PATIENT INFORMATION LEAFLET FOR

IMAVEC/IMAVEC 400

SCHEDULING STATUS: S4

IMAVEC (100 mg, capsules)

IMAVEC 400 (400 mg, capsules)

Contains sugar (159,64 mg Lactose / capsule

Read all of this leaflet carefully before you start using IMAVEC/IMAVEC 400

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- 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 is in this leaflet

1. What IMAVEC is and what it is used for
2. What you need to know before you use IMAVEC
3. How to use IMAVEC
4. Possible side effects
5. How to store IMAVEC
6. Contents of the pack and other information

1. What IMAVEC is and what it is used for

IMAVEC is a medicine containing an active substance called imatinib.

IMAVEC is used to treat blood disorders in adults and children**. IMAVEC** works by inhibiting the abnormal or uncontrolled growth of cells involved in some types of cancer such as chronic myeloid leukaemia (CML) or acute lymphoblastic leukaemia (ALL).

IMAVEC is a treatment for adults and children for:

Newly diagnosed Philadelphia chromosome (bcr-abl) positive (ph+) Chronic myeloid leukaemia (CML)**.** Leukaemia is a cancer of white blood cells. These white cells usually help your body to fight infection. Chronic myeloid leukaemia is a form of leukaemia in which certain abnormal white cells (named myeloid cells) start growing out of control. IMAVEC inhibits the growth of these cells.

Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph-positive ALL).

Leukaemia is a cancer of white blood cells. These white cells usually help your body to fight infection. Acute lymphoblastic leukaemia is a form of leukaemia in which certain abnormal white cells (named lymphoblasts) start growing out of control. IMAVEC inhibits the growth of these cells.

IMAVEC is also in a treatment of rare blood disorders for adults for:

Myelodysplastic/myeloproliferative diseases (MDS/MPD)**.** These are a group of blood diseases in which some blood cells start growing out of control. **I**MAVEC inhibits the growth of these cells in a certain subtype of these diseases.

Systemic mastocytosis (SM) and eosinophilia.

Systemic mastocytosis (SM) is a rare disease in which too many mast cells (immune cells) are found in your skin, bones, joints, lymph nodes, liver, spleen, and the gastrointestinal tract. Eosinophilia represents an increased number of white blood cells (named eosinophils) in your tissues and/or blood.

Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL).

These are blood diseases in which some blood cells (named eosinophils) start growing out of control. IMAVEC inhibits the growth of these cells in a certain subtype of these diseases.

Gastrointestinal stromal tumours (GIST)

GIST is a cancer of the stomach and bowels. It arises from uncontrolled cell growth of the supporting tissues of these organs. IMAVEC inhibits the growth of these cells.

Dermatofibrosarcoma protuberans (DFSP)

DFSP is a cancer of the tissue beneath the skin in which some cells start growing out of control. IMAVEC inhibits the growth of these cells.

In the rest of this leaflet, we will use the abbreviations when talking about these diseases.

If you have any questions about how IMAVEC works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take IMAVEC

IMAVEC treatment will be prescribed by a doctor with experience in medicines to treat blood cancers or solid tumours.

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not take IMAVEC:

- If you are hypersensitive (allergic) to imatinib or any of the other ingredients of IMAVEC (listed in **Section 6**).
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**)
- If you are breastfeeding a baby.

If this applies to you, tell your doctor without taking IMAVEC.

If you think you may be allergic but are not sure, ask your doctor for advice.

Warnings and precautions

Take special care with IMAVEC:

- If you are receiving treatment with levothyroxine because your thyroid has been removed
- If you are taking other medicines that may increase or decrease the amount of IMAVEC in your blood or influence its effect. See "**Other medicines and IMAVEC**"
- If you have liver function problems.
- If you have kidney disease or disease that impairs the working of the kidney.
- If you have heart disease.
- If you have ever had or might now have a hepatitis B infection, inform your 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.
- If you experience bruising, bleeding, fever, fatigue and confusion when taking IMAVEC, contact your doctor. This may be a sign of damage to your blood vessels known as thrombotic microangiopathy (TMA).

Check with your doctor if you think any of these may apply to you.

You may become more sensitive to the sun while taking IMAVEC. 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.

While you are taking IMAVEC, your doctor will regularly check whether the medicine is working. 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. **(PI pg13 L236)**

IMAVEC can be used by patients over the age of 65.

If you suffer from gastrointestinal stromal tumour (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. Patients will be carefully monitored by their doctor for gastrointestinal symptoms at the start of and during imatinib therapy.

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.

