

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

LONQUEX®

Solution for injection in a pre-filled syringe

For subcutaneous injection only

Composition

Each syringe contains:

Lipegfilgrastim 6 mg/0.6 ml

Corresponding to lipegfilgrastim 10 mg per 1 ml solution.

For information on the inactive and allergenic ingredients, see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Further information”.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is intended for subcutaneous injection only.

This medicine is not intended for use in children or adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to reduce the duration of neutropenia (low white blood cell count) and the incidence of febrile neutropenia that may be caused by chemotherapy treatment.

If you would like to find out why this medicine was prescribed for you, please ask your doctor or pharmacist.

Therapeutic group:

A G-CSF-type protein that stimulates production of white blood cells called neutrophils.

2. BEFORE USING THE MEDICINE

Do not use this preparation if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6 in this leaflet – “Further information”).

Special warnings regarding use of the medicine

Before treatment with Lonquex, tell the doctor if:

- you experience left upper abdominal pain or pain at the tip of the shoulder. This could indicate impaired spleen function (see section 4 – “Side effects”).
- you have a cough, fever or breathing difficulties. This can be caused by a lung problem (see section 4 – “Side effects”).
- you have sickle cell anemia – an inherited disease characterized by sickle-shaped red blood cells.
- you have previously experienced allergic reactions to medicines similar to this medicine (e.g., filgrastim, lenograstim or pegfilgrastim, belonging to the group of G-CSF-type proteins). There may be a risk of reacting to Lonquex as well.

Tests and follow-up

The doctor will consider performing routine blood tests to monitor the normalcy and levels of the various blood components. The doctor may also tell you to routinely perform urine tests, as is done with other medicines similar to Lonquex (e.g., medicines belonging to the G-CSF-type proteins such as filgrastim, lenograstim or pegfilgrastim), which may damage the glomeruli (small filters) in the kidney (glomerulonephritis; see section 4 – “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 similar to 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 signs of inflammation. Tell your doctor if you experience these symptoms.

Use in children

This medicine is not intended for use in children and adolescents under 18 years of age, due to limited data regarding the effectiveness and safety in this population.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

Pregnancy

The medicine has not been tested in pregnant women. Therefore, it is important to inform the doctor if you are pregnant, think you are pregnant or are planning to become pregnant. The doctor will decide if you should use the medicine.

Breastfeeding

It is unknown whether the active ingredient passes into breast milk. You should stop breastfeeding during treatment.

Driving and operating machinery

Lonquex has no effect or a negligible effect on the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Lonquex contains 30 mg sorbitol in each pre-filled syringe.

The medicine contains less than 23 mg sodium in each pre-filled syringe and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the medicine dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is generally: one syringe (6 mg lipegfilgrastim) administered subcutaneously, once per chemotherapy cycle.

When to use Lonquex

The medicine should be injected approximately 24 hours after the last dose of the chemotherapy, at the end of the chemotherapy treatment cycle.

How to inject

The medicine is given by injection with a pre-filled syringe; the injection is given subcutaneously.

The doctor may recommend undergoing training for self-injection of the medicine. The doctor or nurse will train you how to self-inject. Do not attempt to inject before receiving this training.

Please carefully read the instructions for use at the end of this leaflet. Remember that proper treatment of the disease requires close and constant cooperation with the doctor.

Do not exceed the recommended dose.

Instructions for using the medicine

Please see the instructions at the end of the leaflet.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take a dose of medicine, consult the doctor in order to receive instructions about when to inject the next dose.

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lonquex may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Most severe side effects

Stop treatment and refer to a doctor immediately if you experience any of the following side effects:

Allergic side effects such as skin rash, raised and itchy areas of the skin, and severe allergic reactions accompanied by weakness, drop in blood pressure, breathing difficulties and swelling of the face, are uncommonly reported effects (affecting up to 1 in 100 patients). If you experience these types of reactions, stop treatment with Lonquex and refer to a doctor immediately.

Refer to a doctor immediately if you experience any of the following side effects:

- Enlarged spleen (these effects are uncommon) and cases of spleen rupture resulting from use of other preparations similar to Lonquex, have been reported. Some of the cases of splenic rupture were fatal. Therefore, it is very important to inform the doctor immediately if you experience pain in the upper left side of the abdomen or of the left shoulder, since this may indicate a problem with the spleen.
- Cough, fever and difficulty or pain while breathing may be signs of severe pulmonary problems, such as pneumonia and acute respiratory distress syndrome (ARDS), which may be fatal (these effects are uncommon). If you have a fever or any of the above effects, refer to a doctor immediately.
- Consult a doctor immediately if you experience any of the following effects: swelling which may be accompanied by reduced frequency of urination, breathing difficulties, abdominal bloating, feeling of a full stomach, and a feeling of general fatigue. These signs can develop quickly (at an unknown frequency) and may indicate a condition called capillary leak syndrome – a condition in which blood leaks out of the capillaries – this condition requires urgent medical treatment.

