Lonquex®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lonquex?

Lonquex contains the active ingredient lipegfilgrastim. Lonquex is used following chemotherapy to help fight infection.

For more information, see Section 1. Why am I using Lonquex? in the full CMI.

2. What should I know before I use Lonquex?

Do not use if you have ever had an allergic reaction to Lonquex or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Lonquex? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lonquex and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Lonquex?

- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section 4. How do I use Lonquex? in the full CMI.

5. What should I know while using Lonquex?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Lonquex. • Keep all of your doctor's appointments so that your progress can be checked
Things you should not do	• Do not take Lonquex to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful driving or operating machinery until you know how Lonquex affects you.
Looking after your medicine	• Store in a refrigerator (2°C to 8°C). Do not freeze. • 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.

For more information, see Section 5. What should I know while using Lonquex? in the full CMI.

6. Are there any side effects?

Common side effects: Reduction in blood platelets, headache, skin reactions, low blood levels of potassium and chest pain.

Serious side effects: Allergic reactions such as skin rash, raised itchy areas of skin and serious allergic reactions with weakness, increased spleen size , cough, fever and difficult or painful breathing , serious pulmonary side effects, such as pneumonia and acute respiratory distress syndrome.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Lonquex®

Active ingredient(s): *lipegfilgrastim*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lonquex. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Lonquex.**

Where to find information in this leaflet:

1. Why am I using Lonquex?
2. What should I know before I use Lonquex?
3. What if I am taking other medicines?
4. How do I use Lonquex?
5. What should I know while using Lonquex?
6. Are there any side effects?
7. Product details

1. Why am I using Lonquex?

Lonquex contains the active ingredient 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.

Lonquex stimulates the bone narrow (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.

Lonquex is used following chemotherapy to help fight infection.

Some chemotherapy will reduce the number of neutrophils in your body. Although Lonquex is not a treatment for cancer, it does help the body to make new neutrophils and this may reduce your chance of developing infections that might require antibiotics and/or hospital stays. It may even increase your chance of receiving your chemotherapy on time and at the right dose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

2. What should I know before I use Lonquex?

Warnings

Do not use Lonquex if:

- you are allergic to lipegfilgrastim, or any other medicines like this one (i.e. filgrastim, lenograstim or pegfilgrastim of the group of G-CSFs), certain sugars, or any of the ingredients listed at the end of this leaflet.
- This medicine contains sorbitol.
- This medicine contains less than 1 mmol (23 mg) sodium per prefilled syringe, i.e. essentially 'sodium-free'.
- Always check the ingredients to make sure you can use this medicine

Check with your doctor if you:

- have sickle cell anaemia, which is an inherited disease characterized by sickle-shaped red blood cells.
- have a cough, fever and difficulty breathing. It could be a consequence of a pulmonary disorder.
- have upper abdominal pain or pain at the tip of your shoulder. It could be a consequence of a spleen disorder.
- have any other medical conditions
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Lonquex has not been tested in pregnant women. It is important that you 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Lonquex.

4. How do I use Lonquex?

Lonquex is given by injection using a prefilled syringe, usually into the tissues just below the skin. This is called a subcutaneous injection and it is a simple procedure.

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

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 sterile gauze swab

How much to use

- The recommended dose is one prefilled syringe (6 mg lipegfilgrastim) ONCE PER CHEMOTHERAPY CYCLE. This medicine should be given approximately 24 hours after your last dose of chemotherapy at the end of each chemotherapy cycle.

When to take / use Lonquex

- Follow the instructions provided and use Lonquex until your doctor tells you to stop.
- Lonquex should be injected 24 hours after the end of each chemotherapy cycle. Your doctor will tell you when to begin your treatment and when to stop.

Instructions for Injecting Lonquex

What you should do before your injection:

- Take the medicine out of the refrigerator.
- 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. This will damage the safety device.
- Check the expiry date on the pre-filled syringe label (EXP). Do not use if the date has passed the last day of the month shown.
- Check the appearance of Lonquex. It must be a clear and colorless liquid. If there are particles in it or if it is cloudy, you must not use it.
- Do not shake Lonquex vigorously as this may affect its activity.
- For a more comfortable injection, let the pre-filled injection 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).
- Do NOT remove the needle cover from the syringe until you are ready to inject.
- Find a comfortable, well-lit place. Place everything where you can reach for it (the Lonquex pre-filled syringe, an alcohol wipe and a piece of gauze bandage or a sterile gauze swab.
- Wash your hands thoroughly.

