testosterone levels.

Diagnostic tests of pituitary gonadal function or sex organs conducted during treatment or after discontinuation of therapy with Decapeptyl 3-month may be misleading.

Other medicines and Decapeptyl 3-month:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Decapeptyl 3-month might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Tell your doctor if you are taking any medication for blood pressure control and management.

Drugs which increase the level of a hormone called prolactin may react with Decapeptyl 3-month. Many different kinds of drugs may increase prolactin levels.

Driving and using machines:
You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment or from the underlying disease. If you experience any of these side effects, you should not drive or use machines.

Decapeptyl 3-month contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., essentially ‘sodium-free‘.

WOMEN
Do not use Decapeptyl 3-month:
- If you are allergic to triptorelin or similar types of drugs (other GnRH agonists) or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or breast-feeding.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Decapeptyl 3-month.

Due to lack of clinical experience in women under 18 years of age, Triptorelin is not recommended in adolescent and young women as it might cause thinning of bone.

There have been reports of depression in patients taking Decapeptyl 3-month which may be severe. If you are taking Decapeptyl 3-month and develop depressed mood, **inform your doctor**. Your doctor may want to monitor your depression during treatment.

If you are using medicines for preventing your blood clotting, since you may experience bruising at the site of the intramuscular injection.

In adults, triptorelin may cause thinning of the bones (osteoporosis) with an increased risk of bone fractures. You should therefore tell your doctor if you have any of the below risk factors as he/she might give you bisphosphonate (drugs used to treat weak bones) to treat bone loss. Risk factors may include:

- If you or any of your close family have thinning of the bones.
- If you drink excessive amounts of alcohol and/or smoke heavily.
- If you take medicines over a long period of time that may cause thinning of the bones, for example medicines for epilepsy or steroids (such as hydrocortisone or prednisolone).

Tell your doctor if you have diabetes.

Tell your doctor if you suffer from heart problems.

If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment. Symptoms include sudden headache, problems with eyesight and paralysis of the eyes.

You may have some vaginal bleeding in the first month of treatment. After that your periods normally stop.

Tell your doctor if you have bleeding after the first month of treatment.

Your periods should start approximatively 5 months after the last injection.

You must use some form of contraception other than a contraceptive pill while you are having treatment and until you start your next period. Your doctor may suggest using a barrier method of contraception such as a condom or diaphragm (cap).

Other medicines and Decapeptyl 3-month:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any medication for blood pressure control and management.

Drugs which increase the level of a hormone called prolactin may react with Decapeptyl 3-month. Many different kinds of drugs may increase prolactin levels.

Pregnancy and breast-feeding:
Do not take Decapeptyl 3-month if you are pregnant or breast-feeding.

Driving and using machines:
You may feel dizzy, tired or have problems with your sight such as blurred vision. These are possible side effects of treatment or from the underlying disease. If you experience any of these side effects, you should not drive or use machines.

Decapeptyl 3-month contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., essentially ‘sodium-free‘.

CHILDREN

Do not use Decapeptyl 3-month:

If you are allergic to triptorelin or similar types of drugs (other GnRH agonists) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Decapeptyl 3-month.

There have been reports of depression in patients taking Decapeptyl 3-month which may be severe. If you are taking Decapeptyl 3-month and develop depressed mood, **inform your doctor**. Your doctor may want to monitor your depression during treatment.

If you are using medicines for preventing your blood clotting, since you may experience bruising at the site of the intramuscular injection.

If you have a progressive brain tumour, **tell your doctor**. This may affect the way your doctor decides to treat you.

If your child suffers from a bad or recurrent headache, problems with eyesight and ringing or buzzing in the ears, contact a doctor immediately (see section 4).
Girls who have an early puberty may have some vaginal bleeding in the first month of treatment.

A pathology of the hip may occur after stopping treatment (slipped capital femoral epiphysis of the hip). It results in stiffness of the hip, a limp and / or severe pain in the groin radiating to the thigh. If this occurs, you should consult your doctor.

Other medicines and Decapeptyl 3-month:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any medication for blood pressure control and management.

Drugs which increase the level of a hormone called prolactin may react with Decapeptyl 3-month. Many different kinds of drugs may increase prolactin levels.

Decapeptyl 3-month contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., essentially ‘sodium-free‘.