Other side effects

Very common side effects (affect more than 1 in 10 patients):

- Musculoskeletal pain, such as bone pain and pain in the joints, muscles, limbs, chest, neck or back. Tell your doctor if you experience strong muscle pain.
- Nausea.

Common side effects (affect up to 1 in 10 patients):

- Reduction in blood platelets, which may increase the risk of bleeding or bruising.
- Headache.
- Skin reactions, such as redness or rash.
- Low blood potassium levels, that may cause muscle weakness, twitching, or irregular heartbeat.
- Chest pain.
- Coughing up blood.

Uncommon side effects (affect up to 1 in 100 patients):

- Increased number of white blood cells.
- Local reactions at the injection site, such as pain or hardening.
- Changes in the blood system may occur; these changes can be detected in routine blood tests.
- Bleeding from the lungs.

Side effects of unknown frequency (frequency cannot be established from the available data):

- Inflammation of the aorta (the large blood vessel which transports blood from the heart to the body), see section 2.
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- Increase in sickle-shaped red blood cells in patients with sickle cell anemia.
- Plum-colored, painful and raised lesions on the limbs and sometimes on the face and neck, accompanied by fever (Sweet's syndrome).
- Inflammation of blood vessels in the skin.
- Damage to the glomeruli (small filters) in the kidney (glomerulonephritis; see section 2 – “Tests and follow-up”).

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store in the refrigerator (at a temperature of 2-8°C).

Do not freeze.

Keep the syringe in the original package in order to protect from light.

Lonquex can be taken out of the refrigerator and kept below 25°C once only, for a maximum single period of up to 7 days. After taking the medicine out of the refrigerator, the medicine must be used within this period or disposed of in an appropriate bin.

Do not use the syringe if particles are visible or if the solution is cloudy. Do not dispose of the medicine in the toilet or household waste. Discard the medicine as per the instructions of the doctor, pharmacist or nurse.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Sorbitol, acetic acid, polysorbate 20, sodium hydroxide (for pH adjustment), water for injections.

What the medicine looks like and the contents of the package

Lonquex is a solution for injection in a pre-filled glass syringe with a fixed needle. The solution is clear and colorless. The product is marketed with or without a safety device.

Each package contains one syringe containing 0.6 ml solution.

Name of License Holder and Address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in November 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 153.25.34055

Carefully read the instructions for use before injecting with the pre-filled syringes.

Instructions for self-injecting Lonquex – pre-filled syringe

General

The information provided in this section is intended to explain how to self-inject Lonquex under the skin. Do not try to give yourself the injection without receiving appropriate training from the doctor or nurse. If you have any doubt about how to inject or if you have questions, consult the doctor or nurse.

How can Lonquex be injected

The medicine is given by subcutaneous injection.

Necessary equipment

- a pre-filled Lonquex syringe.
 - an alcohol wipe.
 - a gauze pad or a sterile gauze swab.
 - a puncture-proof container, used to safely dispose of used syringes.
- Note:** if you use a syringe with a safety device, there is no need for a disposal container.

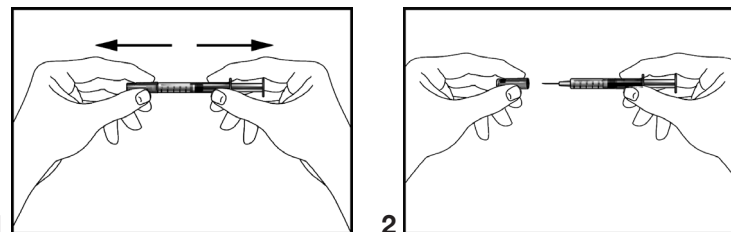
Steps to take before injecting

- Take one pack containing a pre-filled syringe out of the refrigerator.
- Open the pack and take out the pre-filled syringe. When taking out the pre-filled syringe, do not hold the plunger or needle cover.
- Check the expiry date that appears on the syringe label (EXP). Do not use it if the current date has passed the last day of the month appearing on the label.
- Check the appearance of the Lonquex solution. The solution must be clear and colorless. Do not use the syringe if particles are visible or if the solution is cloudy.
- Do not shake the solution vigorously as this may affect the activity of the medicine.
- For a more comfortable injection, let the syringe stand for approximately 30 minutes to reach room temperature (not above 25°C) or alternatively, hold the syringe gently in your hand for a few minutes. Do not warm in any other way (for example, **do not** warm in a microwave or in hot water).
- Do not** remove the needle cover until you are ready to inject.
- Find a comfortable, well-lit place. Put everything you need for the injection in an accessible place (Lonquex pre-filled syringe, an alcohol wipe, a gauze pad or a sterile gauze swab and the puncture-proof container).
- Wash your hands thoroughly.

