

Imukin®

Interferon gamma-1b

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Imukin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using Imukin against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine.

You may need to read it again.

What Imukin is used for

Interferons are substances which are normally produced by the body and which play a role in the body's response to infection. Interferon gamma-1b is just one of several types of interferon. Imukin contains interferon gamma-1b which is produced in the laboratory by recombinant technology. It modifies the body's response to infection in

the same way as naturally-occurring interferon gamma.

Chronic Granulomatous Disease (CGD) is a rare disorder in which the body's own natural defence against infection is not working properly.

Imukin is used with other treatments to reduce the frequency of serious infections in people with CGD.

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

Your doctor may have prescribed it for another reason.

Before you use Imukin

When you must not use it

Do not use Imukin if you have an allergy to:

- any medicine containing interferons
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

Some of the 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
- rash, itching or hives on the skin.

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are using this medicine.

Imukin is not recommended in women who are breast-feeding.

Do not use Imukin after the expiry date printed on the vials or carton or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use it if the solution contains any solid particles or if it is cloudy, hazy or discoloured.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you are allergic to latex.

The stopper of the Imukin glass vial contains natural rubber (a derivative of latex).

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Your response to Imukin may vary depending on a number of things.

It is essential that your doctor knows your medical history before prescribing Imukin.

Your doctor will do some blood tests before starting you on Imukin.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease including angina or irregular heart beats
- epilepsy or other nervous system conditions
- any condition which affects blood cell production in the bone marrow
- liver disease

- kidney disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start using Imukin.

Using other medicines

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

Some medicines and Imukin may interfere with each other. These include:

- medicines for vaccinations
- medicines that affect blood cell production in the bone marrow.

These medicines may be affected by Imukin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Do not mix Imukin with other medicines in the same syringe.

How to use Imukin

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to use

Your doctor will advise you what volume of solution is required in order to achieve the required dose.

For most people the dosage is calculated on the basis of body surface area (BSA).

For people with a BSA greater than 0.5 square metres the recommended dose is 1 million international units (IU) or 50 micrograms per square metre of BSA.

For people with a BSA less than or equal to 0.5 square metres the recommended dose is 30,000 IU or 1.5 micrograms per kilogram bodyweight.

Ask your doctor for more information if you have been prescribed a dose that is different to that recommended above.

How to use it

Follow the Directions for Use at the end of this leaflet on how to use Imukin.

Imukin should be injected immediately after it is withdrawn from the vial and any unused portion of the vial should be thrown away.

Injections are administered under the skin (subcutaneously).

The best sites for injection are the upper arms or fronts of the thighs.

When to use it

Injections are usually administered under the skin three times a week (for example, Monday, Wednesday, Friday) and can be given by a doctor, nurse, family member or by the patient once they are trained in giving the injections correctly.

How long to use it

Continue using Imukin for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

Tell your doctor or pharmacist if any illness occurs during treatment with Imukin. Your doctor will tell you whether treatment with Imukin should continue or stop temporarily.

If you forget to inject it

If it is less than 12 hours before your next dose, skip the dose you missed and administer your next dose when you are meant to.

Otherwise, administer it as soon as you remember, and then go back to using your medicine as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Australia 13 11 26; New Zealand 0800 764 766), or go to Emergency at your nearest hospital, if you think that you or anyone else may have used too much Imukin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include:

- confusion
- disturbance in the manner of walking and dizziness
- frequent signs of infection such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising may occur more easily than normal.

With a large overdose, blood cells, the liver and kidneys can be affected. A laboratory can detect changes in the blood and urine. Very high doses of Imukin may worsen pre-existing heart disease.

While you are using Imukin

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Imukin.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Tell your doctor if, for any reason, you have not used Imukin exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using Imukin, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular blood and urine tests while you are using Imukin.

Things you must not do

Do not give Imukin to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Imukin affects you.

Imukin may alter your ability to drive or operate machinery and this may be made worse by alcohol.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Imukin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- fever
- headache
- chills
- muscle pain or tiredness.

These effects may decrease in severity as treatment continues.

Using Imukin just before you go to bed at night may reduce these effects or you can take paracetamol to treat them.

Other side effects of Imukin include the following:

- nausea
- vomiting
- joint pain
- diarrhoea
- back pain
- stomach pain or discomfort
- feeling depressed
- tenderness at the injection site
- temporary skin rashes.

Occasionally a problem may develop at the injection site.

Tell your doctor as soon as possible if you notice any of the following:

- a lump or swelling that doesn't go away
- bruising that doesn't go away
- any signs of infection or inflammation at an injection site (pus, persistent redness, surrounding skin that is hot to touch, persistent pain after the injection)
- worsening of signs of a heart condition such as swelling in the

legs, shortness of breath, chest pain or irregular heartbeat

- bleeding or bruising that may occur more easily than normal.

