PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

LONQUEX 6 mg solution for injection in pre-filled syringe

Lipegfilgrastim

Contains sugar (sorbitol 30 mg per pre-filled syringe)

Read all of this leaflet carefully before you are given LONQUEX:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LONQUEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT LONQUEX IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LONQUEX

3. HOW TO USE LONQUEX

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE LONQUEX

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT LONQUEX IS AND WHAT IT IS USED FOR:

LONQUEX contains the active substance lipegfilgrastim. Lipegfilgrastim is a long-acting modified

protein produced by biotechnology in bacteria called *Escherichia coli*. It belongs to a group of proteins called cytokines and is similar to a natural protein (granulocyte-colony stimulating factor [G-CSF]) produced by your own body.

Lipegfilgrastim stimulates the bone marrow (the tissue where new blood cells are made) to produce more white blood cells. White blood cells are important as they help your body fight infection. These cells are very sensitive to the effects of chemotherapy which can cause the number of these cells in your body to decrease. If white blood cells fall to a low level, there may not be enough left in the body to fight bacteria and you may have an increased risk of infection.

What LONQUEX is used for:

Your doctor has prescribed LONQUEX for you in order to reduce the duration of a condition called neutropenia (low white blood cell count) and the occurrence of febrile neutropenia (low white blood cell count with a fever). These can be caused by the use of cytotoxic chemotherapy (medicines that destroy rapidly-growing cells).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LONQUEX:

Do not use LONQUEX:

- if you are hypersensitive (allergic) to lipegfilgrastim or any of the other ingredients of LONQUEX (listed in **section 6**)

Warnings and precautions:

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with LONQUEX:

- If you are allergic to any other medicine of the group of G-CSFs (e.g. filgrastim, lenograstim or pegfilgrastim). There could be a risk of reacting to LONQUEX too
- if you have a history of blood cancers
- if you get left upper abdominal pain or pain at the tip of your shoulder. It could be a consequence of a spleen disorder (see **POSSIBLE SIDE EFFECTS**)
- if you have a cough, fever and difficulty breathing. It could be a consequence of a pulmonary disorder (see **POSSIBLE SIDE EFFECTS**)
- if you have symptoms of swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness. These could be symptoms of "capillary leak syndrome"
- if you have sickle cell anaemia, which is an inherited disease characterised by sickle-shaped red blood cells.

Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body) has been reported rarely with other medicines like this one (e.g. filgrastim, lenograstim or pegfilgrastim of the group of G-CSFs). The symptoms can include fever, abdominal pain, malaise, back pain and increased inflammatory markers. Tell your doctor if you experience these symptoms.

A precancerous condition called myelodysplastic syndrome (MDS) or a type of blood cancer called acute myeloid leukaemia (AML) have been reported with pegfilgrastim, a medicine like LONQUEX, when used in combination with chemotherapy and/or radiotherapy in breast and lung cancer patients. Although these conditions have not yet been reported with LONQUEX, your doctor will monitor you for signs and symptoms of MDS/AML, which may include tiredness, fever, and easy bruising or bleeding.

Your doctor will carry out regular blood tests in order to monitor various blood components and their levels. Your doctor will also check your urine regularly as other medicines similar to this one (e.g. other granulocyte colony stimulating factors such as filgrastim, lenograstim or pegfilgrastim) can possibly harm the tiny filters inside your kidneys (glomerulonephritis; see **POSSIBLE SIDE EFFECTS**).

Children and adolescents:

Do not give LONQUEX to children and adolescents under 18 years of age because there is only limited experience in children to show that LONQUEX is safe and works in this age group.

Other medicines and LONQUEX:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

You will normally inject your dose of LONQUEX approximately 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving LONQUEX.

Pregnancy:

The safety and efficacy of LONQUEX has not been established in pregnant women.

Breastfeeding:

It is unknown whether the LONQUEX passes into the breast milk. You should therefore interrupt breastfeeding your baby, during treatment.

Fertility:

No data available with respect to fertility.