How to prepare the injection

Before performing the injection, you must act as follows:

- Hold the syringe and remove the needle cover without twisting it. Pull horizontally (see pictures 1 and 2). Do not touch the needle and do not push the plunger of the syringe.



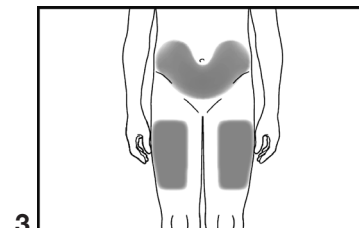
- If there are air bubbles in the syringe, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Hold the syringe pointing upwards, and expel all air by pushing the plunger slowly upwards.

- The syringe is now ready for use.

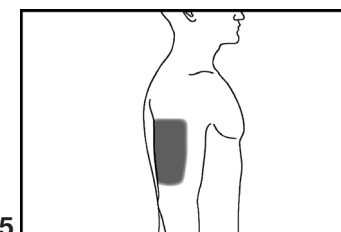
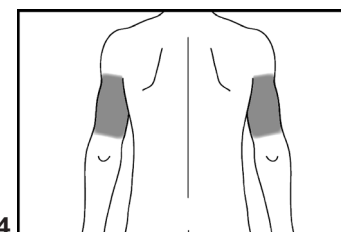
Where can Lonquex be injected

The most suitable places to inject yourself are:

- the upper part of the thighs.
- the abdomen (see grey areas in picture 3), aside from the area around the navel.

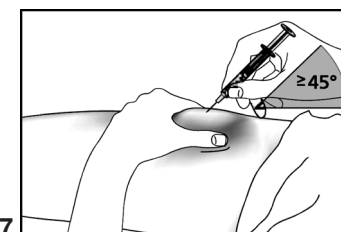
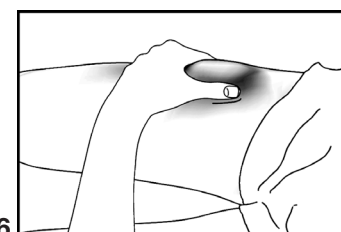


If someone else is injecting you, they can also inject in the back and side of the upper part of the arms (see pictures 4 and 5).

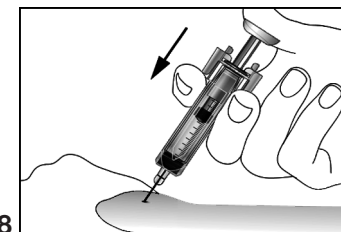


How to inject?

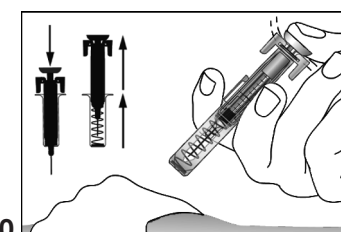
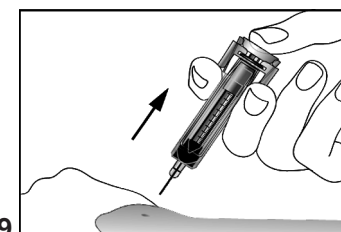
- Disinfect the skin at the injection site by using an alcohol wipe and slightly pinch the skin using your thumb and forefinger (see picture 6).
- Insert the needle fully into the skin as instructed by the doctor or nurse. The angle between the needle and skin should not be too narrow (at least 45°, see picture 7).



- Lightly pull on the plunger of the syringe to ensure that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another area.
- Inject the liquid into the tissue slowly and evenly, while continuing to press the skin (see picture 8).



Note: If you are using a syringe with a safety device, do as follows: push the plunger of the syringe as much as you can, to inject all the liquid. While the plunger is still pressed down, remove the needle from the skin (see picture 9). Then, release the plunger of the syringe. The safety device is immediately activated and the needle and syringe are automatically drawn back and covered, thus preventing the possibility of being pricked by the needle after use (see picture 10).



- After the injection, remove the needle from the skin and let go of the skin.
- Press on the injection site with a gauze pad or a sterile gauze swab for several seconds.
- Use each syringe only once. The syringe is for a single use; do not use any remainder of Lonquex that is left at the end of the injection.

Important to remember

If you encounter any problem, refer to the attending doctor or nurse for help.

Disposing of used syringes

- Do not put the cover back on used needles.
- Throw away used syringes into the disposal container and keep the container out of the reach and sight of children.
- Dispose of the disposal container as instructed by the doctor, nurse or pharmacist.
- Never throw away used syringes into your household waste bin.