PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

TAZATRED 20/50/70/100

Dasatinib

Contains sugar (lactose)

Read all of this leaflet carefully before you start taking

TAZATRED

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- TAZATRED 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 TAZATRED is and what it is used for
2. What you need to know before you take TAZATRED
3. How to take TAZATRED
4. Possible side effects
5. How to store TAZATRED
6. Contents of the pack and other information

1. What TAZATRED is and what it is used for

TAZATRED contains a medicine called dasatinib.

It is used to treat chronic myeloid leukaemia (CML) in adults. Leukaemia is a cancer of white blood cells. These white cells usually help the body to fight infection. In people with CML, white cells called granulocytes start growing out of control. TAZATRED inhibits the growth of these leukaemic cells.

TAZATRED is also used to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) in adults and lymphoid blast CML in adults who are not benefiting from prior therapies. In people with ALL, white cells called lymphocytes multiply too quickly and live too long. TAZATRED inhibits the growth of these leukaemic cells.

2. What you need to know before you take TAZATRED

You should not take TAZATRED if you:

- are hypersensitive (allergic) to dasatinib or any of the ingredients of TAZATRED (see section 6)
- are taking medicines called H_2 antagonists or proton pump inhibitors

Warnings and precautions

Before you start taking TAZATRED tell your doctor or healthcare provider:

- if you are taking medicines to thin the blood or prevent clots (see "Other medicines and TAZATRED")
- if you have lung problems and start having difficulty breathing, chest pain, or a cough when taking TAZATRED: this may be a sign of fluid retention in the lungs or chest (which can be more common in patients aged 65 years and older), or due to changes in the blood vessels supplying the lungs
- if you have heart problems
- if you experience bruising, bleeding, fever, fatigue and confusion when taking TAZATRED, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA)
- if you have a liver problem, or used to have one
- if you have ever had or might now have a hepatitis B infection. This is because TAZATRED 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 have skin problems
- If you are 65 years and older.

Your doctor may regularly monitor your condition to check whether TAZATRED is having the desired

effect. You will also have blood tests regularly while you are taking TAZATRED.

Children and adolescents

The safety and efficacy of TAZATRED in patients younger than 18 years of age have not been established.

Other medicines and TAZATRED

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

In particular, tell your doctor if you are taking any of the following medicines:

- ketoconazole, itraconazole - these are antifungal medicines
- erythromycin, clarithromycin, telithromycin - these are antibiotics
- ritonavir, atazanavir, indinavir, nelfinavir, saquinavir - these are antiviral medicines
- phenytoin, carbamazepine, phenobarbital - these are treatments for epilepsy
- rifampicin - this is a treatment for tuberculosis
- dexamethasone - this is a treatment for inflammation
- omeprazole, cisapride - these are medicines that block stomach acids and for indigestion
- St. John's wort - a herbal preparation obtained without a prescription, used to treat depression and other conditions (also known as *Hypericum perforatum*)
- Do not take medicines that neutralise stomach acids (antacids such as aluminium hydroxide or magnesium hydroxide) in the 2 hours before or 2 hours after taking TAZATRED
- alfentanil, fentanyl - these medicines are used to treat pain
- ergotamine, dihydroergotamine - these medicines are used to treat migraine headaches
- ciclosporin, sirolimus, tacrolimus - these medicines are used to prevent rejection in organ transplants
- astemizole - this medicine is used to treat allergies, hives (urticaria), and other allergic inflammatory conditions
- quinidine - this medicine is used to treat heart problems

- pimozide - this medicine is used to treat schizophrenia
- simvastatin - this medicine is to treat high cholesterol

TAZATRED with food and drink

Do not take TAZATRED with grapefruit or grapefruit juice.

Pregnancy and Breastfeeding

You must not use TAZATRED if you are pregnant.

Both men and women taking TAZATRED will be advised to use effective contraception during treatment.

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

If you are breast feeding, tell your doctor. You should stop breast feeding while you are taking TAZATRED.

Driving and using machines

Take special care when driving or using machines in case you experience side effects such as dizziness and blurred vision.

TAZATRED contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to use TAZATRED

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

TAZATRED will only be prescribed to you by a doctor with experience in treating leukaemia. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. TAZATRED is prescribed for adults.

TAZATRED can be taken with or without a meal and should be taken consistently either in the morning or in the evening.

The starting dose recommended for adult patients with chronic phase CML is 100 mg once a day.

The starting dose recommended for adult patients with accelerated or blast crisis CML or Ph+ ALL is 70 mg twice a day.

Your doctor will decide on the dose and how long your treatment should last. Ask your doctor or other healthcare provider if you have any questions.

Do not crush or cut tablets, they should be swallowed whole.

Take TAZATRED daily until your doctor tells you to stop. Make sure you take TAZATRED for as long as it is prescribed.

If you forget to take TAZATRED

Do not take a double dose to make up for a forgotten tablet. Take the next scheduled dose at the regular time.

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

If you stop taking TAZATRED

Discuss the effects of stopping treatment with TAZATRED if you choose to do so with your doctor.

4. Possible side effects

TAZATRED can have side effects. Not all side effects reported for TAZATRED are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TAZATRED, please consult your health care provider for advice.

