

Patient Information Leaflet

Information for the Patient about IMAVEC / IMAVEC 400 (Capsules)

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

IMAVEC (Imatinib 100 mg) CAPSULES

IMAVEC 400 (Imatinib 400 mg) CAPSULES

Read all of this leaflet carefully before you start taking IMAVEC.

- **Keep this leaflet; you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **IMAVEC 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 IMAVEC CONTAINS:

IMAVEC:

The active substance in **IMAVEC** capsules is imatinib mesylate. Each capsule contains imatinib mesylate equivalent to 100 mg imatinib.

The other inactive ingredients include colloidal silicon dioxide, crospovidone, magnesium stearate and microcrystalline cellulose.

The capsule shells are made of brilliant blue FCF, gelatin, M.P.S, P.P.S, silicon dioxide, sodium lauryl sulphate, sunset yellow and titanium dioxide.

IMAVEC 400:

The active substance in **IMAVEC 400** capsules is imatinib mesylate. Each capsule contains imatinib mesylate equivalent to 400 mg imatinib.

The other inactive ingredients include colloidal silicon dioxide, crospovidone and magnesium stearate. The capsule shells are made of gelatin, purified water, sodium lauryl sulphate, titanium dioxide, yellow iron oxide and red iron oxide.

Contains sugar (159,64 mg lactose per capsule).

WHAT IMAVEC IS USED FOR:

IMAVEC is a medicine containing an active substance called imatinib.

IMAVEC works by inhibiting the abnormal or uncontrolled growth of cells involved in some types of cancer.

BEFORE YOU TAKE IMAVEC:

Do NOT take IMAVEC if you are:

- Hypersensitive (allergic) to imatinib or any of the other ingredients of **IMAVEC**.
- Pregnant or breastfeeding (see "**Pregnancy and breastfeeding**").

Take special care with IMAVEC:

Before using **IMAVEC** you should speak to your doctor if you:

- Are currently using simvastatin for the treatment of high blood cholesterol levels.
- Are taking paracetamol for fever or pain, including over-the-counter preparations.
- Are taking rifampicin (for tuberculosis), ketoconazole (for fungus infections), ciclosporin (for prevention of rejection in kidney, liver and heart transplants) or warfarin (for prevention of blood clotting).
- Have liver function problems.
- Have kidney disease or disease that impairs the working of the kidney.
- Have heart disease.
- Are taking the medicine levothyroxine because your thyroid has been removed.
- Have ever had or might now have a hepatitis B infection inform you doctor. **IMAVEC** 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.

You will have to undergo regular blood tests to evaluate white blood cell and platelet counts. Platelets play a very important role in blood clotting. Your doctor will also regularly check your liver function.

You will have to undergo periodic blood tests to evaluate your blood cell counts, blood uric acid levels, blood electrolyte levels (e.g. potassium), and liver and kidney function. Your doctor will also monitor your blood pressure levels as treatment with **IMAVEC** may increase or decrease your blood pressure.

IMAVEC can cause tiredness, headaches, shortness of breath, dizziness and looking pale (anaemia), fever and/or severe chills due to frequent infections such as flu, sore throat and mouth (due to neutropenia) ulcers and bruising more easily than normal (thrombocytopenia).

Since **IMAVEC** may lead to severe fluid retention (holding back water) with potential serious consequences, your doctor will weigh you regularly. Alternatively, if you notice an unexpected rapid weight gain, please report this to your doctor. Elderly patients and patients with known heart disease have an increased risk of developing this adverse reaction to treatment.

If you suffer from gastrointestinal stromal tumor (GIST), treatment with **IMAVEC** may lead to bleeding from the gastrointestinal tract or from bleeding at the site of the cancer deposits. Please report any blood in your stool, bowel movements, or vomiting material looking like coffee grounds to your doctor as a matter of urgency.

IMAVEC may cause metabolic abnormalities, therefore dehydration and high uric acid level treatment may be required.