Children and adolescents

There is no experience with the use of IMAVEC in children with CML below 2 years of age and with Ph+ ALL below 1 year of age. There is very limited experience with the use of IMAVEC in children below 3 years of age in the other diseases. Some children and adolescents taking IMAVEC may have slower than normal growth. The doctor will monitor their growth at regular visits.

Other medicines and IMAVEC

Always tell your health care professional if you are taking, have recently taken or might take any other medicine, including medicines obtained without a prescription (such as paracetamol) and including herbal medicines (such as St. John's Wort). Before using IMAVEC you should speak to your doctor if you are taking any of the following medicines.

Some medicines can interfere with the effect of IMAVEC when taken together. They may increase or decrease the effect of IMAVEC, either leading to increased side effects or making IMAVEC less effective. IMAVEC may also decrease or increase the effect of other medicines.

Tell your doctor if you are using medicines that prevent the formation of blood clots.

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

- medicines used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome) (indinavir, lopinavir/ritonavir, ritonavir, saquinavir, nelfinavir); medicines used to treat Hepatitic C (telaprevir, boceprevir)
- medicines used to treat infections such as ketoconazole, itraconazole, posaconazole, voriconazole for the treatment of fungal infections.
- Antibiotics, used to treat infections such as erythromycin, clarithromycin and telithromycin.

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

- Dexamethasone, a corticosteroid. dexamethasone (used to treat conditions such as arthritis, blood/hormone disorders, allergic reactions, skin diseases, eye problems, breathing problems, bowel disorders, cancer, and immune system disorders)
- some medicines used to treat epilepsy , such as carbamazepine, oxcarbazepine, phenytoin, fosphenytoin, phenobarbital, primidone)
- 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:

- If you are currently using simvastatin for the treatment of high blood cholesterol levels.
- Are taking the medicine levothyroxine because your thyroid has been removed.
- Medicines that contain paracetamol, including over-the-counter medicines, as this may cause serious adverse reactions.
- Certain calcium channel blockers for the treatment of hypertension, angina, or irregular heartbeat.
- medicines used to treat high blood pressure or heart disorders such as (dihydropyridine calcium channel blockers, metoprolol)
- Warfarin for the treatment and prevention of blood clots.
- Ciclosporin for the treatment of certain auto-immune diseases and the prevention of organ rejection (tacrolimus, sirolimus).
- Pimozide for the treatment of certain psychiatric conditions.
- medicines used to treat psychosis, a severe mental disorder
- medicines used to treat migraines (ergotamine, diergotamine)
- medicines used to treat severe pain (fentanyl, alfentanil)
- antihistamines used to treat allergies (terfenadine)
- medicines used to treat certain types of cancer (bortezomib, docetaxel)
- medicines used to treat heart rhythm disorders (quinidine)
- medicines used to treat anxiety, panic disorders and depression (triazolo-benzodiazepines)
- If you are taking rifampicin (for tuberculosis), ketoconazole (for fungus infections)

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, breastfeeding and fertility

If you are pregnant or intend to become pregnant, or breastfeeding your baby, you should not use IMAVEC (please see **"Do NOT take IMAVEC if you"**), as it may harm your baby.

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 using IMAVEC.

Safety in human pregnancy and lactation has not been established.

Females of child-bearing potential must use effective birth control while taking IMAVEC and for 15 days after ending treatment.

Women of child-bearing potential must use effective contraception during treatment as discussed with your doctor.

IMAVEC is not recommended during pregnancy unless clearly necessary as it may harm your baby. Your doctor will discuss with you the possible risks of taking IMAVEC during pregnancy.

Do not breast-feed during the treatment with IMAVEC during treatment and for 15 days after ending treatment with IMAVEC, as it may harm your baby.

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

If you are a man using IMAVEC, you must use a condom when having sexual intercourse. Birth defects have occurred in babies when pregnant women were treated with IMAVEC or whose father used IMAVEC.

Driving or using machinery

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. You may experience dizziness or blurred vision or drowsy while receiving treatment with IMAVEC. If you experience such adverse events, you should refrain from driving a car or operating machinery. If this happens, do not drive or use any tools or machines until you are feeling well again.

It is not always possible to predict to what extent IMAVEC may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which IMAVEC affects them.

IMAVEC 400 contains lactose

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.

3. How to take IMAVEC

Follow all instructions given to you by your doctor carefully.

Your doctor will advise you on the dose to be taken for your specific condition.

Your doctor has prescribed IMAVEC because you suffer from a serious condition. IMAVEC can help you to fight this condition. 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.

Do not stop taking IMAVEC unless your doctor tells you to. If you are not able to take the medicine as your doctor prescribed or you feel you do not need it anymore, contact your doctor straight away.

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 or your child 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.

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 a child in your care.

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.

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

If you accidentally take more IMAVEC than has been prescribed for you, consult your doctor or pharmacist immediately. If neither is available contact the nearest hospital or poison control centre.