3. How to use Decapeptyl 3-month

MEN

Method of administration:
Intramuscular or subcutaneous route.
Decapeptyl 3-month will be injected into a muscle, usually your bottom, or subcutaneously, by a doctor or nurse. On this leaflet there are instructions for them that explain how to prepare the injection.
You will normally receive an injection once every 3 months.

Also read 'Other medicines and Decapeptyl 3-month' in section 2.

If you are given more Decapeptyl 3-month than you should:
If you are given too much Decapeptyl 3-month you may experience additional or more severe side effects (see section 4 'Possible side effects').

If you forget to take a dose of Decapeptyl 3-month:
As soon as you realise that you have missed an injection you should **tell your doctor**. You will then be given your next injection.

If you stop receiving Decapeptyl 3-month:
If you stop receiving your Decapeptyl 3-month injection before your doctor tells you to then your symptoms are likely to return.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

WOMEN
Method of administration:
Intramuscular route.
Decapeptyl 3-month will be injected into a muscle, usually your bottom, by a doctor or nurse. On this leaflet there are instructions for them that explain how to prepare the injection.
You will normally receive two injections, the second one three months after the first. The first injection will be given in the first five days of your period.
You should not need to be treated for more than 6 months.

Also read 'Other medicines and Decapeptyl 3-month' in section 2.

If you are given more Decapeptyl 3-month than you should:
If you are given too much Decapeptyl 3-month you may experience additional or more severe side effects (see section 4 'Possible side effects').

If you forget to take a dose of Decapeptyl 3-month:
As soon as you realise that you have missed an injection you should **tell your doctor**. You will then be given your next injection.

If you stop receiving Decapeptyl 3-month:
If you stop receiving your Decapeptyl 3-month injection before your doctor tells you to then your symptoms are likely to return.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

CHILDREN

Method of administration:
Intramuscular route.
Decapeptyl 3-month will be injected into a muscle, usually your bottom, by a doctor or nurse. On this leaflet there are instructions for them that explain how to prepare the injection.
You will normally receive an injection once every 3 months.
Your doctor will decide when treatment should be stopped (normally when you are about 12-13 if you are a girl and about 13-14 if you are a boy).

Also read 'Other medicines and Decapeptyl 3-month' in section 2.

If you are given more Decapeptyl 3-month than you should:
If you are given too much Decapeptyl 3-month you may experience additional or more severe side effects (see section 4 'Possible side effects').

If you forget to take a dose of Decapeptyl 3-month:
As soon as you realise that you have missed an injection you should **tell your doctor**. You will then be given your next injection.

If you stop receiving Decapeptyl 3-month:
If you stop receiving your Decapeptyl 3-month injection before your doctor tells you to then your symptoms are likely to return.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In rare cases you may experience a severe allergic reaction (angioedema, anaphylactic reaction). Tell your doctor immediately if you develop symptoms such as swallowing or breathing problems, dizziness, a rash, swelling of your lips, face, throat or tongue.

MEN
Many of the side effects are expected, due to the change in the level of testosterone in your body. These effects include hot flushes, impotence and decreased libido.

Side effects which are **very common** (may affect more than 1 in 10 people) are hot flushes, weakness, excessive sweating, back pain, pins and needles sensation in the legs, reduced libido and impotence.

Side effects which are **common** (may affect up to 1 in 10 people) are nausea, dry mouth, pain, bruising, redness and swelling when injected, muscle and bone pain, pain in the arms and legs, oedema (build-up of fluid in the body tissues), lower abdominal pain, high blood pressure, allergic reaction, increase in weight, dizziness, headache, loss of libido, depression and mood changes.

Side effects that are **uncommon** (may affect up to 1 in 100 people) are increase of blood platelets, feeling your heartbeat, ringing in the ears, vertigo, blurred vision, pain in abdomen, constipation, diarrhoea, vomiting, drowsiness, severe shivering associated with sweating and a fever, sleepiness, pain, swelling of the ankles, feet

or fingers, some blood tests affected (including raised liver function tests), blood pressure increased, weight loss, loss of appetite, increase of appetite, gout (severe pain and swelling in the joints usually in the big toe), diabetes, excessive lipids in the blood, joint pain, muscle cramp, muscle weakness, muscle pain, swelling and tenderness, bone pain, tingling or numbness, inability to sleep, feeling of irritability, development of enlarged breasts in men, breast pain, reduction in testicular size, pain in testicles, difficulty in breathing, acne, hair loss, itching, rash, redness of skin, hives, waking up to pass urine, problems passing urine and nosebleeds.

