

# SEMISTAURO (Midostaurin Soft Capsule 25mg)

Midostaurin (25mg)

## What is in this leaflet

1. What SEMISTAURO is used for
2. How SEMISTAURO works
3. Before you use SEMISTAURO
4. How to use SEMISTAURO
5. While you are using it
6. Side effects
7. Storage and Disposal of SEMISTAURO
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

## What SEMISTAURO is used for

SEMISTAURO contains the active substance midostaurin. It belongs to a class of medicines called protein kinase inhibitors.

SEMISTAURO is used to treat acute myeloid leukaemia (AML) in adults who have a defect in a gene called FLT3. Acute myeloid leukaemia is a form of cancer of certain white blood cells (called myeloid cells) in which the body overproduces an abnormal type of these cells. SEMISTAURO is also used in adults to treat aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated haematological neoplasm (SM-AHN), or mast cell leukaemia (MCL). These are disorders in which the body produces too many mast cells, a type of white blood cell. Symptoms are caused when too many mast cells enter organs such as the liver, bone marrow or spleen, and release substances such as histamine into the blood.

## How SEMISTAURO works

Midostaurin blocks the action of some enzymes (kinases) in the abnormal cells and stops their division and growth.

At the start of treatment in AML SEMISTAURO is always used together with chemotherapy (medicines for treating cancer).

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

## Before you use SEMISTAURO

### • When you must not use it

If you are allergic to midostaurin or any of the other ingredients of SEMISTAURO. If you think you may be

allergic, ask your doctor for advice.

- if you are already taking any of the following medicines:

- medicines used to treat tuberculosis, such as rifampicin;
- medicines used to treat epilepsy, such as carbamazepine or phenytoin;
- enzalutamide, a medicine used to treat prostate cancer;
- St. John's Wort (also known as *Hypericum perforatum*), a herbal medicine used to treat depression.

• These medicines must be avoided during treatment with SEMISTAURO. Talk to your doctor if you are told that you have to start taking one of them during SEMISTAURO treatment.

### Pregnancy and breast-feeding

SEMISTAURO may harm your unborn baby and is not recommended during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

SEMISTAURO could harm your baby. You should not breast-feed during treatment with SEMISTAURO and for at least 4 months after stopping the treatment.

### Contraception in women

If you become pregnant while taking SEMISTAURO, it may harm your baby. Your doctor will ask you to take a pregnancy test before you start treatment with SEMISTAURO to make sure you are not pregnant. You must use an effective method of contraception while taking SEMISTAURO and for at least 4 months after you have stopped taking it. Your doctor will discuss with you the most suitable method of contraception for you to use.

If you become pregnant or think you are pregnant, tell your doctor right away.

### Fertility

SEMISTAURO may reduce fertility in men and women. You should discuss this with your doctor before starting treatment.

### Children and adolescents

SEMISTAURO should not be used in

children and adolescents below 18 years of age who are also receiving other chemotherapy, because it could cause a severe reduction of certain types of blood cells.

### - Before you start to use it

Talk to your doctor, pharmacist or nurse before taking SEMISTAURO:

- if you have any infections.
- if you have a heart disorder.
- if you have problems with your lungs or problems breathing.
- if you have problems with your kidneys.

Tell your doctor, pharmacist or nurse straight away if you get any of these symptoms during treatment with SEMISTAURO:

- if you have fever, sore throat or mouth ulcers, because these may indicate that your white blood cell count is low.
  - if you have new or worsening symptoms such as fever, cough with or without mucous, chest pain, trouble breathing or shortness of breath, because these may be signs of lung problems.
  - if you have or experience chest pain or discomfort, light-headedness, fainting, dizziness, blue discolouration of your lips, hands or feet, shortness of breath, or swelling of your lower limbs (oedema) or skin, because these may be signs of heart problems.
- Your doctor may need to adjust, temporarily stop or completely discontinue your treatment with SEMISTAURO.

### SEMISTAURO contains ethanol anhydrous (alcohol)

This medicine contains 109.418 mg of alcohol (ethanol) in each capsule <which is equivalent to 13.23% w/w>. The amount in each capsule of this medicine is equivalent to less than 2.74 ml beer or 1.10 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. Alcohol may be harmful in patients with alcohol-related problems, epilepsy or liver problems or during pregnancy or breast-feeding.

