

Lonquex[®]

Lipegfilgrastim (rbe)

Consumer Medicine Information

What is in this booklet

This booklet answers some common questions about Lonquex.

Please note that this booklet does not contain everything there is to know about Lonquex. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has prescribed Lonquex after considering its likely benefit to you, as well as the potential risks.

If you have any concerns about taking this medicine, talk to your doctor, nurse or pharmacist.

Keep this booklet with your medicine.

You may need to read this information again.

What is Lonquex used for

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.

How it works

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.

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.

Before you use it

When you must not use it

Do not have Lonquex if you have allergies to:

- **Lipegfilgrastim or any other medicines like this one (i.e. filgrastim, lenograstim or pegfilgrastim of the group of G-CSFs).**
- **certain sugars**
- **This medicine contains sorbitol.**

- **This medicine contains less than 1 mmol (23 mg) sodium per prefilled syringe, i.e. essentially 'sodium-free'**

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives.

Before you start to use it

Tell your doctor if

- 1. you have sickle cell anaemia, which is an inherited disease characterized by sickle-shaped red blood cells.**
- 2. you have a cough, fever and difficulty breathing.**

It could be a consequence of a pulmonary disorder.

- 3. you have upper abdominal pain or pain at the tip of your shoulder.**

It could be a consequence of a spleen disorder.

- 4. 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.

- 5. you are breast-feeding.**

It is unknown whether the active substance in this medicine passes into the breast milk. You should

therefore interrupt breast-feeding during treatment.

- If you have not told your doctor about any of these things, tell him/her before you use Lonquex.**

How to use it

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.

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.

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

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

from 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.

How you should dispose 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, nurse or pharmacist.
- Never put the syringes that you have used back into your normal household rubbish bin.

Further general information

How much to inject

The usual dose is one subcutaneous injection 24 hours after the end of each chemotherapy cycle.

When to inject

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.

If you forget your injection

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

If you inject too much (overdose)

If you inject more Lonquex than you need, you should contact your doctor, nurse or pharmacist. If you feel

unwell in any way you should contact your doctor, nurse or pharmacist immediately.

While you are using it

Things you must do

Be alert for any signs or symptoms of infection.

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 any other doctors who treat you that you are taking this 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.

Things you must not do

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.

Side Effects

Tell your doctor as soon as possible

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Like all medicines, this medicine can cause side effects, although you may not experience any of them.

Do not be alarmed by this list of possible side effects.

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 and cases of spleen 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 (may affect up to 1 in 100 people) 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 other medicines similar to Lonquex 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. Your doctor will tell you what you can take to ease the bone pain.

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

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.

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

- Sickle cell crises in patients with sickle cell anaemia

- Plum-colored 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

If you get any side effects, talk to your doctor, pharmacist or nurse. This also includes any possible side effects not listed above. Tell your doctor if you notice anything that worries you or that is making you feel unwell.

After using it

Storage

- **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.**
- **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 outer carton and on the label of the pre-filled syringe after EXP. The expiry date refers to the last day of that month.**
- **Keep Lonquex out of the sight and reach of children.**
- **Dispose this medicine as instructed by your doctor, nurse or pharmacist**

Disposal

Once you have injected Lonquex, do not put the grey needle cap back on the used syringe.

Discard the used syringe into an approved, puncture-resistant sharps container and keep it out of the reach of children.

Never put the used syringes into your normal household rubbish bin.

Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Product description

What it 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 pre-filled syringe contains 0.6 mL solution.

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

Ingredients

The active ingredient in Lonquex is lipegfilgrastim.

Other ingredients are:

- glacial acetic acid
- sodium hydroxide
- sorbitol
- polysorbate 20
- water for injection

Supplier

In Australia:

Teva Pharma Australia Pty Ltd

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NSW 2113

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