

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

IMAREM 100, 100 mg film-coated tablet

IMAREM 400, 400 mg film-coated tablet

Sugar free

Read all of this leaflet carefully before you start taking IMAREM

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider
- **IMAREM** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. WHAT IMAREM IS AND WHAT IT IS USED FOR:

IMAREM is a medicine containing an active substance called imatinib which belongs to a class of medicines known as protein-tyrosine kinase inhibitors. It is used to treat various types of cancers by inhibiting the growth of abnormal cells.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IMAREM

Do not take IMAREM:

- If you know that you are hypersensitive (allergic) to the active substance in the tablet or any of the other ingredients of **IMAREM** (listed in section 6).
- If you are pregnant or breastfeeding your baby.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking **IMAREM**.

Warnings and precautions

Tell your healthcare professional if you:

- if you have or have ever had a liver, kidney, or heart problem.
- if you are taking the medicine levothyroxine because your thyroid has been removed.
- if you have ever had or might now have a hepatitis B infection. This is because **IMAREM** could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.
- if you experience bruising, bleeding, fever, fatigue, and confusion when taking **IMAREM**, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).
- Experience weakness or numbness in the face, arm, or leg, usually on just one side. Difficulty speaking, blurred vision, loss of balance or dizziness and a severe headache. You may be experiencing a stroke and your doctor might discontinue treatment.

Take Special Care with **IMAREM**:

IMAREM tablets should be taken with food and a large glass of water to minimise the risk of gastrointestinal disturbances.

- When you take **IMAREM** with other medications, there is a potential for medicine interactions.
- If you have liver failure or disease, your doctor will monitor your blood counts and liver enzymes carefully.
- if **IMAREM** is combined with chemotherapy regimens. Your doctor will monitor your liver function.
- if you have a cardiac disease or risk factors for cardiac failure, you should be monitored carefully.

You may become more sensitive to the sun while taking **IMAREM**. It is important to cover sun-exposed areas of skin and use sunscreen with high sun protection factor (SPF). These precautions are also applicable to children.

During treatment with **IMAREM**, tell your doctor straight away if you put on weight very quickly. **IMAREM** may cause your body to retain water (severe fluid retention).

While you are taking **IMAREM**, your doctor will regularly check whether the medicine is working.

Children and adolescents

IMAREM should not be used in children below 2 and 3 years of age with various types of cancers as there is no experience of its use in these children.

Some children and adolescents taking **IMAREM** may have slower than normal growth. The doctor will monitor the growth at regular visits.

Other medicines and IMAREM:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines can interfere with the effect of **IMAREM** when taken together. They (examples listed below) may increase the effect of **IMAREM**:

- Ketoconazole and itraconazole - medicines used to treat fungal infections
- Erythromycin and clarithromycin- antibiotic medicines
- Antiviral medicines such as: indinavir, lopinavir/ ritonavir, ritonavir, saquinavir, telaprevir, nelfinavir, boceprevir.

Some medicines (examples listed below) can interfere with the effect of **IMAREM** when taken together. They may decrease the effect of **IMAREM**:

- Dexamethasone, medicines used to treat conditions such as arthritis, blood/hormone/immune system disorders, allergic reactions, certain skin and eye conditions, breathing problems, certain bowel disorders, and certain cancers
- Phenytoin and carbamazepine. These are medicines used to control epilepsy, also called an anticonvulsant.
- Rifampicin – medicine used to treat TB (tuberculosis).
- Phenobarbitone - medicine used to treat insomnia (difficulty sleeping) and as a sedative to relieve the symptoms of anxiety or tension. It is also used for the control of certain types of seizures.
- Hypericum perforatum (also known as St. John's Wort) - is a commonly used over the counter (OTC) dietary supplement that is used to treat mild depression, anxiety, and sleep disorders

The above interferences may either lead to increased **IMAREM** side effects or making **IMAREM** less effective.

IMAREM may do the same to some other medicines (examples listed below).

IMAREM may increase the effect, and therefore side effects of the following medication:

- Ciclosporin – is a medicine used to prevent organ rejection in people who have received a liver, kidney, or heart transplant
- Simvastatin- medicine used to treat cholesterol
- Pimozide - medicine used to reduce uncontrolled movements (motor tics) or outbursts of words/sounds (vocal tics) caused by Tourette syndrome (a neurological disorder characterised by repetitive, stereotyped, involuntary movements and vocalisations called tics)
- Triazolo-benzodiazepines- medicines that are often **prescribed** to treat generalized anxiety disorder (GAD), panic disorders and insomnia.
- Dihydropyridine calcium channel blockers- medicines used for managing high blood pressure, coronary artery disease, chest pain (angina), irregular heartbeats (arrhythmia), some circulatory conditions, such as Raynaud's disease
- Certain HMG-CoA reductase inhibitors, i.e. statins medicines used in the management of cholesterol.
- Metoprolol-used to treat high blood pressure
- Warfarin- used to treat blood clots or prevent your blood from clotting
- Paracetamol-used in the treatment of mild/moderate pain and fever.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking **IMAREM**.