# SEMISTAURO (Midostaurin Soft Capsule 25mg)

Midostaurin (25mg)

## - Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because SEMISTAURO can affect the way some medicines work. Some other medicines can also affect how SEMISTAURO works.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- some medicines used to treat infections, such as ketoconazole or clarithromycin,
- some medicines used to treat HIV, such as ritonavir or efavirenz,
- some medicines used to treat depression, such as nefazodone or bupropion,
- some medicines used to control levels of fat in your blood, such as atorvastatin or rosuvastatin;
- tizanidine, a medicine used to relax muscles;
- chlorzoxazone, a medicine used for treating discomfort caused by muscle spasms.

If you are taking any of these medicines, your doctor might prescribe a different medicine for you during your treatment with SEMISTAURO.

You should also tell your doctor if you are already taking SEMISTAURO and you are prescribed a new medicine that you have not previously taken during treatment with SEMISTAURO.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

## **How to use SEMISTAURO**

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

Do not exceed the dose prescribed by your doctor.

## How much to use

Your doctor will tell you exactly how many capsules to take.

### **Patients with AML:**

The usual daily dose is 50 mg (2 capsules) twice daily.

### **Patients with ASM, SM-AHN or MCL:**

The usual daily dose is 100 mg (4 capsules) twice daily.

Depending on how you respond to SEMISTAURO, your doctor may lower your dose or temporarily interrupt the treatment.

## - When to use it

• Taking SEMISTAURO at the same time each day will help you to remember to take your medicine.

• Take SEMISTAURO twice a day at about

12 hours intervals (for example, with breakfast and with your evening meal).

• Take SEMISTAURO with food.

## - How to take it

• Swallow the capsules whole with a glass of water. Do not open, crush or chew them to ensure proper dosing and avoid the unpleasant taste of the capsule content.

• For patients with AML, SEMISTAURO is taken with chemotherapy medicines. It is very important to follow your doctor's recommendations.

• If you vomit after you swallow the capsules, do not take any more capsules until your next scheduled dose.

## - How long to take it

Continue taking SEMISTAURO for as long as your doctor tells you. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you are being treated for AML, after you finish taking SEMISTAURO with chemotherapy medicines, you will receive SEMISTAURO alone for up to 12 months.

If you are being treated for ASM, SM-AHN or MCL, you will receive SEMISTAURO as a long-term treatment, possibly lasting for months or years.

If you have any questions about how long to take SEMISTAURO, talk to your doctor or pharmacist.

## - If you forget to use it

If you forget to take SEMISTAURO, skip the missed dose and take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose. Instead, wait until it is time for your next dose.

## - If you use too much (overdose)

If you take more capsules than you should, or if someone else takes your medicine, talk to a doctor or go to a hospital straight away, taking the pack with you, as medical treatment may be necessary.

## **While you are using it**

### - Things you must do

Tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with SEMISTAURO:

• If you have fever, sore throat or mouth ulcers because these may indicate that your white blood cell count is low.

• If you have new or worsening symptoms such as fever, cough with or without mucous, chest pain, trouble breathing or shortness of breath because these may be signs of lung problems

• If you experience chest pain or discomfort, lightheadedness, fainting, dizziness, blue discoloration of your lips, hands or feet, shortness of breath, or swelling of your lower limbs (oedema) or skin because these may be signs of heart problems.

• Your doctor may need to adjust, temporarily stop or completely discontinue your treatment with SEMISTAURO.

## **Monitoring during your treatment with SEMISTAURO**

Your doctor will perform regular blood tests during treatment with SEMISTAURO in order to monitor the amount of blood cells (white blood cells, red blood cells and platelets) and electrolytes (e.g. calcium, potassium, magnesium) in your body. Your heart and lung function will also be checked regularly.

## - Things you must not do

Stopping your treatment with SEMISTAURO may cause your condition to become worse. Do not stop taking your medicine unless your doctor tells you to do so.

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

## - Things to be careful of

### **Driving and using machines**

Take special care when driving and using machines as you may develop dizziness and vertigo while you are taking SEMISTAURO.

