PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

IMTURAS 100 mg film-coated tablets

IMTURAS 400 mg film-coated tablets

Imatinib

Sugar free.

Read all of this leaflet carefully before you start taking IMTURAS

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

1. What IMTURAS is and what it is used for

IMTURAS contains the active ingredient imatinib.

This medicine works by slowing down the uncontrollable growth of abnormal cells in the diseases listed below. These include some types of cancer.

IMTURAS is a treatment for adults and children for:

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.

Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph-positive ALL) – Acute lymphoblastic leukaemia is a form of leukaemia in which certain abnormal white cells (named lymphoblasts) start growing out of control. IMTURAS inhibits the growth of these cells.

IMTURAS is also a treatment 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.

Systemic mastocytosis (SM) and eosinophilia – It is a cancer in which certain blood cells, called “mast” cells, grow out of control. Eosinophilia is 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.

Gastrointestinal stromal tumours (GIST) – It is a cancer of the stomach and bowels. This cancer affects the tissue that surrounds the stomach and bowels and the cells grow uncontrollably.

Dermatofibrosarcoma protuberans (DFSP) – It is a cancer of the tissue beneath the skin in which some cells start growing out of control.

IMTURAS works by slowing the growth of abnormal cells. IMTURAS kills the abnormal cells while leaving normal cells alone.

2. What you need to know before you take IMTURAS

Do not take IMTURAS

- if you are hypersensitive (allergic) to imatinib or to any of the other ingredients of IMTURAS

listed in section 6 of this leaflet;

- if you are pregnant or breastfeeding (see '**Pregnancy and breastfeeding**').

Warnings and precautions

Take special care with IMTURAS if you or a child in your care:

- are taking other medicines that may increase or decrease the amount of IMTURAS in your blood or influence its effect (see '**Other medicines and IMTURAS**');
- are taking the medicine levothyroxine because your thyroid has been removed;
- have or have ever had liver, kidney or heart problems;
- have ever had or might now have a hepatitis B infection. As during treatment with IMTURAS, hepatitis B (an infection of the liver may become active again. Your doctor will check for signs of this infection before treatment is started;
- experience bruising, bleeding, fever, fatigue and confusion when taking IMTURAS, contact your doctor. This may be a sign of damage to your blood vessels known as thrombotic microangiopathy (TMA).

You may become more sensitive to the sun while taking IMTURAS. 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 IMTURAS, tell your doctor straight away if you put on weight very quickly. IMTURAS may cause your body to retain water (severe fluid retention).

While you are taking IMTURAS, your doctor will regularly check whether the medicine is working. You will also have blood tests and be weighed regularly.

Children and adolescents

There is no experience with the use of IMTURAS in children below 2 years of age. There is very

limited experience with the use of IMTURAS in children below 3 years of age in the other diseases. Some children and adolescents taking IMTURAS may have slower than normal growth. The doctor will monitor their growth at regular visits.

Other medicines and IMTURAS

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

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

Tell your doctor or pharmacist if you are using:

- medicines used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome) such as indinavir, lopinavir/ritonavir, ritonavir, saquinavir, nelfinavir;
- medicines used to treat Hepatitis C such as telaprevir, boceprevir;
- medicines used to treat fungal infections such as ketoconazole, itraconazole, posaconazole, voriconazole;
- medicines used to treat bacterial infections (antibiotics), such as erythromycin, clarithromycin and telithromycin;
- dexamethasone, a steroid medicine, used to treat inflammation;
- medicines used to treat epilepsy such as phenytoin, carbamazepine, oxcarbazepine, fosphenytoin, phenobarbital, primidone;
- St John's wort, a herbal medicine used to treat depression;
- medicines used to treat tuberculosis (TB) such as rifampicin;
- medicines used to treat high cholesterol such as simvastatin;
- medicines used to prevent organ rejection ciclosporin, tacrolimus, sirolimus;
- medicines used to treat psychosis, a severe mental disorder, such as pimozide;

- medicines used to help relieve migraines such as ergotamine, diergotamine);
- medicines used to treat severe pain such as fentanyl, alfentanil;
- antihistamines, medicines used to treat allergies such as terfenadine;
- medicines used to treat certain types of cancer such as bortezomib, docetaxel, L-asparaginase;
- medicines used to help regulate the rhythm of the heart such as quinidine;
- medicines used to treat anxiety and depression such as triazolo-benzodiazepines);
- medicines used to treat high blood pressure such as dihydropyridine calcium channel blockers, metoprolol;
- medicines that prevent blood clots such as warfarin;
- paracetamol, a medicine used to treat mild or moderate pain and fever;
- levothyroxine, a medicine used to treat an underactive thyroid gland (levothyroxine).