IMAREM is not recommended during pregnancy as it may harm your baby.

Women who might become pregnant are advised to use effective contraception during and up to six months after treatment with **IMAREM**.

Males are also advised to use contraception during treatment and for at least three months after treatment with **IMAREM**.

Do not breast-feed during the treatment with **IMAREM**.

Patients who are concerned about their fertility while taking **IMAREM** are advised to consult with their doctor.

Driving and using machines

IMAREM tablets may cause dizziness, sleepiness, or blurred vision. Therefore, you should not drive or use machines or perform any other tasks that require your attention until you know how treatment with **IMAREM** affects you.

It is not always possible to predict to what extent **IMAREM** may interfere with the daily activities of a patient.

3. HOW TO TAKE IMAREM

Do not share medicines prescribed for you with any other person.

Always take **IMAREM** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Therapy should be started by a doctor experienced in the treatment of patients with these conditions.

The usual dose for use in adults is 100 mg 400 mg or 600 mg once a day or 800 mg, taken as 400 mg in the morning and 400 mg in the evening.

The usual dose for children is 340 mg/m²

Your doctor will advise you on the dose to be taken depending on the type of cancer you have. During the course of the treatment your doctor may adjust the dose to suit your individual needs.

Your doctor will advise you on the dose specific for children.

- **IMAREM**, tablets should be taken with a meal and large glass of water.
- For patients unable to swallow the film-coated tablets, the tablets may be dispersed in a glass of water or apple juice. The required number of tablets should be placed in the appropriate volume of liquid and stirred with a spoon. The suspension should be taken immediately after complete disintegration of the tablet(s).

To benefit from your medicine, you must take **IMAREM** tablets every day.

Your doctor will tell you how long your treatment with **IMAREM** will last. Do not stop treatment early because your condition may get worse and you may start to feel sick.

If you have the impression that the effect of **IMAREM** is too strong or too weak, tell your doctor or pharmacist.

If you take more IMAREM than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining **IMAREM** with you so the doctor will know what you have taken.

You may experience one or more of the following symptoms in the event that you may have taken an overdose of **IMAREM**: nausea, vomiting, diarrhoea, rash, reddening of the skin, swelling, tiredness, muscle spasms, abdominal pain, headache, decreased appetite and fever.

If you forget to take IMAREM

Do not take a double dose to make up for forgotten individual doses.

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. - Then continue with your normal schedule

If you stop taking IMAREM

Do not stop treatment early. Treatment is continued as long as possible. If the condition gets worse or the side effects are unacceptable, the treatment will be stopped. The healthcare practitioner will take the necessary decisions when treatment is stopped.

4. POSSIBLE SIDE EFFECTS

IMAREM can have side effects.

You may tend to see side effects more frequently when you start your medication or increase to a higher dose. In most cases, side effects will gradually disappear as your body becomes used to the medicine.

Not all side-effects reported for **IMAREM** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **IMAREM**, please consult your healthcare provider for advice.

*If any of the following happens, stop taking **IMAREM** and tell your doctor immediately or go to the casualty department at your nearest hospital.*

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching

*These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **IMAREM**. You may need urgent medical attention or hospitalisation.*

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Rash, red skin with blisters on the lips, eyes, skin, or mouth, peeling skin, fever, raised red or purple skin patches, itching, burning sensation, pustular eruption and fever (signs of skin problems e.g., acute generalised exanthematous pustulosis AGEP).
- Signs of infection such as fever, severe chills, sore throat, or mouth ulcers
IMAREM can reduce the number of white blood cells, so you might get infections more easily.
- Unexpected bleeding or bruising (when you have not hurt yourself).
- Chest pain, irregular heart rhythm (signs of heart problems).