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side effects such as those listed (see **section 4**).

You may require medical attention. In the event of such overdosage, your doctor will then observe and manage this situation and give appropriate supportive treatment.

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.

If a dose is missed or vomiting occurs, do not make up the dose. Instead wait until it is time for your next dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. 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 using IMAVEC, please consult your health care provider for advice.

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 IMAVEC.

The most frequently experienced side effects of IMAVEC include mild nausea, vomiting, diarrhoea, abdominal pain, fatigue, myalgia, muscle pain, muscle cramps, and skin rash, which are easily manageable. Another common side-effect is fluid retention with swelling of the eyelids or lower limbs may also occur and can be managed by supportive measures.

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

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 or thinning, 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
- herpes simplex, herpes zoster, nasopharyngitis, pneumonia, gastroenteritis, sinusitis, influenza, fungal infection upper respiratory tract infection, sepsis
- Tumour lysis syndrome
- Thrombocythaemia, lymphopenia, bone marrow depression, eosinophilia, lymphadenopathy, haemolytic anaemia, thrombotic microangiopathy
- anaphylactic shock
- Pale skin, feeling tired, breathlessness, dark urine (signs of breakdown of red blood cells).
- Crushing chest pain, fever, tiredness, irregular heartbeat (signs of heart disorders such as heart attack, angina).
- Nausea, diarrhoea, vomiting, abdominal pain, fever (signs of inflammatory bowel disease).
- Severe rash, red skin, blistering of the lips, eyes, skin or mouth, skin peeling, fever, red raised or purple skin patches, itching, burning sensation, pustular eruption (signs of skin disorder).
- Pain and having difficulty walking.
- Painful red lumps on the skin, skin pain, skin reddening (inflammation of fatty tissue under the skin; signs of panniculitis).

- Severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (signs of nervous system disorder such as bleeding or swelling in skull / brain).
- Seizure.
- Light-headedness, dizziness or fainting (which may be signs of low blood pressure).
- Severe abdominal pain, vomiting blood, black or bloody stools, or having black stools, swelling of the abdomen/fluid within the abdomen, constipation, stomach pain (signs of gastrointestinal disorders).
- Nausea, loss of appetite, dark-coloured urine or yellowing of your skin or eyes go yellow (sign of liver disorders).
- Thirst, weight loss and severely decreased urine output (signs of low intake of drinks/fluids).
- Blood in urine.
- Swelling and pain in one part of the body (signs of clots in blood vessels).
- Cough, difficult or painful breathing, wheezing, pain in chest when breathing (signs of lung infections/disorders).
- Muscle weakness, muscle spasms, abnormal heart rhythm (signs of changes in level of potassium in the blood).
- Muscle spasms, fever, red-brown urine, kidney disorders, pain or weakness in muscles, (signs of muscle disorders).
- Pelvic pain sometimes accompanied by nausea and vomiting, unexpected vaginal bleeding, feeling dizzy or fainting due to low blood pressure (signs of gynaecological disorder).
- Severe allergic reaction that can result in difficulty breathing, dizziness.
- Nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal laboratory values (such as high potassium, uric acid, and calcium levels and low phosphorous levels in the blood).

- Severe headache, dizziness, blurred vision (signs of increased pressure inside the skull).
- Pain in bones or joints (sign of osteonecrosis).
- Blisters on skin or mucous membranes (sign of pemphigus).
- Numb or cold toes and fingers (signs of Raynaud's syndrome).
- Difficulty hearing

Frequency unknown:

- Recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection)
- Acute respiratory failure (your body does not get enough oxygen from your lungs causing a severe shortness of breath, drowsiness, low blood pressure, blue lips or nails)
- Combination of a widespread severe rash, feeling sick, fever, high level of certain white blood cells or yellow skin or eyes (signs of jaundice) with breathlessness, chest pain/discomfort, severely decreased urine output and feeling thirsty (signs of a treatment-related allergic reaction).
- Chronic renal failure

These are all very serious side effects. If you or a child in your care have them, you may have had a serious 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.
- Difficulty in sleeping
- Dizziness
- Taste disturbance
- Rapid weight gain, swelling of extremities (calves, ankles), generalised swelling such as swelling of the face (signs of water retention).
- Weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of low level of blood cells).
- Unexpected bleeding or bruising (when you have not hurt yourself).

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, eye pain or irritation, bleeding eyes, red, swollen eyelids, flaking of the skin around your eyes, crusted eyelashes upon awakeningChanges in the way the heart beats (faster or slower), or irregular, heart attack, chest pain, discomfort or pressure
- 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.
- Inflammation of the fatty layer under the skin causing painful bumps or nodules to form under your skin, including tender, red bumps, usually found symmetrically on the shins.
- Reduced amount of urine, swelling of your legs, ankles, and feet from fluid retention caused by the failure of your kidneys to eliminate water waste, drowsiness or fatigue.

