

Package leaflet: Information for the user**Lonquex® 6 mg Solution for Injection in Pre-filled Syringe**

(lipegfilgrastim)

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, 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.

This product is called Lonquex 6 mg solution for injection in pre-filled syringe but will be referred to as Lonquex throughout the leaflet.

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**What Lonquex is**

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.

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).

How Lonquex works

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.

2 What you need to know before you use Lonquex**Do not use Lonquex if you:**

- are allergic to lipegfilgrastim or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse **before** using Lonquex 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 section 4 "Possible side effects").
- have a cough, fever and difficulty breathing. It could be a consequence of a pulmonary disorder (see section 4 "Possible side effects").
- have sickle cell anaemia, which is an inherited disease characterised by sickle-shaped red blood cells.
- have previously experienced allergic reactions to other medicines like this one (e.g. filgrastim, lenograstim or pegfilgrastim of the group of G-CSFs). There could be a risk of reacting to Lonquex too.
- are being treated for breast or lung cancer in combination with chemotherapy and/or radiation therapy and experience symptoms such as tiredness, fever, and easy bruising or bleeding. These symptoms could be a consequence of a precancerous blood condition called myelodysplastic syndrome (MDS) or of a blood cancer called acute myeloid leukaemia (AML) which have been associated with another medicine like this one (pegfilgrastim of the group of G-CSFs).

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 section 4 "Possible side effects").

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.

Children and adolescents

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

Other medicines and Lonquex

Tell your doctor or pharmacist if you are using, have recently used or might use any other 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 and breast-feeding

Lonquex has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby, as the doctor may decide that you should not use this medicine.

It is unknown whether the active substance in this medicine passes into the breast milk. You should therefore interrupt breast-feeding during treatment.

Driving and using machines

Lonquex has no or negligible influence on your ability to drive and use machines.

Information about ingredients of Lonquex Sorbitol

This medicine contains 30 mg sorbitol in each pre-filled syringe.

Sodium

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

3 How to use Lonquex

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

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

When to use Lonquex

This medicine 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 this medicine. 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

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.

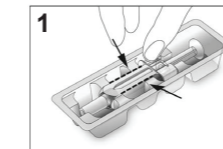
Equipment that you need

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.

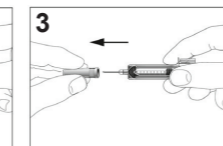
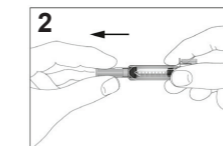
What you should do before your injection

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.**

**How to prepare for your injection**

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

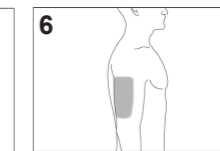
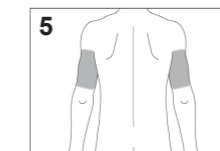
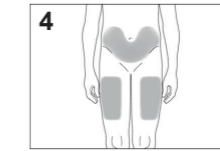
1. Hold the syringe and gently remove the cover from the needle without twisting. Pull straight as shown in pictures 2 and 3. Do not touch the needle or push the plunger.
2. You may notice small air bubbles in the pre-filled syringe. If there are air bubbles present, gently tap the syringe with your 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.

**Where your injection should be given**

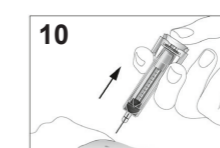
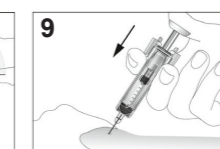
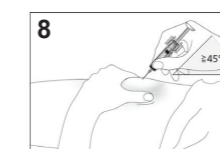
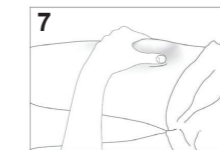
The most suitable places to inject yourself are:

- 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).

**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.

**Remember**

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

If you use more Lonquex than you should

If you use more Lonquex than you should, talk to your doctor.

If you forget to use Lonquex

If you have missed an injection, contact your doctor to discuss when you should inject the next dose.

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

4 Possible side effects

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

Most serious side effects

- Allergic reactions such as skin rash, raised itchy areas of skin and serious allergic reactions with weakness, drop in blood pressure, difficulty breathing and swelling of the face have been reported uncommonly (may affect up to 1 in 100 people). If you think you are having this type of reaction, you must stop your Lonquex injection and get medical help immediately.
- 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 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.
- 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.
- It is important to contact your doctor immediately if you have any of the following symptoms: 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.

Other side effects

Very common (may affect more than 1 in 10 people):

- musculoskeletal pains such as bone pain and pain in the joints, muscles, limbs, chest, neck or back. Tell your doctor if you experience severe musculoskeletal pain
- nausea.

Common (may affect up to 1 in 10 people):

- reduction in blood platelets, which increases risk of bleeding or bruising
- headache
- skin reactions, such as redness or rash
- low blood levels of potassium, which can cause muscle weakness, twitching or abnormal heart rhythm
- chest pain
- coughing up blood.

Uncommon (may affect up to 1 in 100 people):

- rise in white blood cells
- local reactions at the injection site, such as pain or hardening
- some changes may occur in your blood, but these will be detected by routine blood tests
- bleeding from the lung.

Not known (frequency cannot be estimated from the available data):

- inflammation of the aorta (the large blood vessel which transports blood from the heart to the body), see section 2.

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").

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 Lonquex

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

Do not use this medicine after the expiry date which is stated on the outer carton and on the label of the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

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 throw away this medicine via wastewater or household waste. Dispose of this medicine as instructed by your doctor, pharmacist or nurse.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6 Contents of the pack and other information

What Lonquex contains

- The active substance is lipegfilgrastim. Each pre-filled syringe contains 6 mg lipegfilgrastim. Each ml solution contains 10 mg lipegfilgrastim.
- The other ingredients (excipients) are glacial acetic acid, sodium hydroxide, sorbitol (E420), polysorbate 20 and water for injections.

What Lonquex looks like and contents of the pack

Lonquex is a solution for injection (injection) in pre-filled syringe with a fixed injection needle in a blister. Lonquex is a clear and colourless solution. Each pre-filled syringe contains 0.6 ml solution.

Each pack contains 1 pre-filled syringe with safety device.

Not all pack sizes may be marketed.

Manufacturer

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For any information about this medicine, please contact the local representative of the Product Licence Holder:

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