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

- allergic reactions including swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue,

throat and neck which may cause difficulty in swallowing or breathing, throat tightness, shortness of breath and wheezing, rash, “hives” (raised bumps), blisters or itching

- if you have chest pain, difficulty breathing, coughing and fainting
- if you experience unexpected bleeding or bruising without having an injury
- if you find blood in your vomit, stools or urine, or have black stools
- if you get signs of infections such as fever, severe chills
- if you get fever, sore mouth or throat, blistering or peeling of your skin and/or mucous membranes.

These are all very serious side effects. If you experience these, you may have had a serious reaction to TAZATRED. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections (including bacterial, viral and fungal, pneumonia, herpes virus infection (including cytomegalovirus - CMV), upper respiratory tract infection, serious infection of the blood or tissues (including uncommon cases with fatal outcomes)
- low blood platelet count, low white blood cells count (neutropaenia), low iron levels in the blood (anaemia)
- disturbances in appetite, high levels of uric acid
- increase or decrease weight
- feeling sad, having trouble sleeping
- headache, dizziness, feeling of “pins and needles” (peripheral neuropathy), taste disturbances, sleepiness
- eye problems, blurred vision, dry eye
- ringing in the ears
- heart failure, fast-beating, fluttering or pounding heart (palpitations)
- bleeding, high blood pressure, feeling flushed
- shortness of breath, fluid in the lungs, inflammation of the lungs, cough
- feeling and being sick (nausea and vomiting), loose stools (diarrhoea), stomach pain, bloated or

distended tummy (abdomen), inflammation of the tongue, stomach and colon, indigestion, hard stool (constipation)

- skin rashes, itching, hair loss, pimples, dry skin, hives, increased sweating
- muscle and joint pain, muscles weakness and stiffness
- swelling, tiredness, fever, pain, weakness, chills
- bruises

Less frequent side effects:

- immune system: severe allergic reaction
- skin inflammation that is located in a part of the fatty layer of skin
- thyroid problems, high and low thyroid levels
- high cholesterol and sugar (picked up in blood tests), feeling dehydrated
- feeling anxious and confused, decreased of libido
- memory loss, shaking, fainting, problems with balance, seizures (fits), lack of muscle control
- eye problems, inflammation of the eye, light sensitivity, increased tearing in the eye
- hearing loss, feeling off-balance
- heart problems, heart attack (including fatal outcome), inflammation of the lining (fibrous sack) surrounding the heart, irregular heartbeat, chest pain due to lack of blood supply to the heart (angina)
- low blood pressure, inflammation of the vein and blood clot formation, blockage of arteries in the lung therefore you may feel short of breath, coughing up blood and chest pain, lace-like purplish discoloration of the skin
- problems breathing, difficulty in speaking
- inflammation of the oesophagus and pancreas, ulcers, pain on swallowing, heartburn
- inflammation of the liver and gall bladder, problem with bile flow
- a skin disease characterised by tender, red, well-defined blotches with the sudden onset of fever and raised white blood cell count (neutrophilic dermatosis), sensitivity to light, pigmentation problems, problems with hair
- muscle inflammation, pain and weakness, inflammation of the tendons and joints, a disease of

reduced blood flow to the bones, which can cause bone loss and bone death (osteonecrosis), irregular bone growth

- kidney problems, changes in urinary frequency, protein in the urine (picked up in tests)
- abortion
- breast enlargement in men, menstrual disorder
- tiredness, skin swelling anywhere in the body, problems walking
- blood tests may show increased enzymes

Unknown frequency side effects:

- recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection)
- abnormal heart rhythm in the atrial chambers of the heart
- damage to blood vessels known as thrombotic microangiopathy (TMA), including decreased red blood cell count, decreased platelets, and formation of blood clots
- inflammation of the lungs
- bleeding in the stomach or bowels that can cause death
- a reaction with fever, blisters on the skin, and ulceration of the mucous membranes

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 health care professional. 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 TAZATRED.

5. How to store TAZATRED

TAZATRED must be stored at or below 30 °C.

Keep the tablets in the original packaging.

The tablets must not be used after the expiry date.

Store all medicines out of the sight and reach of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What TAZATRED contains

The active substance is dasatinib

Each film-coated tablet contains 20 mg, 50 mg, 70 mg, or 100 mg dasatinib.

The other ingredients of TAZATRED are anhydrous lactose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, hydrogenated castor oil (powder), Opadry® white.

Opadry® white contains: hypromellose, titanium dioxide and triacetin.

What TAZATRED looks like and contents of the pack

TAZATRED 20 film-coated tablets are available as white to off-white, round shaped tablets debossed with “599” on one side and plain on other side.

TAZATRED 50 film-coated tablets are available as white to off-white, round shaped tablets debossed with “600” on one side and plain on other side.

TAZATRED 70 film-coated tablets are available as white to off-white, round shaped tablets debossed with “601” on one side and plain on other side.

TAZATRED 100 film-coated tablets are available as white to off-white, round shaped tablets debossed with “603” on one side and plain on other side.

TAZATRED 20, 50, 70, 100 film-coated tablets are packaged in Alu-Alu blisters of 10, in pack sizes of 30’s.

TAZATRED 20, 50, 70, 100 film-coated tablets are packaged in 75cc HDPE bottles closed with child resistant closures in pack sizes of 30’s or 60’s, The bottles contain one silica gel desiccant.

Holder of Certificate of Registration

Dr. Reddy’s Laboratories (Pty) Ltd.

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2057

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TAZATRED 20: 55/26/0797

TAZATRED 50: 55/26/0798

TAZATRED 70: 55/26/0790

TAZATRED 100: 55/26/0800

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories web site:

http://www.drreddys.co.za