Driving and using machines:

It is not known whether LONQUEX has an effect on you being able to drive or use any tools or machines.

It is not always possible to predict to what extent LONQUEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or use machines until they are aware of the measure to which LONQUEX affects them.

LONQUEX contains sugar (sorbitol):

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) receive LONQUEX.

LONQUEX contains less than 1 mmol sodium (23 mg) per pre-filled syringe, that is to say essentially sodium-free.

3. HOW TO USE LONQUEX:

Do not share medicines prescribed for you with any other person.

Always use LONQUEX exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is one pre-filled syringe (6 mg lipegfilgrastim) once per chemotherapy cycle.

When to use LONQUEX:

LONQUEX should be given approximately 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

How are the injections given?

This medicine is given as an injection using a pre-filled syringe.

The injection is given into the tissue just under the skin (subcutaneous injection).

Your doctor may suggest that you learn how to inject yourself with LONQUEX. Your doctor or nurse will give you instructions on how to do this.

Do not attempt to give LONQUEX to yourself without this training. Information required for using the pre-filled syringe can be found under **Information for injecting yourself**. Proper treatment of your disease, however, requires close and constant co-operation with your doctor.

Information for injecting yourself without a safety device:

This section contains information on how to give yourself an injection of LONQUEX under the skin. It is important that you do not try to give yourself the injection unless you have received special training from

your doctor or nurse. If you are not sure about giving yourself the injection or you have any questions, please ask your doctor or nurse for help.

How LONQUEX is used:

You will need to give yourself the injection into the tissue just under the skin. This is known as a subcutaneous injection.

Equipment that you need:

To give yourself an injection into the tissue under the skin you will need:

- a pre-filled syringe of LONQUEX,
- an alcohol wipe,
- a piece of gauze bandage or a sterile gauze swab.

What you should do before your injection:

1. Take the medicine out of the refrigerator.
2. Open the blister and take the pre-filled syringe out of the blister. Do not pick up the pre-filled syringe by the plunger or needle cover.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of LONQUEX. It must be a clear and colourless liquid. If there are particles in it or if it is cloudy, you must not use it.
5. Do not shake LONQUEX vigorously as this may affect its activity.
6. For a more comfortable injection, let the pre-filled syringe stand for 30 minutes to reach room temperature (not above 25 °C) or hold the pre-filled syringe gently in your hand for a few minutes.

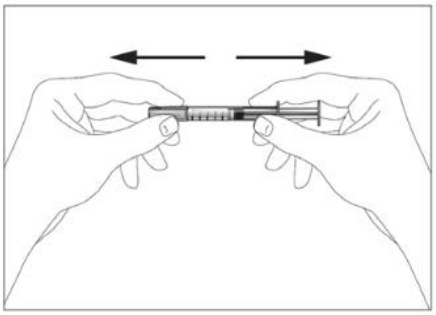
Do ***not*** warm LONQUEX in any other way (for example, do ***not*** warm it in a microwave or in hot water).

7. Do ***not*** remove the needle cover from the syringe until you are ready to inject.
8. Find a comfortable, well-lit place. Put everything you need within easy reach (the LONQUEX pre-filled syringe, an alcohol wipe, a piece of gauze bandage or a sterile gauze swab and the puncture-proof container).
9. ***Wash your hands thoroughly.***

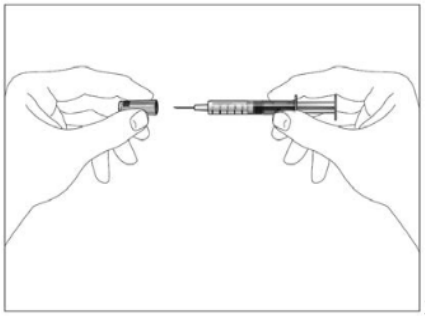
How to prepare for your injection:

Before you give yourself a LONQUEX injection, you must do the following:

1. Hold the syringe and gently remove the cover from the needle without twisting. Pull straight as shown in pictures 1 and 2. Do not touch the needle or push the plunger.
2. You may notice small air bubbles in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. With the syringe pointing upwards, expel all air from the syringe by pushing the plunger slowly upwards.
3. You can now use the pre-filled syringe.



