Package leaflet: Information for the user

Decapeptyl® SR 3 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 SR 3 mg is and what it is used for

The active ingredient in Decapeptyl SR 3 mg 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 SR 3 mg is used in men and women to treat completely different conditions.

Decapeptyl SR is available in two other strengths: Decapeptyl SR 11.25 mg is used once every 3 months and Decapeptyl SR 22.5 mg is used once every 6 months. Not all dose strengths are approved for all indications. Ask your doctor if you would like to discuss changing your treatment.

This leaflet gives information for the use of Decapeptyl SR 3 mg in men and women. Please read all the sections that are about you and your condition.

MEN
In men, Decapeptyl SR 3 mg is used to treat prostate cancer.

WOMEN
In women, Decapeptyl SR 3 mg is used to treat:
- **Endometriosis - a condition in which the tissue that normally lines the uterus (endometrium) grows in other places.**
- **Uterine fibroids - abnormal (benign) growth of cells in your uterus.**
- **Hormone responsive early stage breast cancer in pre-menopausal women who have received chemotherapy.**

- **Decapeptyl SR 3 mg is used together with hormone medicines. You will also be asked to take:**
  A medicine called 'tamoxifen' – you will be asked to take this medicine if you are at high risk of the cancer coming back.
  Or
  An 'aromatase inhibitor' medicine such as 'exemestane' – you will have treatment with Decapeptyl SR 3 mg for at least 6 to 8 weeks before you start taking this medicine.
- **Remember to read the patient leaflet for the medicine you take with Decapeptyl SR 3 mg.**

2. What you need to know before you use Decapeptyl SR 3 mg

MEN

Do not use Decapeptyl SR 3 mg

- 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 SR 3 mg.

- There have been reports of depression in patients taking Decapeptyl SR 3 mg which may be severe. If you are taking Decapeptyl SR 3 mg 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, 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 wark 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).
- If any convulsions occur, inform immediately your doctor. There have been reports of convulsions in patients receiving triptorelin or similar medicines. These occurred in patients with or without medical history of epilepsy.
- When you first start treatment with Decapeptyl SR 3 mg 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 SR 3 mg.
- If you have an enlargement (benign tumour) of the pituitary gland that you were unaware of, this may be discovered during treatment with Decapeptyl SR 3 mg. Symptoms include sudden headache, problems with eyesight and paralysis of the eye muscles.
- 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 SR 3 mg may be misleading.

- Testosterone decreasing agents may cause changes in ECG associated with heart rhythm abnormalities (QT prolongation).
- **Tell your doctor** if you have back pain, weakness, numbness or tingling in your legs.
- Treatment with GnRH analogues including Decapeptyl SR 3mg might increase the risk of anaemia (defined as a decrease in the count of red blood cells).

Your doctor may give you another drug to help you feel better during this time.

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

Decapeptyl SR 3 mg 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).

Drugs which increase the level of a hormone called prolactin may react with Decapeptyl SR 3 mg. 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 SR 3 mg contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., essentially 'sodium-free'.

WOMEN
Do not use Decapeptyl SR 3 mg
- 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.
- If you are using Decapeptyl SR 3 mg for breast cancer, do not use an 'aromatase inhibitor' medicine (such as exemestane) with Decapeptyl SR 3 mg until you have been treated with Decapeptyl SR 3 mg for at least 6 to 8 weeks.

Warnings and precautions
Talk to your doctor or pharmacist before taking Decapeptyl SR 3 mg.
- 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 SR 3 mg which may be severe. If you are taking Decapeptyl SR 3 mg 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, 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 wark 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).
- If any convulsions occur, inform immediately your doctor. There have been reports of convulsions in patients receiving triptorelin or similar medicines. These occurred in patients with or without medical history of epilepsy.
- 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 approximately 2 months after the last injection.
- **You must use some form of contraception other than the '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).
- If you are a woman with submucous fibroids (benign tumours in the muscle underneath the lining of the womb), Triptorelin can cause bleeding when the fibroids break-down within the first 6-10 weeks after starting treatment. Contact your doctor immediately if you experience severe or unusual bleeding or pain.
- 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 eye muscles.

If you are using Decapeptyl SR 3mg for Breast cancer:

If you have anything wrong with you that affects your bones, such as osteoporosis, inform your doctor. This may affect the way you doctor decides to treat you. Your doctor will do a bone scan before treatment starts if you are at risk of osteoporosis and monitor you during treatment.