IMTURAS with food and drink

There are no known interactions between IMTURAS and food.

Pregnancy and breastfeeding

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 IMTURAS.

If you are pregnant or breastfeeding your baby, you should not use IMTURAS as it may harm your baby. Women who might become pregnant are advised to use effective contraception during treatment and for 15 days after ending treatment. If you are concerned about your fertility while taking IMTURAS, please consult your doctor.

Driving and using machines

You may feel dizzy or drowsy or get blurred vision while taking IMTURAS. If this happens, do not drive a vehicle or use any tools or machines until you are feeling well again.

3. How to take IMTURAS

Do not share medicines prescribed for you or a child in your care with any other person.

Always take or give IMTURAS exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

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

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.

IMTURAS should be taken with food and a large glass of water. This will help protect you from stomach problems that may occur when taking IMTURAS.

If you or a child in your care are unable to swallow the tablet(s), you can dissolve them in a glass of water or apple juice:

- Use about 50 mL for a 100 mg tablet and 200 mL for each 400 mg tablet;
- Stir with a spoon until the tablet(s) have completely dissolved;
- Once the tablet(s) have dissolved, drink everything in the glass straight away. Traces of the dissolved tablet(s) may be left behind in the glass.

Your doctor will tell you how long your treatment with IMTURAS will last. Do not stop treatment with IMTURAS unless your doctor tells you to.

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

Your doctor will keep a close check on you to make sure you are still benefiting from treatment.

If you take more IMTURAS than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may require medical attention. Take the medicine pack with you.

If you forget to take IMTURAS

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

If you stop taking IMTURAS

It is important to keep taking or receiving IMTURAS every day, as long as your doctor prescribes it for you or a child in your care.

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

4. Possible side effects

IMTURAS can have side effects.

Not all side effects reported for IMTURAS are included in this leaflet. Should you or a child in your care's general health worsen or if you experience any untoward effects while taking IMTURAS, please consult your health care provider for advice.

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

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

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 IMTURAS. 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:

- signs of infection such as fever, severe chills, sore throat or mouth ulcers;
- unexpected bleeding or bruising (when you have not hurt yourself);
- rapid weight gain as IMTURAS may cause your body to retain water (severe fluid retention);
- difficulty in breathing;
- pneumonia (fever, chills, shortness of breath, cough which produces yellow-green phlegm and occasionally blood);
- sepsis (often called blood poisoning, a severe infection which can lead to death);
- blood clots in small blood vessels (thrombotic microangiopathy);
- 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 your skull/brain);
- fits (seizures);
- fast or irregular heartbeats, changes in the way your heart beats;
- heart problem which can cause shortness of breath and swelling of the feet or legs;
- heart attack;
- a feeling of tightness, pressure or heaviness in the chest, chest pain;
- feeling light-headed, dizzy of fainting (hypotension);
- shortness of breath, difficulty breathing, cough;
- severe abdominal pain, blood in your vomit, stools or urine, black stools (signs for gastrointestinal disorders);
- inflammation of your pancreas (severe upper stomach pain, that radiates to your back, often with nausea (feeling sick) and vomiting (being sick));
- nausea (feeling sick), vomiting (being sick) of blood, stomach pain, clay coloured stool, dark urine, unpleasant breath odour, unusual tiredness, yellowing of skin or eyes (signs or liver

problems);

- a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface – toxic epidermal necrolysis);
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea),
- a rare skin eruption characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (acute generalised exanthematous pustulosis (AGEP));
- drug rash with eosinophilia and systemic symptoms (DRESS syndrome) (skin rash, fever, swelling of lymph nodes and an increase of white blood cells;
- rhabdomyolysis (rapid breakdown of muscle tissue causing muscle pain or weakness, dark coloured urine, fever);
- kidney problems (drowsiness, shortness of breath, fatigue, confusion, nausea, vomiting, passing less urine than is normal for you), bladder pain;
- blood in the urine, persistent urge to urinate and burning with urination;
- 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);
- intestinal obstruction (crampy abdominal pain that comes and goes, loss of appetite, inability to have a bowel movement or pass gas, swelling of your abdomen);
- gastrointestinal perforation (when a hole forms all the way through the stomach, large bowel, or small intestine causing severe stomach pain that worsens when moving.