# SEMISTAURO (Midostaurin Soft Capsule 25mg)

Midostaurin (25mg)

## Side effects

Like all medicines, SEMISTAURO can cause side effects, although not everybody gets them.

STOP taking SEMISTAURO and tell your doctor straight away if you notice any of the following as these could be signs of an allergic reaction:

- difficulty breathing or swallowing
- dizziness
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

## *Some side effects in patients with AML could be serious*

Tell your doctor, pharmacist or nurse straight away if you notice any of the following:

- 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)
- Fever, cough with or without mucus, chest pain, trouble breathing or shortness of breath (signs of non infectious interstitial lung disease or pneumonitis)
- Severe shortness of breath, laboured and unusually rapid breathing, dizziness, light-headedness, confusion and extreme tiredness (signs of acute respiratory distress syndrome)
- Infections, fever, low blood pressure, decreased urination, rapid pulse, rapid breathing (signs of sepsis or neutropenic sepsis)

## *Other possible side effects in patients with AML*

Other side effects include those listed below. If any of these side effects become severe, tell your doctor or pharmacist.

Most of the side effects are mild to moderate and will generally disappear after a few weeks of treatment.

**Very common:** may affect more than 1 in 10 people

- Infection at catheter site
- Red or purple, flat, pinhead spots under the skin (petechiae)
- Problems falling asleep (insomnia)
- Headache
- Shortness of breath, laboured breathing (dyspnoea)
- Abnormal electrocardiogram results which can indicate to your doctor that you have an abnormality of the electrical activity of your heart known as QT prolongation

- Dizziness, light headedness (low blood pressure)
- Nose bleeds
- Throat pain (laryngeal pain)
- Mouth sores (stomatitis)
- Nausea, vomiting
- Upper abdominal pain
- Haemorrhoids (piles)
- Excessive sweating
- Skin rash with flaking or peeling (exfoliative dermatitis)
- Back pain
- Joint pain (arthralgia)
- Fever
- Thirst, high urine output, dark urine, dry flushed skin (signs of high levels of sugar in the blood, known as hyperglycaemia)
- Muscle weakness, drowsiness, confusion, convulsions, impaired consciousness (signs of high level of sodium in the blood, known as hypernatraemia)
- Muscle weakness, muscle spasms, abnormal heart rhythm (signs of low levels of potassium in the blood, known as hypokalaemia)
- Bruising and bleeding (defect in blood clotting)
- Abnormal blood test results which can indicate to your doctor how well certain parts of your body are functioning: high levels of alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (indicative of liver function)

**Common:** may affect up to 1 in every 10 people

- Upper respiratory tract infection
- Nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching (signs of high levels of calcium in the blood, known as hypercalcaemia)
- Fainting
- Involuntary shaking of the body
- Headache, dizziness (high blood pressure)
- Fast heart beat (sinus tachycardia)
- Collection of fluid around the heart, which, if severe, can decrease the heart's ability to pump blood (pericardial effusion)
- Fluid collection in the lungs/chest cavity, which, if severe, could make you breathless (pleural effusion)
- Sore throat and runny nose
- Swelling of the eyelid
- Discomfort in the anus and rectum
- Abdominal pain, nausea, vomiting,

constipation (abdominal discomfort)

- Dry skin
- Eye pain, blurred vision, intolerance to light (keratitis)
- Neck pain
- Bone pain
- Pain in limbs
- Increased weight
- Blood clotted in the catheter

Abnormal blood test results which can indicate to your doctor how well certain parts of your body are functioning: high levels of uric acid

## **Not known (frequency cannot be estimated from the available data)**

- Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms, legs, face and neck, with a fever (signs of acute febrile neutrophilic dermatosis)

## *Some side effects in patients with ASM, SM-AHN and MCL could be serious.*

Tell your doctor, pharmacist or nurse straight away if you notice any of the following:

- weakness, spontaneous bleeding or bruising, frequent infections with signs such as fever, chills, sore throat or mouth ulcers (signs of a low level of blood cells)
- fever, cough, difficult or painful breathing, wheezing, chest in pain when breathing (signs of pneumonia)
- fever, cough with or without mucus, chest pain, trouble breathing or shortness of breath (signs of non-infectious interstitial lung disease or pneumonitis)
- infections, fever, dizziness, light-headedness, decreased urination, rapid pulse, rapid breathing (signs of sepsis or neutropenic sepsis)
- vomiting of blood, black or bloody stools (signs of gastrointestinal bleeding)

## *Other possible side effects in patients with ASM, SM-AHN and MCL*

Other side effects include those listed below. If any of these side effects become severe, tell your doctor or pharmacist.