Frequency unknown:

- intestinal obstruction (swelling of your abdomen, crampy abdominal pain that comes and goes, loss of appetite, inability to have a bowel movement or pass gas)

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

Tell your doctor if you notice any of the following:

Frequent:

- Diarrhoea and vomiting
- Mouth ulceration
- Anorexia
- Nose bleeds
- Swelling of the eyelids
- Extreme tiredness or weakness
- Conjunctivitis (inflammation of the membrane covering the inside of the eyelids), discharge from the eye with itching, increased tearing, or dry eyes

- Dyspepsia, stomach pain, nausea, stomach distension, flatulence, constipation, or heartburn
- Numbness of the hands or feet.
- Decreased or increased skin sensitivity.
- Dry mouth
- Hot flushes, chills or night sweats.
- 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
- Neutropenia, thrombocytopenia, anaemia, febrile neutropenia, pancytopenia

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Less frequent:

- Cough, runny or stuffy nose, feeling of heaviness or pain on pressing the area above the eyes or on the sides of the nose, nasal congestion, sneezing, sore throat, with or without headache (signs of upper respiratory tract infection).
- Severe headache felt as a throbbing pain or pulsing sensation, usually on one side of the head and often accompanied by nausea, vomiting and sensitivity to light or sound (signs of migraine).
- Sleepiness/drowsiness/excessive sleep.
- Trembling or shaky movements (tremor).
- Memory impairment.
- Overwhelming urge to move the legs (restless leg syndrome).
- Hearing noises (e.g. ringing, humming) in the ears that have no external source (tinnitus).
- High blood pressure (hypertension).

- Burping/belching.
- Inflammation of the lips.
- Skin discolouration.
- Red bumps or white-headed pimples around the roots of the hair, possibly with pain, itching or burning sensation (signs of inflammation of the hair follicles, also called folliculitis).
- Fever blisters or shingles
- Sudden swelling and redness of the skin (signs of a skin infection called cellulitis)
- Pain or burning feeling when you urinate, increased body temperature, pain in groin or pelvic area, red-or brown coloured or cloudy urine, frequent urge to urinate (signs of a urinary tract infection)
- Increase frequency of passing urine.
- Fungal infection
- Viral infection such as cold sore.
- Generally feeling unwell (malaise).
- Gout – a painful inflammation of the joints
- Loss of sensation in the fingers or toes
- Flushing or coldness of the fingers or toes
- Loss of appetite, or increased appetite
- Pain or burning sensation in upper abdomen and/or chest (heartburn), nausea, vomiting, acid reflux, feeling of fullness and bloating, black-coloured stools (signs of stomach ulcer).
- A constant feeling of sadness and loss of interest, which stops you carrying out your normal activities (signs of depression)
- A feeling of apprehension and worry along with physical symptoms such as pounding heart,
- sweating, trembling, dry mouth (signs of anxiety)

- Dull pain and/or feeling of heaviness in the testicles or lower abdomen, pain during urination, sexual intercourse or ejaculation, blood in urine (signs of oedema of the testicles).
- Inability to get or keep an erection (erectile dysfunction).
- Heavy or irregular menstrual periods.
- Difficulty achieving/maintaining sexual arousal.
- Decreased libido
- Lower back pain resulting from kidney disorder.
- Ringing in the ears, sensation of swaying or spinning (vertigo), hearing loss
- Breast enlargement, swelling of the scrotum, menstrual pain, nipple pain, or sexual drive or ability
- Abnormal laboratory test results when blood tests are done (e.g. low phosphorus, sodium and magnesium levels or high uric acid and calcium levels)
- Confusion
- An episode of spasm(s) and reduced consciousness (convulsions).
- Nail discolouration

Frequency unknown

- 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.
- Painful and/or blistering skin lesions.
- Slowing of growth in children and adolescents.

If any of these affects you severely, **tell your doctor**.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of IMAVEC.

5. How to store IMAVEC

Store at or below 25 °C

Store all medicines out of reach of children.

Store 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.

Do not use this medicine if the pack is damaged or shows signs of tampering.

6. Contents of the pack and other information

What IMAVEC contains

The active substance in IMAVEC capsules is imatinib (as mesylate).

IMAVEC

Other ingredients are 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 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 looks like and contents of the pack

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 can and brown body.

IMAVEC:

Carton containing 60 capsules in PVC / Alu blister strips.

IMAVEC 400:

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

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Customer Care: 080 222 6662

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.