

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

RYDAPT®

midostaurin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RYDAPT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RYDAPT against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What RYDAPT is used for

RYDAPT contains the active ingredient midostaurin.

RYDAPT belongs to a group of medicines called protein kinase inhibitors. It is used to treat certain types of white blood cell disorders.

RYDAPT is used to treat:

- acute myeloid leukemia (AML) in adults who have a defect in a gene called FLT3. AML is a type of cancer of white blood cells. White blood cells usually help the body to fight infections, and in the case of AML, the body produces too many abnormal white blood cells (named "myeloid" cells).
- a disease called advanced systemic mastocytosis in adults. This is a disorder in which the body produces too many mast cells, a type of white blood cell. Symptoms are caused when too many mast cells get into organs like the liver, bone marrow and spleen, or release substances like histamine into the blood.

RYDAPT works by blocking the action of some enzymes (kinases) of the abnormal cells and stops their division and growth. At the start of the treatment in AML, RYDAPT is always used together with other chemotherapies.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take RYDAPT

When you must not take it

Do not take RYDAPT if you have an allergy to:

- midostaurin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take RYDAPT if you are pregnant, think you may be pregnant, or are planning to become pregnant during the course of treatment and for 4 months after your final dose of the medicine.

It may affect your developing baby if you take it during pregnancy.

Do not take RYDAPT if you are breast-feeding or plan to breast-feed while on treatment with RYDAPT and for 4 months after your final dose of the medicine.

It is not known if the active ingredient in RYDAPT can pass into breast milk and can cause harm to your baby.

Do not give this medicine to a child under the age of 18 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- any infection at the time of being prescribed RYDAPT
- heart disorders
- problems with your lungs or problems breathing

If you have not told your doctor about any of the above, tell him/her before you start taking RYDAPT.

Fertility preservation

Talk to your doctor about fertility preservation if you plan to have children in the future.

RYDAPT may have an impact on fertility in men and women. Discuss with your doctor fertility preservation before starting treatment with RYDAPT.

Women with the potential to become pregnant

Discuss with your doctor if you are able to become pregnant. Even if your periods have stopped (menopause), it is important to check with your doctor whether there is a risk that you could become pregnant. If you are able to become pregnant you must:

- use a highly effective method of birth control (contraception) so that you do not become pregnant while on treatment with RYDAPT
- continue to use a highly effective method of birth control (contraception) for 4 months after your final dose of the medicine.

Talk to your doctor about the most suitable method of birth control (contraception) for you.

Talk to your doctor about a pregnancy test before starting treatment with RYDAPT. During treatment and 4 months after treatment, tell your doctor immediately if:

- you believe your contraception has failed for any reason
- your periods stop
- you stop using contraception
- you need to change your contraception.

Men taking RYDAPT

Always use a condom when you have sex with a female partner, even if you have had a vasectomy. Do this during treatment and for 4 months after your final dose of the medicine.

Do not donate semen while on treatment with RYDAPT and for 4 months after your final dose of the medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and RYDAPT may interfere with each other. These include:

- some medicines used to treat infections, such as ketoconazole or clarithromycin
- some medicines used to treat epilepsy, such as carbamazepine

- rifampicin, a medicine used to treat tuberculosis
- some medicines used to treat depression such as nefazodone or the herbal medicine St. John's Wort (also known as hypericum perforatum)
- medicines used to treat HIV, such as ritonavir.

These medicines may be affected by RYDAPT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take RYDAPT

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

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

Treatment of Acute Myeloid Leukemia

The usual daily dose is 50 mg (2 capsules) twice daily (4 capsules per day).

Treatment of Advanced Systemic Mastocytosis

The usual daily dose is 100 mg (4 capsules) twice daily (8 capsules per day).

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

How to take it

Swallow the capsules whole with a full glass of water.

RYDAPT capsules should be swallowed whole with a glass of water. RYDAPT capsules should not be opened, crushed or chewed.

For patients with acute myeloid leukemia, RYDAPT is administered according to a dosage regimen together with other chemotherapy treatments. It is very important to follow your doctor's recommendation.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take RYDAPT twice a day at approximately 12 hours intervals (for example during breakfast and during dinner).

Take your medicine with food.

Take RYDAPT with food to help to prevent nausea.

How long to take it

Continue taking your medicine 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 treated for AML, after the period where RYDAPT is used together with other chemotherapies, you will get RYDAPT alone for up to 12 months.

If you are treated for advanced systemic mastocytosis this is a long-term treatment, possibly lasting for months or years.

If you forget to take it

If you miss a dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RYDAPT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

While you are using RYDAPT

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RYDAPT.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Both men and women (who are able to become pregnant) need to take precautions so that a pregnant woman is not exposed to RYDAPT. Both men and women will need to do this for 4 months after stopping treatment. Women taking the oral contraceptive pill should also use a condom or a diaphragm.

Talk to your doctor immediately if you have unprotected sex or if you think your contraception has failed.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests such as checking blood cells (white blood cells, red blood cells and platelets) and electrolytes (e.g. calcium, potassium, magnesium) in your body from time to time to make sure the medicine is working and to prevent unwanted side effects. Your heart and lung function will also be checked regularly.

