

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 IMUKIN?

IMUKIN contains the active ingredient interferon gamma-1b recombinant human. IMUKIN is used with other treatments to reduce the frequency of serious infections in people with Chronic Granulomatous Disease (CGD). For more information, see Section [1. Why am I using IMUKIN?](#) in the full CMI.

2. What should I know before I use IMUKIN?

Do not use if you have ever had an allergic reaction to interferon gamma-1b recombinant human 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 IMUKIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMUKIN 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 IMUKIN?

- Your doctor will advise you what volume of solution is required to achieve a dose.
- IMUKIN should be injected under the skin (subcutaneously) immediately after it is withdrawn from the vial and any unused portion should be thrown away.

More instructions can be found in Section [4. How do I use IMUKIN?](#) in the full CMI.

5. What should I know while using IMUKIN?

Things you should do	<ul style="list-style-type: none"> Tell any doctor, dentist or pharmacist you visit that you are taking IMUKIN.
Things you should not do	<ul style="list-style-type: none"> Do not stop using IMUKIN without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> Be careful driving or operating machinery until you know how IMUKIN affects you. IMUKIN may cause fatigue, convulsion, confusional state, disorientation or hallucination during treatment.
Drinking alcohol	<ul style="list-style-type: none"> Using IMUKIN in combination with alcohol may impact your reflexes and reduce your ability to drive.
Looking after your medicine	<ul style="list-style-type: none"> Keep it 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). Do not shake the vials.

For more information, see Section [5. What should I know while using IMUKIN?](#) in the full CMI.

6. Are there any side effects?

- Common side effects may include depression, diarrhoea, vomiting, nausea, stomach pain, rash, fever, headache, chills, muscle aches and pain (myalgia), joint pain, back pain, fatigue, injection site pain. Severe side effects may include chest pain, difficulty breathing, seizures, or confusion; shortness of breath during activity or when lying flat, swelling in the legs, ankles, or feet due to fluid build up.

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.

IMUKIN®

Active ingredient: *interferon gamma-1b recombinant human*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMUKIN. **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 IMUKIN.**

Where to find information in this leaflet:

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

1. Why am I using IMUKIN?

IMUKIN contains the active ingredient *interferon gamma-1b recombinant human*.

IMUKIN is used with other treatments to reduce the frequency of serious infections in people with Chronic Granulomatous Disease (CGD).

2. What should I know before I use IMUKIN?

Warnings

Do not use IMUKIN if:

- You are allergic to interferon gamma 1b, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other similar interferons

Check with your doctor if you:

- have pre-existing heart disease, including symptoms of angina, heart failure or irregular heartbeat (arrhythmia).
- have seizure disorders and/or disorders of the central nervous system (brain or spinal cord).
- are allergic to latex. The stopper of the glass vial with IMUKIN contains natural rubber (a derivative of latex).
- have reduced liver function.

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

Discuss with your doctor if you are pregnant or intend to become pregnant. IMUKIN may affect your baby if you take it during pregnancy.

Discuss with your doctor if you are breastfeeding or intend to breastfeed. It is not known if IMUKIN passes into breast milk. Because of its potential to effect the baby, it is not recommended to breastfeed while taking IMUKIN.

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.

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

- Other medical proteins made using recombinant technology
- Vaccines
- Anti-inflammatory medicines such as steroids (prednisone and prednisolone)
- Non-steroidal anti-inflammatory medicines (NSAIDs) used for the treatment of pain and fever, such as aspirin, ibuprofen, naproxen, diclofenac.
- A medicine used to treat lung conditions such as asthma and emphysema called theophylline.

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

4. How do I use IMUKIN?

How much to inject

- Your doctor will advise you what volume of solution is required to achieve the required dose.
- Follow the instructions provided and use IMUKIN until your doctor tells you to stop.

When to inject IMUKIN

- IMUKIN should be injected immediately after it is withdrawn from the vial and any unused portion of the vial should be thrown away.
- IMUKIN is usually injected three times each week (for example, Monday, Wednesday, Friday). Your doctor will advise on which days of the week IMUKIN should be injected.

How to inject IMUKIN

- Injections are administered under the skin (subcutaneously). The best sites for injection are the upper arms or fronts of the thighs.
- IMUKIN can be given by a doctor or nurse, or by the patient or a family member once they are trained in giving the injections correctly.

Directions for Use

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 center 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 center 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.

If you forget to use IMUKIN

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

Inject IMUKIN at the times recommended by your doctor. You can still administer it on the same or following day. Contact your doctor if you think you have gone too long without taking a dose.

If you use too much IMUKIN

If you think that you or anyone else may have taken too much IMUKIN, 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 IMUKIN?

Things you should do

Be sure to keep all of your doctor's appointments so that your progress can be checked. Your doctor will check your progress and may want to take some tests (e.g. blood tests, urine tests) from time to time. These tests may help to prevent side effects.

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

Things you should not do

Do not stop using this medicine suddenly unless you have discussed it with your doctor.

Driving or using machines

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

IMUKIN may cause fatigue, convulsion, confusional state, disorientation or hallucination during treatment. It can also affect reactions which can alter your ability to drive or operate machinery and this may be made worse by alcohol.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol used in combination with IMUKIN may affect your reflexes.

Looking after your medicine

Store 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, for example, use an insulated container.

Do not shake the vials. IMUKIN should not be used if the solution contains any solid particles or if it's cloudy, hazy or discoloured.

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

When to discard your medicine

Once opened, the contents of a vial should be used immediately, and any unused portion of any vial should be discarded.

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
Psychiatric disorders <ul style="list-style-type: none"> • Depression 	Speak to your doctor if you have any of these less
Disorders of the brain or nerves	

<ul style="list-style-type: none"> • Change in the usual pattern of walking • Shaking, especially in the hands 	serious side effects and they worry you.
General disorders <ul style="list-style-type: none"> • Headache • Fever • Chills • Fatigue • Injection site pain • Chest discomfort • Dizziness • Bleeding or bruising more easily than normal 	
Musculoskeletal and connective tissue disorders <ul style="list-style-type: none"> • Muscle aches and pain • Joint pain • Back pain 	
Skin related disorders <ul style="list-style-type: none"> • Rash 	
Stomach (gastrointestinal) related <ul style="list-style-type: none"> • Diarrhoea • Vomiting • Nausea • Abdominal pain 	

Serious side effects

Serious side effects	What to do
Lung related <ul style="list-style-type: none"> • Wheezing • Difficulty breathing • Tightening of airways • Rapid breathing 	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.
Heart related <ul style="list-style-type: none"> • Abnormal heartbeat or palpitations • Severe chest pain • Shortness of breath during activity or when lying flat, swelling in the legs, ankles, or feet due to fluid build up 	
Psychiatric disorders <ul style="list-style-type: none"> • Confusion • Disorientation • Hallucination 	
Disorders of the brain or nerves <ul style="list-style-type: none"> • Convulsions, fits or seizures 	

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 IMUKIN contains

Active ingredient (main ingredient)	Interferon gamma-1b recombinant human
Other ingredients (inactive ingredients)	Mannitol Sodium succinate hexahydrate Succinic acid Polysorbate 20 Water for injections

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

What IMUKIN looks like

IMUKIN comes as a sterile, clear, colourless solution in clear glass vials which are packed into cartons containing 6 vials.

Australian Registration Number:

IMUKIN 2 million IU (100 mcg)/0.5 mL – AUST R 48404

Who distributes IMUKIN

Link Medical Products Pty Ltd

5 Apollo Street

Warriewood, NSW, 2102

Australia

1800 181 060

linkhealthcare.com.au

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