If you have diabetes or high blood pressure, inform your doctor. Your doctor will check your blood sugar levels and blood pressure during treatment.

Tell your doctor if you suffer from heart problems.

If you suffer from depression, inform your doctor. Your doctor may want to monitor your depression during treatment.

If you discontinue triptorelin treatment, you must discontinue at the same time aromatase inhibitor (such as exemestane) treatment.

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

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

Pregnancy and breast-feeding
Do not take Decapeptyl SR 3 mg 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 SR 3 mg contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e., essentially 'sodium-free'.

3. How to use Decapeptyl SR 3 mg

MEN
Decapeptyl SR 3 mg 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 28 days.

Also read 'Other medicines and Decapeptyl SR 3 mg' in section 2.

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

If you forget to take a dose of Decapeptyl SR 3 mg
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 SR 3 mg
If you stop receiving your Decapeptyl SR 3 mg 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
Decapeptyl SR 3 mg 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 one injection every 28 days. This injection should be given in the first 5 days of your menstrual cycle.

If you are being treated for uterine fibroids you should be treated for at least 3 months.

You should not need to be treated for more than 6 months.

If you are being treated for breast cancer, the recommended dose of Decapeptyl SR 3 mg is one injection into a muscle, every 4 weeks (28 days). Treatment may last up to five years.
Decapeptyl SR 3 mg is used together with a medicine called 'tamoxifen' or an 'aromatase inhibitor', such as 'exemestane'. If you need to take an 'aromatase inhibitor', you will have treatment with Decapeptyl SR 3 mg for at least 6 to 8 weeks before you start taking it. You will be receiving at least 2 injections of Decapeptyl SR 3 mg (with an interval of 4 weeks between injections) before you start taking it.

Also read “Taking other medicines” in section 2.

If you stop using Decapeptyl SR 3 mg
Do not stop treatment with Decapeptyl SR 3 mg without talking to your doctor first. This is especially important if you are using Decapeptyl SR 3 mg with an aromatase inhibitor. This is because stopping treatment could cause an increase in oestrogen levels. Your doctor will monitor your oestrogen levels during your treatment with Decapeptyl SR 3 mg.
If you stop using Decapeptyl SR 3 mg, you must also stop using treatment of aromatase inhibitors within 1 month of stopping your treatment.

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

If you forget to take a dose of Decapeptyl SR 3 mg
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 SR 3 mg
If you stop receiving your Decapeptyl SR 3 mg 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, Decapeptyl SR 3 mg can have 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 at injection site, 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 which 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, 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 which 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 the 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): changes in ECG (QT prolongation), 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), convulsions, general discomfort, anxiety, rapid formation of wheals due to swelling of the skin or mucous membranes and urinary incontinence, if there is an existing pituitary tumour there is an increased risk of bleeding to the area, anaemia (decrease in count of red blood cells).

An increase in white blood cell count may be found, as with other GnRH analogues, in patients being treated with Decapeptyl SR 3 mg.

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

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, weakness, 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 (long term treatment), nervousness, abdominal pain or discomfort, pain, bruising, redness and swelling at injection site, swelling of ankles, feet or fingers, allergic reaction, pain in the arms and legs, dizziness.

Side effects which are **uncommon** (may affect up to 1 in 100 people**)** are feeling your hearbeat, 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 change, anxiety, disorientation, depression (short term treatment), 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, 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), convulsions, some blood tests affected (including raised liver function tests) 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, hives, if there is an existing pituitary tumour there is 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.

Side effects when used for breast cancer in combination with either tamoxifen or an aromatase inhibitor
The following side effects have been seen when Decapeptyl SR 3 mg has been used for breast cancer in combination with either tamoxifen or an aromatase inhibitor:

Very common effects (affect more than 1 patient in 10): nausea, feeling very tired, joint and muscle pain, osteoporosis, hot flushes, excessive sweating, difficulty in sleeping, depression, decreased libido, dryness of the vagina, pain during or after sexual intercourse, urinary incontinence, increased blood pressure.

Common side effects (affect 1 to 10 patients of 100): diabetes, high blood sugar (hyperglycaemia), pain, bruising, redness and swelling at injection site, allergic reaction, bone fractures, blood clot in a blood vessel.