- Cough, having difficulty breathing or painful breathing (signs of lung problems).
- Feeling sick (nausea), with loss of appetite, light-coloured urine, yellow skin or eyes (signs of liver problems).
- Severely decreased urine output, feeling thirsty (signs of kidney problems).
- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system problems such as bleeding or swelling in skull/brain).
- Loss of appetite, nausea and vomiting, weakness and fatigue, yellowing of your skin and the whites of your eyes (jaundice) (possible indication of a recurrence (reactivation) of a Hepatitis B infection when you have had hepatitis B in the past (a liver infection)).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Headache or feeling tired.
- Being sick (vomiting), diarrhoea or indigestion.
- Rash.
- Muscle cramps or joint, muscle or bone pain.
- Swelling such as round your ankles or puffy eyes.
- Weight gain.
- Anorexia, weight loss or a disturbed sense of taste.
- Feeling dizzy or weak.

- Difficulty in sleeping (insomnia).
- Discharge from the eye with itching, redness and swelling (conjunctivitis), watery eyes or having blurred vision.
- Nose bleeds.
- Pain or swelling in your abdomen, flatulence, heartburn, or constipation.
- Itching.
- Unusual hair loss or thinning.
- Numbness of the hands or feet.
- Mouth ulcers.
- Joint pain with swelling.
- Dry mouth, dry skin or dry eye.
- Decreased or increased skin sensitivity.
- Hot flushes, chills or night sweats.

Less frequent

- Feeling light-headed, dizzy, or fainting (signs of low blood pressure).
- Severe abdominal pain, blood in your vomit, stools or urine, black stools (signs of gastrointestinal disorders).
- Feeling sick (nausea) with diarrhoea and vomiting, abdominal pain or fever (signs of bowel problems).
- Pale skin, feeling tired and breathlessness and having dark urine (signs of low levels of red blood cells).
- Eye pain or deterioration in vision, bleeding in the eyes.
- Pain in your hips or difficulty walking.

- Numb or cold toes and fingers (signs of Raynaud's syndrome).
- Sudden swelling and redness of the skin (signs of a skin infection called cellulites).
- Difficulty hearing.
- Muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood).
- Bruising.
- Stomach pain with feeling sick (nausea).
- Muscle spasms with a fever, red-brown urine, pain or weakness in your muscles (signs of rhabdomyolysis and myopathy).
- Pelvic pain sometimes with nausea and vomiting, with unexpected vaginal bleeding, feeling dizzy or fainting due to low blood pressure (signs of problems with your ovaries or womb).
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory test results (eg. high potassium, uric acid and phosphorous levels and low calcium levels in the blood).
- Burping or belching
- Nausea, vomiting, diarrhoea, muscle cramps or twitches, weakness, numbness or tingling, fatigue, decreased urination, irregular heart rate, seizures (signs that you may be suffering with tumour lysis syndrome)

Frequency not known:

- Reddening and/or swelling on the palms of the hands and soles of the feet which may be accompanied by tingling sensation and burning pain.
- Black/red tarry stools, fatigue, weak and blood loss (signs you are suffering with a condition called gastric antral vascular ectasia (GAVE))
- Chronic renal failure
- recurrent episodes of high-grade fever, pain and inflammation (signs of tumour necrosis)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse drug Reaction reporting Form**”, found online under SAHPRA’s publications :

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **IMAREM**.

5. HOW TO STORE IMAREM

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

Store at or below 25 ° C in the original pack

Protect from moisture. The blisters should not be removed from the carton until required for use.

Keep out of the reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Applicant/PHCR: *Innovata Pharmaceuticals Pty (Ltd)*

Product Proprietary Name: *Imarem 100 and Imarem 400*

Dosage Form & Strength: *Film-coated Tablets, Imatinib 100 mg and Imatinib 400 mg*

CTD, Module 1

What IMAREM contains:

The active substance is imatinib mesilate.

The other ingredients **IMAREM** are microcrystalline cellulose, low substituted hydroxypropyl cellulose, povidone, crospovidone, silica colloidal anhydrous, magnesium stearate, hypromellose, macrogol 400, talc, red iron oxide, yellow iron oxide.

What IMAREM looks like and contents of the pack

30 or 60 film-coated tablets are packed in PVC/PE/PVDC

(polyvinylchloride/polyethylene/polyvinylchloride) blisters with an aluminium foil backing. The outer carton is a printed cardboard box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

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100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

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Registration number

IMAREM 100 51/34/0842

IMAREM 400 51/34/0843

Applicant/PHCR: *Innovata Pharmaceuticals Pty (Ltd)*

Product Proprietary Name: *Imarem 100 and Imarem 400*

Dosage Form & Strength: *Film-coated Tablets, Imatinib 100 mg and Imatinib 400 mg*

CTD, Module 1

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **IMAREM**.