

# TAZATRED (Dasatinib Film-Coated Tablets 50mg)

# TAZATRED (Dasatinib Film-Coated Tablets 70mg)

## Dasatinib (50mg, 70mg)

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### What Tazatred is used for

TAZATRED contains the active substance dasatinib. This medicine is used to treat chronic myeloid leukaemia (CML) in adults at least 18 year of age who are not benefiting from prior therapies.

TAZATRED is also used to treat Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) in adults at least 18 year of age, and lymphoid blast CML in adults who are not benefiting from prior therapies.

Leukaemia is a cancer of white blood cells. White blood cells usually help the body to fight infection

### How Tazatred works

In people with CML, white cells called granulocytes start growing out of control. TAZATRED inhibits the growth of these leukaemic cells.

In people with ALL, white cells called lymphocytes multiply too quickly and live too long. TAZATRED inhibits the growth of these leukaemic cells. If you have any questions about how TAZATRED works or why this medicine has been prescribed for you, ask your doctor

### Before you use Tazatred

#### - When you must not use it

Do not take Tazatred if you are allergic to dasatinib or any of the other ingredients of this medicine.

If you could be allergic, ask your doctor for advice.

#### - Before you start to use it

#### *Warnings and precautions*

Tell your doctor if you have or have had any medical conditions, especially the following:

- problems with your immune system
- liver problem
- heart problem
- lactose intolerant
- hepatitis B infection

If you have not told your doctor about any of the above, tell them before you take Tazatred.

#### *Children and adolescents*

Do not give this medicine to children. There is limited experience with the use of TAZATRED in this age group. Bone growth and development will be closely monitored in children taking TAZATRED.

#### *Pregnancy and breast-feeding*

If you are pregnant or think you may be pregnant, tell your doctor immediately. TAZATRED is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risk of taking TAZATRED during pregnancy.

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

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

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.

#### - Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

TAZATRED is mainly handled by the liver. Certain medicines may interfere with the effect of TAZATRED when taken together.

These medicines are not to be used with TAZATRED:

- ketoconazole, itraconazole - these are antifungal medicines
- erythromycin, clarithromycin,

telithromycin - these are antibiotics

- ritonavir - this is an antiviral medicine

- phenytoin, carbamazepine, phenobarbital

- these are treatments for epilepsy

- rifampicin - this is a treatment for tuberculosis

- famotidine, omeprazole - these are medicines that block stomach acids

- 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.

Tell your doctor if you are taking medicines to thin the blood or prevent clots.

#### *TAZATRED with food and drink*

Do not take TAZATRED with grapefruit or grapefruit juice

### How to use Tazatred

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### - How much to use

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 at least 18 year of age.

Take your tablets at the same time every day. Swallow the tablets whole. Do not crush, cut or chew them. Do not take dispersed tablets. You cannot be sure you will receive the correct dose if you crush, cut, chew or disperse the tablets. TAZATRED tablets can be taken with or without a meal.

#### *Special handling instructions for TAZATRED*

It is unlikely that the TAZATRED tablets will get broken. But if they do, persons other than the patient should use gloves when handling TAZATRED.

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### - When to use it

Take the tablet every day until your doctor tells you to stop.  
Try to take the tablet at the same time every day to help you to remember it.  
Your doctor will decide how long you must continue treatment.

### - How long to use it

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 use it

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

### - If you use too much (overdose)

If you have accidentally taken too many tablets, talk to your doctor immediately. You may require medical attention

### **While you are using it**

#### - Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Tazatred

#### - Things you must not do

- Do not stop taking your medicines without consulting your doctor.
- Do not use Tazatred after the expiry date which is stated on the carton and blister
- Do not give this medication to anyone else, even if they have the same condition as you.

#### - Things to be careful of

##### Driving and using machines

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

### **Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tazatred.

Like all medicines, it is possible that Tazatred may have unwanted side effects in some people. There are

many side effects caused by medicines used to treat leukaemia. During treatment with Tazatred you will require close medical supervision.

Ask your doctor or pharmacist to answer any questions you may have.

### **Less serious side effects**

Tell your doctor or pharmacist if you notice any of the following and they worry you

### **Speak to your doctor of you have any of these less serious side effects and they worry you.**

- headache; dizziness; numbness or tingling in arms, legs, fingers or toes; altered taste
- diarrhoea, nausea, vomiting
- shortness of breath, cough, accumulation of fluid in or around the lungs, pneumonia, chest pain
- infection, fever
- abdominal pain, bloating, flatulence, constipation, indigestion
- high blood pressure
- mouth ulcers
- skin rash, dermatitis (including eczema), dry skin, itching or peeling skin, flushing
- hair loss
- visual disturbances: blurry or diminished vision, dry eye
- fatigue
- swelling of the liver, abdomen, hands, lower legs, feet or face
- back pain, bone pain, joint pain, pain in fingers or toes, muscle aches or spasm, muscle weakness
- weight decrease, appetite disturbance
- gout
- conjunctivitis
- tinnitus (ringing in the ears)
- accumulation of fluid, foamy urine, weight gain (also known as nephrotic syndrome)

### **Serious side effects**

Tell your doctor immediately if you notice any of the following:

These may be serious side-effects. Your doctor may interrupt your Tazatred treatment.

**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

- swelling, weight gain, shortness of breath or chest pain
- swelling around your eyes
- skin infection - folliculitis, herpes
- shortness of breath and fatigue
- dark coloured urine or yellowing of your skin and eyes
- changes in the way your heart beats, for example - if you notice it beating faster
- bleeding - for example from: gastrointestinal tract; eye; nose; gums; serious bruising or excessive menstrual bleeding
- infections - urinary tract; eye infection; difficulty breathing; coughing
- fever
- painful rash with blisters

The use of Tazatred is also associated with a reduction in certain types of blood cells in the body:

- a reduction in red blood cells, which may result in fatigue or dizziness
- a reduction in white blood cells, which are used to fight infection
- a reduction in cells that help your blood to clot after injury

These may be very serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

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website [npra.gov.my](http://npra.gov.my) [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and Disposal of Tazatred****- Storage**

Store below 30C.

**- Disposal**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Product Registration Holder**

Dr. Reddy's Laboratories Malaysia Sdn. Bhd. (1238154-X)  
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MENARA 1,  
STRATA OFFICE, NO. 3, JALAN  
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59200 KUALA LUMPUR MALAYSIA

**Date of revision**

04/11/2024

**Serial Number**

NPRA (R1/1) 04112024/199

**Product Description****- What it looks like**

TAZATRED (Dasatinib Film-Coated Tablet 50mg) - White to off-white colored, oval shaped tablets debossed with "600" on one side and plain on other side

TAZATRED (Dasatinib Film-Coated Tablet 70mg) - White to off-white colored, round shaped tablets debossed with "601" on one side and plain on other side

**- Ingredients**

Active ingredient: The active substance is dasatinib. Each film-coated tablet contains 50 mg, 70 mg dasatinib

- Inactive ingredients: Hydrogenated Castrol oil, Microcrystalline cellulose, Colloidal Silicon Dioxide, Anhydrous Lactose, Croscarmellose Sodium, Magnesium Stearate

Coating - Opadry white 03K580004

- MAL number: MAL24026020ACZ,

MAL24026019ACZ

**Manufacturer**

Aizant Drug Research Solutions Private Limited.

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