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

IMAVEC may have side effects such as stroke or a minor stroke. A stroke or minor stroke may occur in patients on treatment with **IMAVEC** with or without having being at risk for a stroke or minor stroke and may occur at any time during treatment with **IMAVEC**. Your doctor will carefully monitor your treatment to reduce your risk with this medication. Treatment with **IMAVEC** should be discontinued, and alternative treatment options be considered if you developed a stroke or minor stroke.

Hepatitis B reactivation, including death have occurred in patients treated with **IMAVEC**. Your hepatitis B virus status should be established before starting treatment with **IMAVEC**. You should be monitored for signs and symptoms like fever, chills, weakness, confusion, vomiting and jaundice, and the correct treatment should be started as indicated. If you tested positive for hepatitis B viral infection, speaking to a doctor with experience in treating hepatitis B is recommended.

Taking IMAVEC with food and drink:

IMAVEC should be taken once daily with a meal and a large glass of water to minimise the risk of bowel disturbances.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, you should not use **IMAVEC** (please see "**Do NOT take IMAVEC if you**").

<p>If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking IMAVEC.</p>
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Women of child-bearing potential must use effective contraception during treatment as discussed with your doctor.

Driving or using machinery:

You may experience dizziness or blurred vision while receiving treatment with **IMAVEC**. If you experience such adverse events, you should refrain from driving a car or operating machinery.

Important information about some of the ingredients of IMAVEC:

IMAVEC 400 contains lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus. You should not take **IMAVEC 400** if you have hereditary galactose intolerance, *lapp* lactase deficiency or glucose-galactose malabsorption, usually indicated by intolerance to dairy products.

Taking other medicines with IMAVEC:

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

The following medicines or substances may increase blood levels of **IMAVEC**, so please inform your doctor if you are taking:

- Ketoconazole or itraconazole for the treatment of fungal infections.
- Antibiotics, such as erythromycin and clarithromycin.
- Grapefruit juice.

The following medicines may lower blood levels of **IMAVEC**; so please inform your doctor if you are taking:

- Dexamethasone, a corticosteroid.
- Anti-epileptic medicines, such as phenytoin or carbamazepine.
- Antibiotics, such as rifampicin for the treatment of tuberculosis.
- St John's Wort.

IMAVEC may alter the blood levels of the following medicines; so please inform your doctor if you are currently taking:

- Medicines that contain paracetamol, including over-the-counter medicines, as this may cause serious adverse reactions.
- Certain benzodiazepines for the treatment of anxiety and sleeplessness.
- Certain calcium channel blockers for the treatment of hypertension, angina, or irregular heartbeat.
- Certain statins for the treatment of high blood cholesterol levels.
- Warfarin for the treatment and prevention of blood clots.
- Ciclosporin for the treatment of certain auto-immune diseases and the prevention of organ rejection.
- Pimozide for the treatment of certain psychiatric conditions.

HOW TO TAKE IMAVEC:

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

Always take IMAVEC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

IMAVEC should be taken once daily with a meal and a large glass of water. Your doctor will determine the most appropriate dosage. He/she may decide to alter your dosage if you develop adverse reactions, such as impairment of liver function or low white blood cell and low platelet counts.

If you are unable to swallow the capsules, you can dissolve them in a glass of water or apple juice. Stir the mixture until the content of the capsule have been dissolved completely. Drink everything in the glass straight away.

If you are pregnant the handling of opening **IMAVEC** capsules may be harmful to your baby.

If you have the impression that the effect of **IMAVEC** is too strong or too weak, talk to your doctor or pharmacist.

Children:

IMAVEC should not be used in children.

Elderly patients:

Elderly patients do not require specific dosage adjustments; however, your doctor may decide to alter your dosage depending on your liver function.

Impaired liver function:

Cases of liver failure including death have occurred in patients treated with **IMAVEC**. (see **Possible Side Effects**).

If you take more IMAVEC than you should:

In the event of an overdose, or if someone else has taken your medicine by mistake, you, or this other person, may experience side effects such as those listed below. **In the event of**

overdosage, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take IMAVEC:

Always take **IMAVEC** as prescribed. If you miss a dose, take it as soon as you remember. However, if it is close to your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose. It is important to take **IMAVEC** regularly.