1



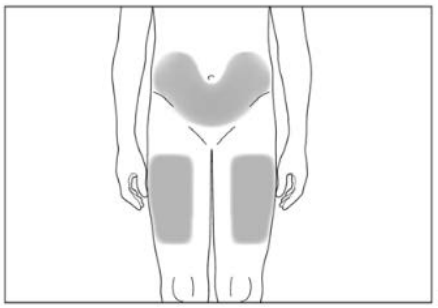
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Where your injection should be given:

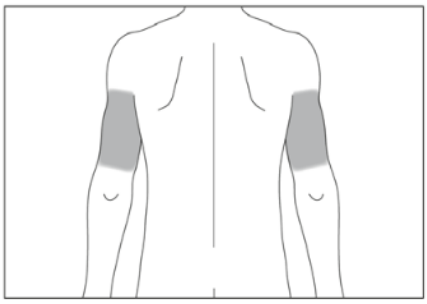
The most suitable places to inject yourself are:

- the top of your thighs,
- the abdomen (see grey areas in picture 3) avoiding the skin directly surrounding the navel.

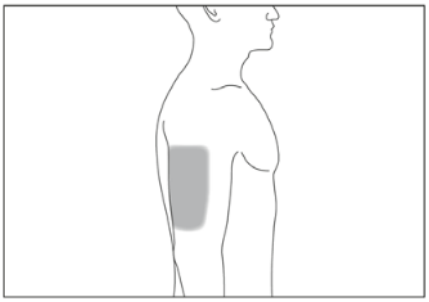
If someone else is injecting you, they can also use the back and side of your upper arms (see grey areas in pictures 4 and 5).



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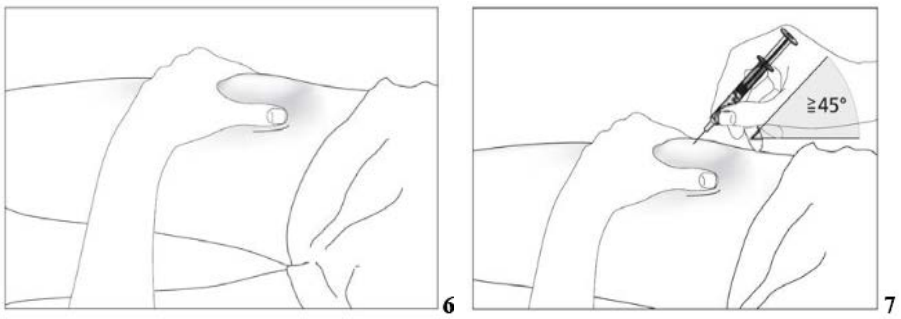


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How you should inject yourself:

1. Disinfect the injection site on the skin by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it (see picture 6).
2. Put the needle fully into the skin as shown by your doctor or nurse. The angle between the syringe and skin should not be too narrow (at least 45°, see picture 7).
3. Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.
4. Inject the liquid into the tissue slowly and evenly, always keeping your skin pinched.

5. After injecting the liquid, remove the needle and let go of your skin.
6. Press the injection site with a piece of gauze bandage or a sterile gauze swab for several seconds.
7. Only use each syringe for one injection. Do not use any LONQUEX that is left in the syringe.



Remember:

If you have any problems, please ask your doctor or nurse for help and advice.

Disposing of used syringes:

- Do not put the cover back on used needles.
- Put used syringes into the puncture-proof container and keep this container out of the sight and reach of children.
- Dispose of the full puncture-proof container as instructed by your doctor, pharmacist or nurse.
- Never put the syringes that you have used into your normal household rubbish bin.

Information for injecting yourself with a safety device:

This section contains information on how to give yourself an injection of LONQUEX under the skin. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. If you are not sure about giving yourself the injection or you have any questions, please ask your doctor or nurse for help.

How LONQUEX is used:

You will need to give yourself the injection into the tissue just under the skin. This is known as a subcutaneous injection.