How to prepare for your injection

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

- Hold the syringe and gently remove the cover from the needle without twisting. Pull straight. Do not touch the needle or push the plunger.
- 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 form the syringe by pushing the plunger slowly upwards.
- You can now use the pre-filled syringe.
- Keep pre-filled syringes out of the sight and reach of children.

Where your injection should be given

The most suitable places to inject yourself are:

- the top of your thighs.
- the abdomen 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.

How you should inject yourself

- Disinfect the injection site on the skin by using an alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it.
- Put the needle fully into the skin as shown by your nurse or doctor. The angle between the syringe and skin should not be too narrow (at least 45°).
- 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.
- Inject the liquid into the tissue slowly and evenly, always keeping your skin pinched.
- 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. 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.
- Press the injection site with a piece of gauze bandage or a sterile gauze swab for several seconds.
- Each pre-filled syringe is for single use only.
- If you have any problems, please ask your doctor or pharmacist for help and advice.

If you forget to use Lonquex

If you miss your scheduled dose, advise your doctor, nurse or pharmacist as soon as possible about your missed dose

Do not take a double dose to make up for the dose you missed.

If you use too much Lonquex

If you think that you have used too much Lonquex, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Lonquex?

Things you should do

There are many ways an infection may show itself.

You should watch for:

- fever (a temperature of 38.2°C or greater, or as your doctor suggests)
- chills
- rash
- sore throat
- diarrhea
- ear ache
- difficult or painful breathing, coughing or wheezing.

Go straight to your hospital if you develop any of these symptoms.

Tell your doctor, nurse and pharmacist that you are using Lonquex if you are about to be started on any new medicine.

Tell your doctor immediately if you become pregnant while taking this medicine.

Keep all of your doctor's appointments so that your health can be monitored.

Remind any doctor, dentist or pharmacist you visit that you are using Lonquex.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Lonquex to treat any other complaint unless your doctor tells you to.
- Do not give Lonquex to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lonquex affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep Lonquex in a refrigerator at a temperature of 2°C to 8°C.
- Do not freeze.
- 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.
- Keep the pre-filled syringe in the outer carton, in order to protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

- Do not use this medicine if you notice that it is cloudy or there are particles in it.
- Once you have injected Lonquex, do not put the grey needle cap back on the used syringe.
- 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, nurse or pharmacist.
- Never put the syringes that you have used back into your normal household rubbish bin.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Very common Symptoms: • Musculoskeletal pains • bone pain • pain in the joints, muscles, limbs, chest, neck or back **Common Symptoms:** • Headache • Chest pain Reduction in blood platelets: • bleeding or bruising Skin reactions: • redness or rash Low blood levels of potassium:	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• muscle weakness • twitching or abnormal heart rhythm **Uncommon Symptoms** • Rise in white blood cells • changes your blood, will be detected by routine blood tests Local reactions at the injection site: • pain or hardening **Other symptoms seen with similar medicines but not with Lonquex** • Inflammation of the blood vessels in the skin • Sickle cell crises in patients with sickle cell anaemia Sweet's syndrome: • Plum-colored raised painful sores on the limbs and sometimes the face and neck • fever	

Serious side effects

Serious side effects	What to do
Allergic reactions may include : • skin rash • raised itchy areas of skin and serious allergic reactions with weakness, • drop in blood pressure • difficulty breathing • swelling of the face **Symptoms of spleen size or spleen ruptures:** • pain in the upper left side of the abdomen or left shoulder pain	**If you think you are having allergic reaction to Lonquex stop using this medicine and get medical help immediately.**
Symptoms of pulmonary side effects, such as pneumonia and acute respiratory distress syndrome: • Cough, fever and difficult or painful breathing **Symptoms of capillary leak syndrome:** • swelling or puffiness • passing water less frequently • difficulty breathing • abdominal swelling and feeling of fullness, and a general feeling of tiredness.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Lonquex contains

Active ingredient (main ingredient)	lipegfilgrastim
Other ingredients (inactive ingredients)	glacial acetic acid sodium hydroxide sorbitol polysorbate 20 water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What Lonquex looks like

Lonquex is a solution for injection (injection) in a pre-filled syringe with a fixed injection needle in a blister.

Lonquex is a clear and colorless solution.

Each prefilled syringe contains 0.6 mL solution.

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

(Aust R 231016).

Who distributes Lonquex

In Australia:

Teva Pharma Australia Pty Ltd

37 Epping Road

Macquarie Park

NSW 2113

Australia

Toll Free number: 1800 288 382

In New Zealand:

Teva Pharma New Zealand Ltd.

PO Box 128 244, Remuera

Auckland 1541,

New Zealand

Telephone: 0800 800 097

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