

# New Zealand Consumer Medicine Information

## **IMUKIN<sup>®</sup>**

### ***Interferon gamma-1b***

---

#### **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. Keep this information with your medicine. You may need to read it again.

#### ***To find out more about ATROVENT***

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. Ask your doctor or pharmacist if you have any questions about your medicine or if you have any trouble before, during or after using IMUKIN. Keep this information 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.

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

---

#### **Before you use IMUKIN**

---

##### ***When you must not use IMUKIN***

Do not use IMUKIN if you are allergic to interferons or to any of the ingredients in IMUKIN. These ingredients are listed in full at the end of this leaflet. If you are uncertain as to whether you have these allergies you should raise those concerns with your doctor. You must tell your doctor if you are allergic to any other medicine. In some cases you should not use IMUKIN if you are allergic to certain other medicines.

You should never use IMUKIN after the expiry date on the vials or carton has passed. IMUKIN should not be used if the solution contains any solid particles or if it is cloudy, hazy or discoloured.

##### ***Before you start to use IMUKIN***

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. Before using IMUKIN, you must tell your doctor if you have, or have had, any of the following 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.

If you are not sure if you have, or have had, any of these conditions you should raise those concerns with your doctor.

### ***Using other medicines***

Before using IMUKIN it is important to tell your doctor if you are taking any other medicines, obtained with or without a doctor's prescription. You should also advise your doctor if you intend to get vaccinated while using IMUKIN.

### ***Pregnancy***

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. IMUKIN is not generally recommended for use in pregnant women, unless the benefits of treatment outweigh the risks to the unborn child.

### ***Breastfeeding***

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Use of IMUKIN while breastfeeding is not recommended.

---

## **How to use IMUKIN**

---

Please read the Directions for Use at the end of this leaflet on how to use IMUKIN.

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 who can be trained in giving the injections correctly.

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

Keep using IMUKIN until your doctor tells you to stop.

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.

### ***Recommended Dose***

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. For people with a body surface area greater than 0.5 square metres the recommended dose is 1 million IU or 50 micrograms per square metre. For people with a body surface area less than or equal to 0.5 square metres then 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.

### ***If you forget to take a dose***

It is important to use IMUKIN as directed. If you remember more than 12 hours before the next dose is due: inject the missed dose when you remember and the next dose at the usual time. If you remember less than 12 hours before the next dose is due: do not inject the missed dose. Simply inject the next dose at the normal time. If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

### ***If you take too much (overdose)***

Immediately telephone your doctor or Poisons Information Centre (0800 764 766), or go to Accident and Emergency at your nearest hospital, if you have used more than the recommended or prescribed dose of IMUKIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

Signs of overdose may include drowsiness or tiredness, disturbance in the manner of walking and dizziness. Frequent infections such as fever, severe chills, sore throat or mouth ulcers can occur. 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***

Tell all doctors and pharmacists who are treating you that you are taking IMUKIN. Tell your doctor or pharmacist if you begin taking any other medicine while you are using IMUKIN. 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. Tell your doctor if you become pregnant while using IMUKIN.

### ***Things you must not do***

Do not give IMUKIN to anyone else, even if they have the same symptoms as yours.

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

### ***Effects on Ability to Drive or Operate Machinery***

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**

---

Check with your doctor or pharmacist as soon as possible if you have any problems while taking IMUKIN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet. Like other medicines, IMUKIN can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention. Ask your doctor or pharmacist to answer any questions you may have.

The more common side effects of IMUKIN are:

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

These effects may decrease in severity as treatment continues. Injecting 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.

Contact your doctor if you notice any of the following symptoms:

- 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)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising that may occur more easily than normal.

Rare, but sometimes serious, unwanted effects have occurred with IMUKIN during clinical trials of medical conditions when very much higher doses were used on a more frequent basis than you are using for Chronic Granulomatous Disease (CGD). These included a broad range of effects on various parts of the body, including metabolism, heart and blood vessels, brain, kidneys, liver, lungs, gastrointestinal tract, skin and pancreas. Your doctor has more details and can advise you further. However, none of these effects has occurred in CGD patients using the recommended dose of IMUKIN.

A very small number of patients given gamma interferon have also developed a condition called systemic lupus erythematosus (SLE). SLE is a chronic inflammatory disorder affecting many organs in the body.

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. Tell your doctor or pharmacist if you notice anything unusual, during or after using IMUKIN. Ask your doctor or pharmacist if you don't understand anything in this list.

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

---

## **After using IMUKIN**

---

### ***Storage***

Keep IMUKIN in the refrigerator (at 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 e.g. use an insulated container during transport.

Do not shake the vials as shaking can make IMUKIN go cloudy. IMUKIN should not be used if the solution contains any solid particles or if it is cloudy, hazy or discoloured.

Keep IMUKIN where young children cannot reach it.

### ***Disposal***

If your doctor tells you to stop using IMUKIN or it has passed its expiry date, the unused medicine should be returned to your pharmacist so that it can be disposed of safely.

---

## **Product Description**

---

### ***What is IMUKIN***

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 6 vials each.

### ***Ingredients***

IMUKIN is an injection and each vial contains 2 million International Units (IU) or 100 micrograms of interferon gamma-1b (recombinant) in 0.5 mL of solution. The solution also contains mannitol, sodium succinate, succinic acid, polysorbate 20 and water for injections.

### ***Manufacturer***

IMUKIN is made in Germany.

IMUKIN is supplied is supplied in New Zealand by:  
BOEHRINGER INGELHEIM (N.Z.) LIMITED  
PO Box 76-216  
Manukau City  
Auckland  
Ph 0800 802461

This leaflet was prepared on 8 April 2009.

© Boehringer Ingelheim 2009

---

## Directions for Use

---

### ***Before Using IMUKIN***

1. Wash hands thoroughly with soap and water 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. Take care not to hit the needle tip on the needle cap.

### ***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.

### ***Giving 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 that the correct amount of IMUKIN solution is in the syringe.

14. Squeeze the skin between your fingers before and during the injection. Insert the needle into the skin at a 45° angle with a quick, firm motion. This hurts less than slowly pushing the needle in.

15. After the needle is in, pull back very slightly with one hand on the plunger to see if blood comes into the syringe. This is to be sure that the needle has not entered a blood vessel. If blood does come into the syringe, do not inject the IMUKIN solution. Withdraw the needle and insert at another location.

16. If blood does not come into the syringe, slowly (within a few seconds), inject the solution by gently pushing the plunger until the syringe is empty.

17. 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.

18. Any unused portion of IMUKIN remaining in the vial should be thrown away.