Tell your doctor if you notice any of the following:

Frequent side effects:

- pale skin, feeling tired and breathlessness and having dark urine (signs of low levels of red blood cells);
- anorexia (lack or loss of appetite);
- difficulty in sleeping (insomnia);
- headaches, dizziness;
- tingling or numbness of your hands and feet (pins and needles);
- disturbed sense of taste;
- diminished sense of touch;
- puffy eyes, watery eyers, discharge from the eye with itching and crusty eyelids, redness and swelling (conjunctivitis), dry eyes or having blurred vision;
- hot flushes,
- nose bleeds;
- cough;
- nausea (feeling sick), diarrhoea, vomiting (being sick), indigestion, stomach pain, flatulence (wind), bloating, heartburn, constipation, dry mouth;
- increased liver enzymes when blood tests are done;
- dry skin, swelling of your face, eyelid swelling, redness of your skin;
- unusual hair loss or thinning;
- night sweats;
- decreased or increased skin sensitivity;
- muscle spasms or cramps, muscle pain, muscle tenderness or weakness, bone or joint pain, joint swelling;
- feeling tired or weak;
- fever or chills;
- increased or decreased weight.

Less frequent side effects:

- runny or stuffy nose, postnasal drip, facial pain, sneezing, scratchy or sore throat;
- swollen and red skin and may be hot and tender (signs of a skin infection called cellulitis);
- increased urge to urinate, pain with urination and blood in the urine (signs of a urinary tract infection);
- fungal infection;
- increased or decreased appetite;
- abnormal laboratory test results when blood tests are done (e.g. low phosphorus, sodium and magnesium levels or high uric acid and calcium levels);
- dehydration;
- severe attacks of pain, swelling, redness and tenderness in one or more joints (signs of gout);
- high blood sugar levels;
- muscle weakness and spasms with an abnormal heart rhythm (signs of changes in the amount of potassium in your blood);
- feeling depressed, anxious or confused;
- loss of interest in sex, problems with sexual function;
- migraine;
- sleepiness, drowsiness;
- fainting;
- numbness, prickling or tingling in your feet or hands, which can spread upward into your arms and may be accompanied by a sharp or burning pain;
- difficulty remembering things;
- pain in your hips or difficulty walking;
- an uncontrollable urge to move your legs (restless legs syndrome (RLS));
- shakiness (tremors);
- eye pain, irritated, red or itchy eyers, in the eyes, blurred vision;
- vertigo (sensation of spinning or swaying);

- ringing in your ears, hearing loss;
- high or low blood pressure;
- numb or cold toes and fingers (signs of Raynaud's syndrome);
- sore mouth, mouth ulcers and cold sores;
- burping;
- difficulty and or painful swallowing;
- increased sweating;
- bruising more easily;
- patches of skin that are light or darker than overall skin tone;
- painless separation of the nail from the nailbed;
- nail discolouration;
- joint and muscle stiffness, painful, swollen and red joints;
- breast enlargement in men and women;
- sexual problems, including the inability to develop or maintain an erection in men;
- nipple pain;
- irregular or heavy menstruation in women;
- scrotal swelling in men;
- generally feeling unwell;
- increased liver enzymes when blood tests are done.

Frequency unknown side effects:

- slowing of growth in children and adolescents.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP

(Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of IMTURAS.

5. How to store IMTURAS

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Keep the blister strips in the outer carton until required for use.
- Protect from moisture.
- Do not use after the expiry date printed on the carton or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IMTURAS contains

The active substance in IMTURAS is imatinib.

IMTURAS 100 mg: Each film-coated tablet contains 100 mg imatinib (as mesilate).

IMTURAS 400 mg: Each film-coated tablet contains 400 mg imatinib (as mesilate).

The other ingredients are:

Tablet core:

Povidone

Magnesium stearate

Tablet coating:

Opadry Brown (containing hypromellose, iron oxide yellow, talc, macrogol, titanium dioxide (E171), iron oxide red).

What IMTURAS looks like and contents of the pack

IMTURAS 100 mg: Dark yellow to brownish orange coloured, film-coated tablets, round, biconvex with bevelled edges debossed with `S´ and `1´ on either side of break line on one side and plain on other side.

IMTURAS 400 mg: Dark yellow to brownish orange coloured, film-coated tablets, capsule shaped, biconvex with bevelled edged debossed with `S´ and `2´ on either side of break line on one side and plain on other side.

IMTURAS film-coated tablets are available in clear PVC/PVDC/Aluminium foil blister packs.

Pack sizes:

IMTRUAS 100 mg: Blister pack containing 20, 30, 60, 120 or 180 film-coated tablets.

IMTURAS 400 mg: Blister pack containing 10, 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Alturas Healthcare (Pty) Ltd

Unit 18a, First floor, Key Largo Shopping Centre

Corner of North Rand and Trichardt Road

Boksburg, Gauteng

1459

This leaflet was last revised in

To follow

Registration numbers

IMTURAS 100 mg:570023

IMTURAS 400 mg: 570024

Access to the corresponding Professional Information

To follow