Side effects that are **rare** (may affect up to 1 in 1,000 people) are red or purple discolorations on the skin, abnormal sensation in the eye, blurring or disturbance in vision, sensation of fullness in the abdomen, flatulence, abnormal sense of taste, chest pain, difficulty in standing, flu-like symptoms, fever, anaphylactic reaction (serious allergic reaction which can cause dizziness or difficulty in breathing, swelling of the face or throat), inflammation of the nose/throat, increased body temperature, stiff joints, joint swelling, musculoskeletal stiffness, osteoarthritis, memory loss, feeling confused, decreased activity, having a feeling of elation, shortness of breath when lying flat, blisters and low blood pressure.

During post-marketing surveillance the following side effects have also been reported (their frequency cannot be estimated from the available data): serious allergic reaction which can lead to a swelling of the face, the tongue and the neck, dizziness or breathing difficulties (Quincke oedema, anaphylactic shock), general discomfort, anxiety, rapid formation of wheals due to swelling of the skin or mucous membranes, urinary incontinence and changes in ECG (QT prolongation), if an existing pituitary tumour an increased risk of bleeding to the area.

As with other GnRH analogues, an increase in white blood cell count may be found in patients being treated with Decapeptyl 3-month.

Patients receiving long-term treatment by GnRH analogue in combination with radiation may have more side effects especially gastrointestinal, related to radiotherapy.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance: Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

WOMEN
Many of the side effects are expected due to the change in the level of oestrogens in your body.

These **very common** side effects (may affect more than 1 in 10 people) include headache, decreased libido, mood swings, difficulty in sleeping, breast disorder, ovarian hyperstimulation syndrome, pain during or after sexual intercourse, painful periods, genital bleeding, pelvic pain, dryness of the vagina, excessive sweating acne, oily skin and hot flushes.

Side effects which are **common** (may affect up to 1 in 10 people) are breast pain, muscle cramps, painful joints, weight gain, feeling sick, depression, nervousness, abdominal pain or discomfort, pain, bruising, redness and swelling at injection site, swelling and tenderness, allergic reaction, pain in the arms and legs, dizziness.

Side effects that are **uncommon** (may affect up to 1 in 100 people) are feeling your heartbeat, vertigo, dry eye, blurred vision, bloating, vomiting, diarrhoea, dry mouth, flatulence, mouth ulcer, weight decrease, decrease in

appetite, water retention, back pain, muscle pain, abnormal taste, loss of sensations, temporary loss of consciousness, memory loss, lack of concentration, tingling or numbness, involuntary muscle movement, mood changes, anxiety, disorientation, bleeding after sex, prolapse, irregular period, painful period and heavy period, small cysts (swelling) on the ovaries which can cause pain, discharge from the vagina, difficulty breathing, nosebleed, hair loss, dry skin, excessive bodily hair, brittle nails, itching, hives and skin rash.

During post-marketing surveillance the following side effects have also been reported (their frequency cannot be estimated from the available data): general discomfort, increased blood pressure, increased body temperature, serious allergic reaction which can lead to a swelling of the face, the tongue and the neck, dizziness or breathing difficulties (Quincke oedema, anaphylactic shock)), some blood tests affected (including raised liver function tests), hives, muscle weakness, confusion, absence of menstrual periods, rapid formation of wheals due to swelling of the skin or mucous membranes, abnormal sensations in the eyes and/or changes in sight, if an existing pituitary tumour an increased risk of bleeding to the area.

In endometriosis treatment, the disorders for which the treatment has been justified (pelvic pain, dysmenorrhea) may be exacerbated at the beginning of the treatment, but should disappear in one to two weeks. This may occur even if the treatment is producing a favorable effect. You should nevertheless immediately notify your doctor of this phenomenon.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance: Website: www.hpra.ie.
By reporting side effects, you can help provide more information on the safety of this medicine.

CHILDREN
Side effects which are **very common** (may affect more than 1 in 10 people) include vaginal bleeding which may occur in girls in the first month of treatment.

Side effects which are **common** (may affect up to 1 in 10 people) include pain in abdomen, pain, bruising, redness and swelling at injection site, headache, hot flushes, weight gain, acne, allergic reactions.