POSSIBLE SIDE EFFECTS:

IMAVEC can have side effects.

Not all side effects reported for IMAVEC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IMAVEC, please consult your doctor, pharmacist or other healthcare professional for advice.

The most frequently experienced side effects of **IMAVEC** include mild nausea, vomiting, diarrhoea, muscle pain, muscle cramps, and skin rash. Another common side-effect is fluid retention with swelling of the eyelids or lower limbs.

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

Frequent:

- Severe swelling of the whole body.

Less frequent:

- Symptoms suggestive of stroke, such as weakness in a limb, difficulty speaking or alteration in consciousness.
- Swelling of the limbs, face or abdomen with rapid heart rate, extreme tiredness and shortness of breath.
- Any blistering skin rash.
- Skin rash, itching, red discolouration of the skin, dry skin, hair loss, breaking of your nails, night sweats, increased sweating, hives, rash or darker pigmentation of sun-exposed skin, decreased skin pigmentation, or inflammation or cracking of the corners of the mouth or lips.

Frequency unknown:

- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection).

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **IMAVEC**. 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:

Frequent:

- Fever, cough with sputum production, difficulty breathing, shortness of breath, and extreme tiredness.
- Bleeding from the gums, easy bruising, or pin point red spots on the skin.
- Foul-smelling diarrhoea.

Less frequent:

- Jaundice – a yellow discolouration of the whites of the eyes and skin.
- Fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat.
- Bleeding from the gums, easy bruising, or pin point red spots on the skin.
- Symptoms suggestive of stroke, such as weakness in a limb, difficulty speaking or alteration in consciousness.
- Loss of vision or visual disturbances.
- Swelling of the limbs, face or abdomen with rapid heart rate, extreme tiredness and shortness of breath.
- Foul-smelling diarrhoea.
- Blood in your stool.
- Difficulty urinating, passing large amounts of urine, decreased urination, or blood in the urine.

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

Tell your doctor if you notice any of the following:

Frequent:

- Fever blisters or shingles.
- Diarrhoea and vomiting.
- Mouth ulceration.
- Nose bleeds.
- Swelling of the eyelids.

- Extreme tiredness or weakness.
- Conjunctivitis (inflammation of the membrane covering the inside of the eyelids), increased tearing, or dry eyes.
- Flushing or coldness of the fingers or toes.
- Dyspepsia, stomach pain, nausea, stomach distension, flatulence, constipation, or heartburn.
- Muscle pain and/or cramps, swelling of the joints, back pain radiating to the legs, and muscle stiffness.
- Increased or decreased weight.
- Fluid retention and swelling, fatigue, fever, weakness, chills.

Less frequent:

- Gout – a painful inflammation of the joints.
- Loss of sensation in the fingers or toes.
- Loss of appetite, or increased appetite.
- Depression or anxiety.
- Decreased libido.
- Ringing in the ears.
- Breast enlargement, swelling of the scrotum, menstrual pain, nipple pain, or sexual drive or ability.

Not all side effects reported for **IMAVEC** are included in this leaflet.

Please tell your doctor or pharmacist of any undesirable effects you think may be due to **IMAVEC**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF IMAVEC:

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.

Do not use the medicine after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF IMAVEC:

IMAVEC

Carton containing 60 capsules in PVC / ALU blister strips.

IMAVEC 400:

Carton containing three Alu/ PVC blister strips of 10 capsules each.

IDENTIFICATION OF IMAVEC:

IMAVEC

Pale yellow powder filled in hard gelatin capsule of size “1” with mud brown coloured cap and mud brown coloured body, printed with ITB.

IMAVEC 400:

Light yellow granules filled in size 00EL hard gelatin capsules with brown cap and brown body.

REGISTRATION NUMBERS:

IMAVEC: 42/34/0496

IMAVEC 400: 50/34/0118

NAME AND ADDRESS REGISTRATION HOLDER:

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