Tell your doctor as soon as possible if you experience any side effects during or after using Imukin, so that these may be properly treated.

Other side effects not listed above may also occur in some patients.

After using Imukin

Storage

Keep Imukin in the refrigerator where the temperature stays between 2-8°C.

Do not freeze Imukin.

Imukin should not be left for more than 12 hours at room temperature (25°C).

Avoid exposing Imukin to high temperatures during transport e.g. use an insulated container.

Do not shake the vials.

Imukin should not be used if the solution contains any solid particles or if it is cloudy, hazy or discoloured.

Keep Imukin where children cannot reach it.

Disposal

If your doctor tells you to stop using Imukin or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Imukin is the brand name of your medicine.

Imukin comes as a sterile, clear, colourless solution in clear glass

vials which are packed into cartons containing 1 vial* or 6 vials each.

* Not currently distributed in Australia.

Ingredients

Imukin is an injection and each vial contains 2 million IU or 100 micrograms of interferon gamma-1b (recombinant) in 0.5 mL of solution. The solution also contains:

- mannitol
- sodium succinate hexahydrate
- succinic acid
- polysorbate 20
- water for injections.

Supplier

Imukin is supplied in Australia by:
Link Medical Products Pty Ltd.
5 Apollo Street
Warriewood NSW 2102

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Australian Registration Number

AUST R 48404

Imukin®

Interferon gamma-1b

Directions for Use

Before using Imukin

1. Wash hands with soap and water and dry thoroughly to help prevent infection.
2. Check that the Imukin solution is clear. NEVER SHAKE THE VIAL. Shaking can cause the solution to become cloudy or hazy. If the solution is cloudy, hazy or discoloured or if it contains any solid particles, do not inject it, but return it to your doctor or pharmacist.
3. Check the expiry date on the Imukin vial to ensure it has not passed.
4. Remove the protective cap from the vial and wipe the rubber stopper on the top of the vial with a cotton ball saturated with rubbing alcohol, or with an alcohol swab.
5. Leaving the needle cap in place, pull back on the plunger of the syringe until you have drawn an amount of air into the syringe equal to the volume of Imukin your doctor has ordered for each dose.
6. Remove and save the needle cap from the syringe. Holding the syringe by the side of the plastic tube, slowly insert the needle straight through the centre of the rubber stopper of the Imukin vial to be used.
7. Gently push the plunger to discharge the air into the vial.
8. Turn the vial upside down with the syringe needle still in it and hold it in one hand. Be sure the tip of the needle is in the solution. Using your other hand, slowly pull on the plunger in a continuous motion until the correct amount of Imukin solution is in the syringe. Avoid injecting the solution back into the vial as this may cause the formation of small colourless particles.
9. With the syringe and vial still held upside down in one hand, gently tap the syringe with your hand to dislodge any large air bubbles. The bubbles will rise to the top of the syringe and can be pushed back into the vial by gently pushing in the plunger. Make sure the correct amount of Imukin solution remains in the syringe. You may need to withdraw more Imukin solution if there were a lot of bubbles in the syringe.
10. Remove the needle from the Imukin vial and carefully replace the needle cap until time of administering the injection. Place the needle and syringe on a clean surface.

Selecting the injection site

11. The best sites for injection are the upper arms or fronts of the thighs. It is very important that you alternate the site of injection every time you give the medication. The exact same spot within each area should not be used time after time.

Injecting the dose

Needles and syringes should be used only once to ensure they remain sterile.

12. Applying firm pressure, clean the injection site with an alcohol-saturated cotton ball or cotton swab using a circular motion and working outward from the inside of the circle. Once you have cleaned the centre of the circle, do not go back to it with the same swab. Allow the alcohol to dry before inserting the needle. This will reduce the stinging sensation.
13. Remove the needle cap from the syringe filled with the proper dose of Imukin and hold the syringe the way you would hold a pencil. Double check the correct amount of Imukin solution is in the syringe.
14. Gently pinch up the skin surrounding the site of injection and hold firmly with your other hand. Insert the needle into the skin at a 45 degree angle with a quick, firm motion. This hurts less than slowly pushing the needle in.
15. Once the needle has been inserted into the skin, you can release your hold of the skin. Inject the solution by gently pushing the plunger until the syringe is empty.
16. Withdraw the needle quickly, pulling it straight out, and apply pressure over the injection site

with a dry gauze or cotton ball.

A drop of blood may appear. Put a dressing on the injection site if desired.

17. Any unused portion of Imukin remaining in the vial should be thrown away.
18. Dispose of the needle and syringe in a sharps container. These are available from your pharmacist.