Side effects that are **uncommon** (may affect up to 1 in 100 people) are blurred vision, vomiting, constipation, nausea, general discomfort, overweight, neck pain, changes in mood, pain in breast, nosebleeds, itching, rash or hives in the skin.

During post-marketing surveillance the following side effects have also been reported (their frequency cannot be estimated from the available data): high blood pressure, abnormal vision, serious allergic reaction which can lead to a swelling of the face, the tongue and the neck, dizziness or breathing difficulties (Quincke oedema, anaphylactic shock)), some blood tests affected include hormone levels, rapid formation of wheals due to swelling of the skin or mucous membranes, muscle pain, mood disorders, depression, nervousness, Idiopathic intracranial hypertension (increased intracranial pressure around the brain characterised by headache, double vision and other visual symptoms, and ringing or buzzing in the ears).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance: Website: www.hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Decapeptyl 3-month

Keep Decapeptyl 3-month out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and on the outer box.
The expiry date refers to the last day of the month.

Once opened/reconstituted, immediate use is recommended.

This medicine should be stored below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Decapeptyl 3-month contains:
The active substance of Decapeptyl 3-month is triptorelin. Each vial contains the quantity of triptorelin (as triptorelin pamoate) to ensure that the minimum triptorelin quantity injected is 11.25 mg.
The other ingredients are D,L lactide-glycolide copolymer, mannitol, carmellose sodium, polysorbate 80.
The solvent contains mannitol and water for injections.

What Decapeptyl 3-month looks like and contents of the pack
Decapeptyl 3-month is supplied as an off-white powder in a clear glass vial. Each vial contains enough product for one injection. The solvent contains 2 mL of a clear, colourless liquid in a glass ampoule.
The injection is prepared using the syringe and needles provided. Around 2 mL of milky liquid is obtained.

This product is for single use only, any remaining product should be discarded.

Each pack contains:
1 clear glass vial with a rubber stopper and an aluminium cap containing the powder
1 glass ampoule containing the solvent
1 syringe
2 needles (38 mm and 25 mm) with safety device and 1 needle (38 mm) with no safety device.

Marketing Authorisation Holder
Ipsen Pharmaceuticals Limited, Blanchardstown Industrial Park, Blanchardstown, Dublin 15, Ireland.

Manufacturer
Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, 83870 Signes, France.

Is this leaflet hard to see or read? Phone +353 1 809 8256 and ask for help.

This leaflet was last revised in January 2023

The following information is intended for medical or healthcare professionals only:

INSTRUCTIONS FOR RECONSTITUTION

1. PREPARATION OF THE PATIENT BEFORE RECONSTITUTION

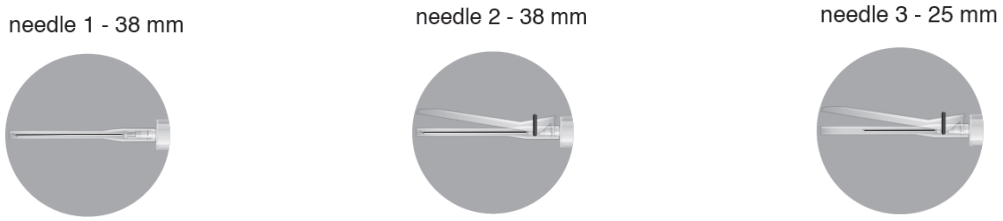
Prepare the patient by disinfecting the injection site. This operation needs to be performed first because once reconstituted, the drug should be injected immediately. The injection site is:

- For **WOMEN** and **CHILDREN**: the buttock (**intramuscular** administration)
- For **MEN** only: the buttock (**intramuscular** administration) or the abdomen or thigh (**subcutaneous** administration)

2. PREPARATION OF THE INJECTION

Three needles are provided in the box, ONLY TWO are to be used:

- **Needle 1**: a long 20G needle (38 mm of length) without safety device to be used for reconstitution in all cases
- **Needle 2**: a **long** 20G needle (38 mm of length) with safety device to be used for **intramuscular** injection (**MEN, WOMEN, CHILDREN**)
- **Needle 3**: a **short** 20G needle (25 mm of length) with safety device to be used for **subcutaneous** injection (**MEN ONLY**)