Equipment that you need:

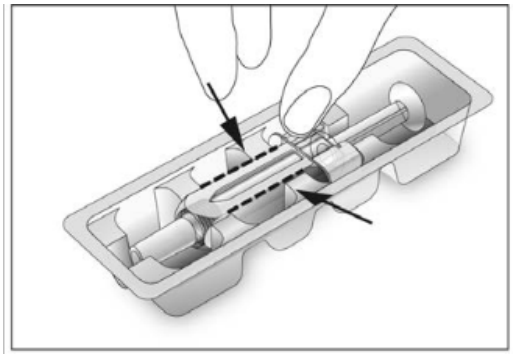
To give yourself an injection into the tissue under the skin you will need:

- a pre-filled syringe of LONQUEX,
- an alcohol wipe,
- a piece of gauze bandage or a sterile gauze swab.

What you should do before your injection:

1. Take the medicine out of the refrigerator.
2. Open the blister and take the pre-filled syringe out of the blister (see picture 1). Do not pick up the pre-filled syringe by the plunger or needle cover. This could damage the safety device.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of LONQUEX. It must be a clear and colourless liquid. If there are particles in it or if it is cloudy, you must not use it.
5. Do not shake LONQUEX vigorously as this may affect its activity.
6. For a more comfortable injection, let the pre-filled syringe stand for 30 minutes to reach room temperature (not above 25 °C) or hold the pre-filled syringe gently in your hand for a few minutes. Do ***not*** warm LONQUEX in any other way (for example, do ***not*** warm it in a microwave or in hot water).
7. Do ***not*** remove the needle cover from the syringe until you are ready to inject.
8. Find a comfortable, well-lit place. Put everything you need within easy reach (the LONQUEX pre-filled syringe, an alcohol wipe and a piece of gauze bandage or a sterile gauze swab).

9. Wash your hands thoroughly.

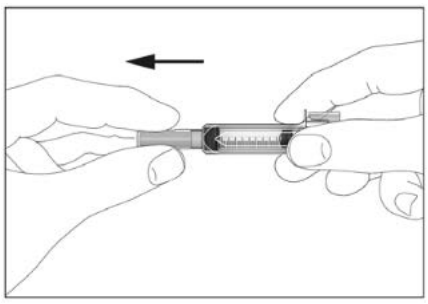


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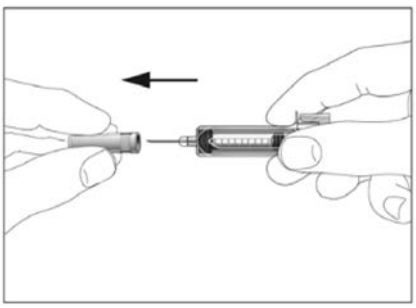
How to prepare for your injection:

Before you give yourself a LONQUEX injection, you must do the following:

1. Hold the syringe and gently remove the cover from the needle without twisting. Pull straight as shown in pictures 2 and 3. Do not touch the needle or push the plunger.
2. You may notice small air bubbles in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. With the syringe pointing upwards, expel all air from the syringe by pushing the plunger slowly upwards.
3. You can now use the pre-filled syringe.



2



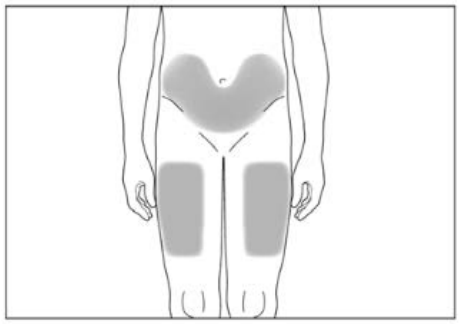
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Where your injection should be given:

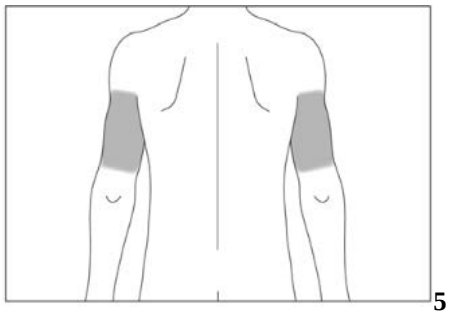
The most suitable places to inject yourself are:

- the top of your thighs,
- the abdomen (see grey areas in picture 4) avoiding the skin directly surrounding the navel.

