FINAL PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

IMATINIB ACCORD 100 (film-coated tablets)

IMATINIB ACCORD 400 (film-coated tablets)

Imatinib

Sugar free

Read all of this leaflet carefully before you start taking IMATINIB ACCORD

- 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.
- **IMATINIB ACCORD** 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 IMATINIB ACCORD IS AND WHAT IT IS USED FOR

Treatment for adults and children for:

Chronic myeloid leukaemia (CML): Leukaemia is a cancer of white blood cells.

Treatment for adults for certain other types of leukaemia or cancer of the stomach and skin.

2. WHAT YOU NEED TO KNOW BEFORE YOU IMATINIB ACCORD

Do not take IMATINIB ACCORD:

- if you are hypersensitive (allergic) to imatinib mesylate or any of the other ingredients of **IMATINIB ACCORD** listed in section 6.
- if you are pregnant, planning to become pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with IMATINIB ACCORD:

- If you have or ever had a liver, kidney or heart disorder. In patients with liver dysfunction, blood counts and liver enzymes should be carefully monitored.
- If you are taking a medicine called levothyroxine, because your thyroid has been removed (severe fluid retention), your Thyroid-Stimulating Hormone (TSH) levels should be carefully monitored.
- If you notice that you put on weight very quickly. **IMATINIB ACCORD** may cause your body to retain water. You should therefore be weighed regularly.
- If you notice bleeding at the site of the tumours or bleeding from the gastrointestinal tract (you may notice dark, tarry stool or vomiting blood).
- If you have ever had or might now have a Hepatitis B infection (a liver infection). This is because **IMATINIB ACCORD** could cause Hepatitis B to become active again, which can be fatal in some cases. You will be carefully checked by your doctor for signs of the infection before treatment is started.
- if you notice or someone notices in you: sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, sudden severe headache with no known cause. These may be signs and symptoms of stroke,
- If you have any blood disorders.
- If you are dehydrated or have gout (high uric acid levels).
- If you are going out in the sun as you may be more sensitive to sunlight. Wear sunscreen with a high SPF and protective clothing (long sleeves, a hat)

Children and adolescents

If **IMATINIB ACCORD** is used in children, close monitoring of growth in children is recommended

Other medicines and IMATINIB ACCORD

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

Before taking **IMATINIB ACCORD** tell your doctor if you are using any of the following:

*Medicines that may increase the quantity of **IMATINIB ACCORD** in your blood*

- some medicines that treat fungal skin infections or antibacterial medicines (e.g. ketoconazole, itraconazole, erythromycin and clarithromycin)

*Medicines that may decrease the quantity of **IMATINIB ACCORD** in your blood*

- anticonvulsants (used to prevent seizures), e.g. phenytoin, carbamazepine, phenobarbitone
- anti-inflammatory medicines, e.g. dexamethasone
- rifampicin (used to treat tuberculosis)
- St. John's Wort (a herbal medicine for treating depression)

*Other medicines that may be altered by **IMATINIB ACCORD***

- medicines that prevent the formation of blood clots (e.g. warfarin)
- immunosuppressant medicines (e.g. ciclosporin or pimozide)
- medicines used to treat high cholesterol (e.g. simvastatin)
- medicines to treat migraines (e.g., ergotamine)
- other cancer medicines (e.g., bortezomib, docetaxel)
- terfenadine (an antihistamine)
- quinidine & metoprolol (medicines to treat heart problems)
- paracetamol
- levothyroxine (used to treat low thyroid hormone levels)

IMATINIB ACCORD with food and drink:

IMATINIB ACCORD should be taken with food and a large glass of water to minimise the risk of upsetting your digestive system.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ~~your baby~~, please consult your doctor, pharmacist or other healthcare professional for advice before taking **IMATINIB ACCORD.**
- You should not take IMATINIB ACCORD if you are pregnant or plan to become pregnant.
- **IMATINIB ACCORD** is not recommended during pregnancy, as it may harm your baby. Your doctor will discuss with you the possible risks of taking **IMATINIB ACCORD** during pregnancy.
- You should use highly effective contraception during treatment with **IMATINIB ACCORD** and for 15 days after you stop treatment.
- Do not breastfeed during treatment with **IMATINIB ACCORD**.
- Patients who are concerned about their fertility while taking **IMATINIB ACCORD** are advised to consult with their doctor, pharmacist or healthcare professional.

Driving and using machines

IMATINIB ACCORD may cause dizziness, ~~or~~ blurred vision or make you feel sleepy and therefore may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **IMATINIB ACCORD** affects you.

3. HOW TO TAKE IMATINIB ACCORD

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

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

Your doctor will advise you on the dose you should be taking for your specific condition.