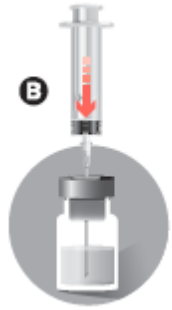
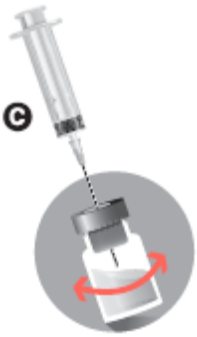
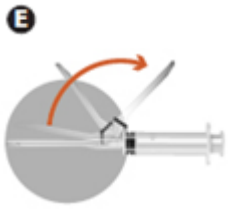


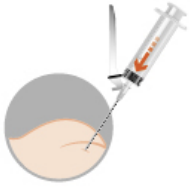
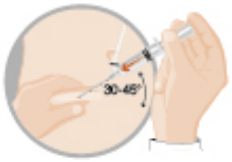
The only difference between Needle 2 and Needle 3 is the length.

The presence of bubbles on top of the lyophilisate is a normal appearance of the product.

2a

- Take out the ampoule containing the solvent. Tap any solution within the tip of the ampoule back to the main body of the ampoule.
- Screw **Needle 1** (without safety device) on to the syringe. Do not remove the needle protection yet.
- Break open the ampoule with dot face up.
- Remove the needle protection from Needle 1. Insert the needle in the ampoule and draw up all the solvent into the syringe.
- Put aside the syringe containing the solvent.

	**2b** • Take out the vial containing the powder. Tap any powder which has accumulated at the top of the vial back to the bottom of the vial. • Remove the plastic tab on top of the vial. • Take back the syringe containing the solvent and insert the needle through the rubber stopper vertically into the vial. Inject the solvent slowly, so that, if possible, it washes down the entire upper part of the vial.
	**2c** • Pull up Needle 1 above the liquid level. Do not remove the needle from the vial. Reconstitute the suspension, by swirling gently from side to side. Do not invert the vial. • Continue swirling long enough to obtain a homogeneous and milky suspension. • **Important**: **Check there is no unsuspended powder in the vial (if any powder clumps are present, continue swirling until they disappear**).
 	**2d** • When the suspension is homogeneous pull down the needle and without inverting the vial, draw up all of the suspension. A small amount will remain in the vial and should be discarded. An overfill is included to allow for this loss. • Grasp the coloured hub to disconnect the needle. Remove Needle 1 used for the reconstitution from the syringe. Screw on to the syringe corresponding to the type of injection: o For **intramuscular** injection, **Needle 2** (long needle with safety device) **or** o For **subcutaneous** injection in **men only**, **Needle 3** (short needle with safety device). • Move the safety sheath away from the needle and towards the syringe barrel. The safety sheath remains in the position you set. • Remove the needle protection from the needle. • Prime the needle to remove air from the syringe and inject immediately.

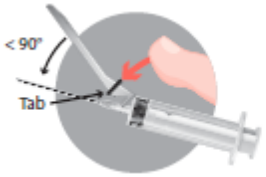
3. INJECTION	
Men, women, children intramuscular 	**WOMEN, CHILDREN** • To avoid precipitation inject immediately with **Needle 2** (**long needle**) **intramuscular** injection into the gluteal muscle previously disinfected.
Or men only subcutaneous 	**MEN** • To avoid precipitation inject immediately: o With **Needle 2** (**long needle**) **intramuscular** injection in to the gluteal muscle previously disinfected **or** o With **Needle 3** (**short needle**) **subcutaneous** injection into the abdomen wall or lateral aspects of the thigh previously disinfected. Grasp the skin of the abdomen or thigh, elevate the subcutaneous tissue and insert the needle with an angle between 30 and 45 degrees.

4. AFTER USE

- Activation of the safety system using a one-handed technique.
- Note: keep your finger behind the tab at all times.

There are two alternatives to activate the safety system:

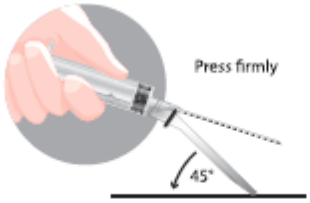
- Method A: push the tab forward with your finger



Method A

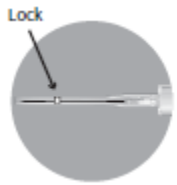
or

- Method B: push the sheath to a flat surface



Method B

- In both cases press down with a firm quick motion until a distinct audible click is heard.
- Visually confirm that the needle is fully engaged under the lock.



- Used needles, any unused suspension or other waste materials should be disposed of in accordance with local requirements.