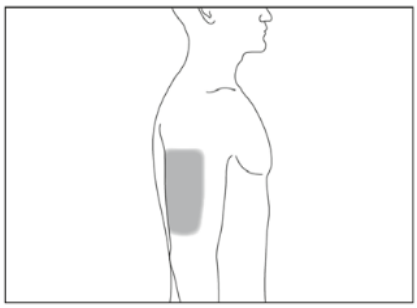
If someone else is injecting you, they can also use the back and side of your upper arms (see grey areas in pictures 5 and 6).



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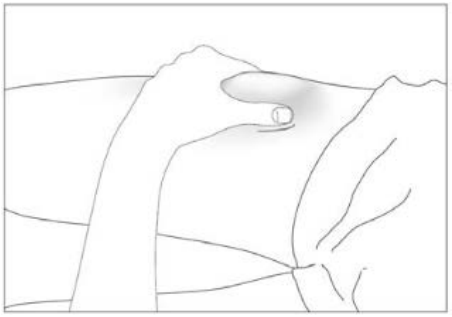
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How you should inject yourself:

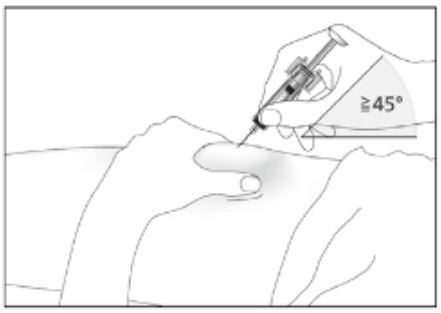
1. Disinfect the injection site on the skin by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it (see picture 7).
2. Put the needle fully into the skin as shown by your doctor or nurse. The angle between the syringe and skin should not be too narrow (at least 45°, see picture 8).
3. Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.
4. Inject the liquid into the tissue slowly and evenly, always keeping your skin pinched (see picture 9).
5. Push the plunger as far as it will go to inject all the liquid. While the plunger is still pressed all the way

down, remove the needle from the skin (see picture 10). Then release the plunger. The safety device will be activated immediately. The entire needle and syringe will be drawn back automatically and covered so that you cannot prick yourself (see picture 11).

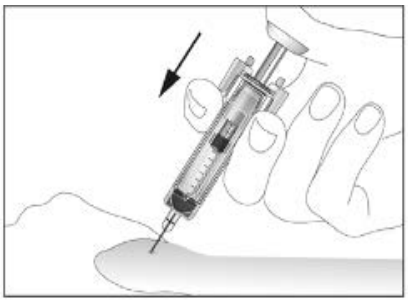
6. Press the injection site with a piece of gauze bandage or a sterile gauze swab for several seconds.
7. Each pre-filled syringe is for single use only.



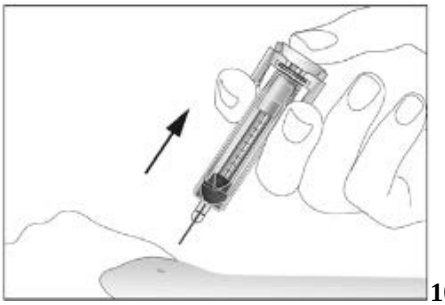
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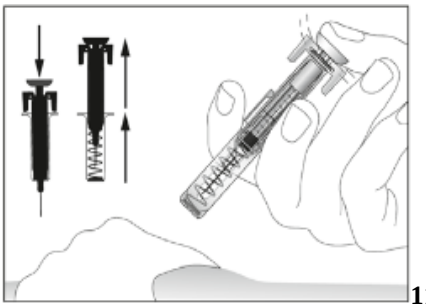
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Remember:

If you have any problems, please ask your doctor or nurse for help and advice.