Your doctor may adjust the dosage if necessary for any of the conditions mentioned above depending on the severity of the condition and the side effects you experience.

Your doctor will tell you how long your treatment with **IMATINIB ACCORD** will last. Do not stop treatment early without consulting your doctor because it may decrease the effectiveness of the treatment. If you have the impression that the effect of **IMATINIB ACCORD** is too strong or to weak, tell your doctor or pharmacist.

If you take more IMATINIB ACCORD than you should:

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

If you forget to take IMATINIB ACCORD:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **IMATINIB ACCORD** at the next regularly scheduled time.

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

4. POSSIBLE SIDE EFFECTS

IMATINIB ACCORD can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

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

- chest pain,
- angina (cramping of the heart muscle),
- changes in the way your heart beats, for example, if you notice it beating faster,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you, blood in the urine or more frequent urinating,
- unexpected bleeding or bruising, coughing/vomiting up blood
- blurred vision, bleeding of the blood vessels in the eye,
- glaucoma (sudden ocular pain, seeing halos around lights, red eye, very high pressure in the eye).
- sudden numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination, sudden severe headache with no known cause. These may be signs and symptoms of stroke
- muscle pain, weakness, cramping and fatigue accompanied by dark urine or low urine production (these may be signs of a serious condition called rhabdomyolysis)

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects occur frequently:

- weight gain, swelling of the body,
- headache, dizziness, tingling or pins and needles sensation in arms or legs, difficulty sleeping,
- nose bleeds, shortness of breath,
- red and swollen eyes, watery eyes, blurred vision,
- nausea (feeling sick), vomiting (being sick), diarrhoea (loose stools), indigestion, stomach pain, bloating, flatulence, constipation, heartburn, mouth sores,

- muscle spasm and cramps, muscle pain, joint swelling, muscle stiffness,
- tiredness, fever,
- loss of appetite,
- dry skin, hair loss, night sweats,
- changes in taste

The following side effects occur less frequently:

- chest infection, flu-like symptoms, skin infections, bladder infections, fungal infections
- cough, throat infection, difficulty breathing
- Dehydration (dry mouth), gout (painful swelling of ankle or foot), taste disturbances, increased or decreased appetite, difficulty swallowing
- severe headache, weakness or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness, drowsiness, fits (seizures), tremor
- blood clots, high or low blood pressure, flushes, coldness in fingers or toes
- blood in stools, stomach ulcers,
- liver infection
- red or purple spots on skin, increased sweating, breaking of finger or toe nails, skin sensitivity to light, peeling of skin on the lips, skin discolouration, dry scaly patches, skin blisters, nail discolouration
- eye irritation, eye pain or deterioration of vision, bleeding in the eye
- ringing in the ear, difficulty hearing
- depression, anxiety, decreased sexual drive, confusion,
- breast enlargement (in men and women), nipple pain, sexual dysfunction, heavy menstrual periods in woman
- swelling of the skin or body
- feeling unwell
- muscle weakness, arthritis pain (stiff and swollen joints)

The following side effects may also occur:

- 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.
- Slowing of growth in children and adolescents
- Recurrence (reactivation) of Hepatitis B infection when you have had Hepatitis B in the past (a liver infection)

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. This includes any possible side effects not listed in this leaflet. 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 **IMATINIB ACCORD**.

5. HOW TO STORE IMATINIB ACCORD

Store at or below 25 °C. Protect from moisture.

Keep blisters in the carton until required for use. Store all medicines out of reach of children.

Do not use after the expiry date printed on the label or carton. Return all unused medicine to your pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IMANTINIB ACCORD contains:

The active substance is imatinib mesylate.

The other ingredients are hypromellose, cellulose microcrystalline, crospovidone, colloidal anhydrous silica, magnesium stearate & Opadry yellow (consisting of hypromellose, talc, macrogol, iron oxide yellow and iron oxide red).

What IMATINIB ACCORD looks like and contents of the pack

IMATINIB ACCORD 100: Brownish orange, round, biconvex, film-coated tablets, debossed with 'IM' and 'T1' on either side of the score and plain on the other side.

IMATINIB ACCORD 400: Brownish orange, oval shaped, biconvex, film-coated tablets, debossed with 'IM' and 'T2' on either side of the score and plain on the other side.

IMATINIB ACCORD film-coated tablets are packed into clear transparent PVC/PVdC-Alu blisters or plain matt finish Alu-Alu blisters, containing 10 tablets per blister.

Pack size: 20, 30 or 60 film-coated tablets per carton.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place

Rivonia

Gauteng

South Africa

This leaflet was last revised in

30 September 2016

26 August 2022

REGISTRATION NUMBER

IMATINIB ACCORD 100: 49/26/0740

IMATINIB ACCORD 400: 49/26/0741