Most of the side effects are mild to moderate and will generally disappear after a few weeks of treatment.

# SEMISTAURO (Midostaurin Soft Capsule 25mg)

Midostaurin (25mg)

**Very common:** may affect more than 1 in 10 people

- urinary tract infection
- upper respiratory tract infection
- headache
- dizziness
- shortness of breath, laboured breathing (dyspnoea)
- cough
- fluid collection in the lungs/chest cavity, which, if severe, could make you breathless (pleural effusion)
- abnormal electrocardiogram results which can indicate to your doctor that you have an abnormality of the electrical activity of your heart known as QT prolongation
- nose bleeds
- nausea, vomiting
- diarrhoea
- constipation
- swelling of the limbs (calves, ankles)
- feeling very tired (fatigue)
- fever
- thirst, high urine output, dark urine, dry flushed skin (signs of high levels of sugar in the blood, known as hyperglycaemia)
- yellow skin and eyes (sign of high bilirubin in the blood)
- abnormal blood test results which indicate possible problems with the pancreas (high levels of lipase or amylase) and liver (high levels of alanine aminotransferase (ALT) or aspartate aminotransferase (AST))

**Common:** may affect up to 1 in every 10 people

- involuntary shaking of the body
- cough with phlegm, chest pain, fever (bronchitis)
- cold sores in the mouth due to viral infection (oral herpes)
- painful and frequent urination (cystitis)
- feeling of pressure or pain in the cheeks and forehead (sinusitis)
- red, swollen painful rash on any part of the skin (erysipelas)
- shingles (herpes zoster)
- disturbance in attention
- feeling dizzy with spinning sensation (vertigo)
- bruising (haematoma)
- upset stomach, indigestion
- feeling weak (asthenia)
- chills
- generalised swelling (oedema)

- increased weight
  - contusion (bruises)
  - falls
  - dizziness, light-headedness (low blood pressure)
  - sore throat
  - rapid gain weight
- If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## Storage and Disposal of SEMISTAURO

### - Storage

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the box.
- Store in the original package to protect from moisture.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

SEMISTAURO is supplied as soft capsules in aluminum blisters. Pale yellow to yellow colored oblong shaped soft capsules filled with colorless, light yellow to yellow colored clear transparent solution; imprinted with 'R49' in Black Ink.

### - Ingredients

- Active ingredient is midostaurin

- Inactive ingredients:-

Capsule Content: Polyoxyl 40  
Hydrogenated Castor Oil, Polyethylene Glycol 400, Glyceryl Monolinoleate, Dehydrated Ethanol & dl-Alpha Tocopherol

Capsule shell: Gelatin, Glycerin, Titanium dioxide, Iron oxide yellow & Purified water

Printing ink: Shellac Glaze, Isopropyl Alcohol, Ferrosoferric Oxide, N-Butyl Alcohol, Propylene Glycol & Ammonia Hydroxide

- MAL number:  
MAL25086020AZ

## Manufacturer

Dr. Reddy's Laboratories Limited,  
FTO-SEZ - Process Unit-02  
Survey No. 70, 71 & 73,  
Devunipalavalasa, Ranasthalam Mandal,  
Srikakulam District, Andhra Pradesh - 532409,  
India.

## Product Registration Holder

Dr. Reddy's Laboratories Malaysia Sdn. Bhd.,  
Unit No. SO-29-07 and SO-29-08,  
Menara 1, Strata Office, No. 3, Jalan  
Bangsar, KL Eco City,  
59200 KUALA LUMPUR WILAYAH  
PERSEKUTUAN KUALA LUMPUR,  
MALAYSIA

## Date of revision

18/09/2025

## Serial Number

NPRA (R2) 24/145