If you receive more LONQUEX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you missed a dose of LONQUEX:

Do not use a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

LONQUEX can have side effects.

Not all side effects reported for LONQUEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LONQUEX, please consult your doctor, or healthcare provider for advice.

If any of the following happens, stop using LONQUEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LONQUEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at you nearest hospital if you notice any of the following:

- If you experience pain in the upper left side of the abdomen or left shoulder pain since this may relate to a problem with your spleen. Increased spleen size has been reported uncommonly and cases of splenic ruptures have been reported with other medicines similar to LONQUEX. Some cases of splenic rupture were fatal. It is important to contact your doctor immediately.
- Cough, fever and difficult or painful breathing can be signs of uncommon serious pulmonary side effects, such as pneumonia and acute respiratory distress syndrome, which may be fatal. If you have a fever or any of these symptoms, it is important to contact your doctor immediately.
- Swelling or puffiness, which may be associated with passing water less frequently, difficulty breathing, abdominal swelling and feeling of fullness, and a general feeling of tiredness. These symptoms generally develop in a rapid fashion. These could be symptoms of a condition reported with frequency not known (cannot be estimated from the available data), called "capillary leak syndrome", which causes blood to leak from the small blood vessels into your body and needs urgent medical attention.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- reduction in blood platelets, which increases risk of bleeding or bruising
- low blood levels of potassium, which can cause muscle weakness, twitching or abnormal heart rhythm
- headache
- coughing up blood

- nausea
- skin reactions, such as redness
- musculoskeletal pain such as bone pain and pain in the joints, muscles, limbs, chest, neck or back
- chest pain

Less frequent side effects:

- increase in the number of white cells in the blood, especially during an infection
- bleeding from the lung
- local reactions at the injection site, such as pain or hardening
- changes may occur in your blood, but these will be detected by routine blood tests.

Not known (it is not known how often these side effects happen):

- inflammation of the aorta (the large blood vessel which transports blood from the heart to the body),

Side effects that have been seen with similar medicines, but not yet with LONQUEX:

- sickle cell crises in patients with sickle cell anaemia
- plum-coloured raised painful sores on the limbs and sometimes the face and neck with fever (Sweet's syndrome)
- inflammation of the blood vessels in the skin
- damage to the tiny filters inside your kidneys (glomerulonephritis; see **section 2** under Warnings and precautions).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LONQUEX.

5. HOW TO STORE LONQUEX:

- Store all medicines out of reach of children.
- Store in a refrigerator (2 °C – 8 °C).
- Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- LONQUEX may be removed from the refrigerator and stored below 25 °C for a maximum single period of up to 7 days. Once removed from the refrigerator, the medicine must be used within this period or disposed of.
- Do not use this medicine if you notice that it is cloudy or there are particles in it.
- Do not use this medicine after the expiry date which is stated on the carton and the vial after "EXP". The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What LONQUEX contains:

The active substance is lipegfilgastrim.

Each pre-filled syringe contains 6 mg lipegfilgastrim in 0,6 ml solution.

Each ml solution contains 10 mg lipegfilgrastim.

The other ingredients are acetic acid, polysorbate 20, sodium hydroxide (for pH-adjustment), sorbitol (E420) and water for injection.

What LONQUEX looks like and contents of the pack:

LONQUEX is a clear, colourless solution.

LONQUEX is a solution for injection (injection) in a pre-filled type I glass syringe with a plunger stopper consisting of poly(ethylene-co-tetrafluoroethylene)-coated bromobutyl rubber and a fixed injection needle (stainless steel, 29G [0,34 mm] or 27G [0,4 mm] x 12,7 mm). Each pre-filled syringe contains 0,6 ml solution.

Each pack contains 1 pre-filled syringe with or without safety device.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park,

Magwa Crescent West,

Waterfall City,

Midrand,

Gauteng,

South Africa

2090

Tel: + 27 (011) 055 0200

This leaflet was last revised in:

30 October 2025

Registration /Application number

48/8.5/0745