Uncommon side effects (affect 1 to 10 patients of 1000): bleed in the brain, lack of blood supply to the brain or the heart.

Rare side effects (affect 1 to 10 patients of 10,000): change in ECG (QT prolongation).

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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Decapeptyl SR 3 mg

Keep this medicine out of the sight and reach of children.

Do not use the vial or ampoule after the expiry date printed on the box.

This medicine should not be stored above 25°C. The vial and ampoule should be kept in the outer box.

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 SR 3 mg contains:
The active substance of Decapeptyl SR 3 mg is triptorelin. Each vial contains sufficient quantity of triptorelin (as triptorelin acetate) to ensure that the minimum triptorelin quantity injected is 3 mg.
The other ingredients are D,L lactide-glycolide copolymer, mannitol, carmellose sodium, polysorbate 80.

What Decapeptyl SR 3 mg looks like and contents of the pack
Each pack contains:
1 clear glass vial with a rubber stopper and an aluminium cap containing the powder
1 glass ampoule containing the suspension vehicle
1 syringe
2 needles.

Marketing Authorisation Holder
Ipsen Limited, 5th Floor, The Point, 37 North Wharf Road, Paddington, London, W2 1AF, UK.

Manufacturer
Ipsen Pharma Biotech, Signes, France.

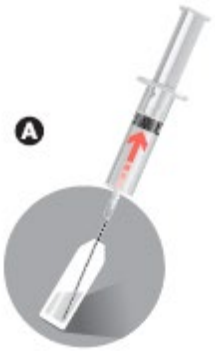
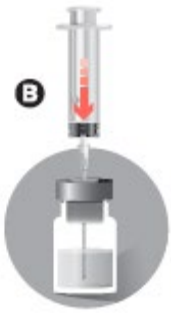
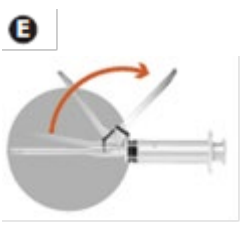
This leaflet was last revised in July 2024.

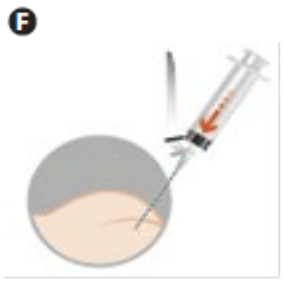
Is this leaflet hard to see or read? Please phone +44 (0)1753 627777 and ask for help.

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

INSTRUCTIONS FOR RECONSTITUTION

<table>
<tr><td colspan="2">1. PREPARATION OF THE PATIENT BEFORE RECONSTITUTION</td></tr>
<tr><td colspan="2">• Prepare the patient by disinfecting the injection site. This operation needs to be performed first because once reconstituted, the drug should be injected immediately.</td></tr>
<tr><td colspan="2">2. PREPARATION OF THE INJECTION</td></tr>
<tr><td colspan="2">Two needles are provided in the box:
• Needle 1: a 20G needle (38 mm of length) without safety device to be used for reconstitution
• Needle 2: a 20G needle (38 mm of length) with safety device to be used for injection
  </td></tr>
<tr><td colspan="2">The presence of bubbles on top of the lyophilisate is a normal appearance of the product.
The following steps must be completed in a continuous sequence.</td></tr>
<tr><td></td><td>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.</td></tr>
</table>

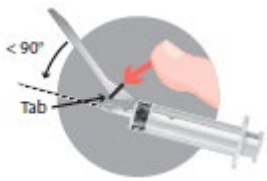
	• Remove the needle protection from Needle 1. Insert the needle in the ampoule and draw up all the solvent into the syringe. • Put aside the syringe containing the solvent.
	**2b** • Take out the vial containing the powder. Tap any powder which has accumulated at the top of the vial back to the bottom 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 (at least 30 seconds) 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 **Needle 2**. • 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. INTRAMUSCULAR INJECTION	
	• To avoid sedimentation, inject immediately into the disinfected area as quickly as possible (within 1 minute from reconstitution).
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:

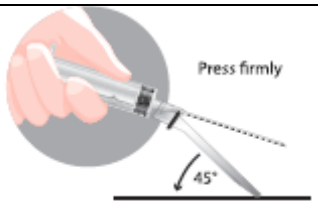
- Method A: push the tab forward with your finger



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.