Women taking RYDAPT

Women who are able to become pregnant will need to show a negative pregnancy test done by your doctor before starting treatment with RYDAPT.

If you become pregnant while taking this medicine or suspect you could be pregnant, stop taking RYDAPT and tell your doctor immediately.

Men taking RYDAPT

Always use a condom when you have sex with a female partner, even if you have had a vasectomy. Do this during treatment and for 4 months after your final dose of the medicine.

Do not donate semen while on treatment with RYDAPT and for 4 months after your final dose of the medicine.

Tell your doctor immediately if your partner becomes pregnant or thinks she is pregnant while you are taking RYDAPT.

Things you must not do

Do not take RYDAPT to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how RYDAPT affects you.

This medicine may cause (dizziness, light-headedness, tiredness) in some people. If you have any of these symptoms,

do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

This medicine helps most people with AML or advanced systemic mastocytosis, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- Infection at catheter site (device related infection)
- Red or purple, flat, pinhead spots under the skin (petechiae)
- Problem to fall asleep (insomnia)
- Urinary tract infection
- Upper respiratory tract infection

- Headache
- Dizziness
- Shortness of breath, laboured breathing (dyspnoea)
- Cough
- Fluid collection on the lungs/chest cavity, which if severe, could make you breathless (pleural effusion)
- Dizziness, light headedness (hypotension)
- Nose bleeding (epistaxis)
- Throat pain (laryngeal pain)
- Mouth sores (stomatitis)
- Nausea
- Vomiting
- Upper abdominal pain
- Haemorrhoids
- Diarrhoea
- Constipation
- Excessive sweating (hyperhidrosis)
- Skin rash with flaking or peeling (dermatitis exfoliative)

- Back pain
- Joint pain (arthralgia)
- Rapid weight gain, swelling of the extremities (calves, ankles) (oedema peripheral)
- Fatigue
- Fever (pyrexia)
- Thirst, low urine output, dark urine, dry flushed skin (signs of high level of sugar in 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 level of potassium in the blood known as hypokalaemia)
- Defect in blood clotting (activated partial thromboplastin time prolonged)
- Nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching (signs of high level of calcium in the blood known as hypercalcaemia)
- High level of uric acid in the blood (abnormal blood results known as hyperuricaemia)

- Fainting (syncope)
- Involuntary shaking of the body (tremor)
- Fast heart beat (sinus tachycardia)
- Sore throat and runny nose (nasopharyngitis)
- Swelling of the eyelid (eyelid oedema)
- Anorectal discomfort
- Dry skin
- Eye pain, blurred vision, abnormal intolerance to light (keratitis)
- Neck pain
- Bone pain
- Pain in extremity
- Weight increased
- 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)
- Herpes zoster
- Disturbance in attention
- Dizziness with spinning sensation (vertigo)
- Bruise (haematoma)
- Upset stomach, indigestion (dyspepsia)
- Weakness (asthenia)
- Chills
- Generalized swelling (oedema)
- Contusion
- Fall
- Coagulated blood in catheter (catheter-related thrombosis).

The above list includes the more common side effects of your medicine.

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

- fever, sore throat or mouth ulcers because these may be signs of low level of white blood cells

- 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
- chest pain or discomfort, lightheadedness, fainting, dizziness, blue discoloration of your lips or extremities, shortness of breath, or swelling of your lower limbs (edema) or skin because these may be signs of heart problems.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 mucous, chest pain, trouble breathing or shortness of breath (signs of infections or lung problems)
- Fever, sore throat or mouth ulcers due to infections (signs of lymphopenia or neutropenia)
- Severe shortness of breath, labored and unusually rapid breathing, low blood pressure, confusion and extreme tiredness (signs of acute respiratory distress syndrome)

- Fever, cough, difficult or painful breathing, wheezing, chest in pain when breathing (signs of pneumonia)
- Infections, fever, decreased urination, rapid pulse, rapid breathing (signs of sepsis or neutropenic sepsis)
- Vomiting of blood, black or bloody stools (signs of gastrointestinal haemorrhage).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are generally rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, high levels of the following enzymes, lipase and/or amylase (pancreas function), alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (liver function), high blood sugar levels, low or high blood pressure, unusual electrocardiogram) can only be found when your doctor does tests from time to time to check your progress.

After using RYDAPT

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 30°C.

Do not store RYDAPT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

RYDAPT capsules are pale orange oblong capsules with red imprint "PKC NVR".

RYDAPT is available in blister packs of 112 and 56 capsules.

Ingredients

RYDAPT contains 25 mg of midostaurin as the active ingredient.

It also contains the following inactive ingredients:

- PEG40 hydrogenated castor oil
- macrogol 400
- Glycerol
- ethanol anhydrous
- Corn oil PEG6 esters
- titanium dioxide (E171)
- dl-alpha-tocopherol
- carmine (E120)
- hypromellose
- propylene glycol
- purified water.

The capsule shell contains:

- gelatin (may contain sulfites)
- iron oxide yellow (E172)

- iron oxide red (E172)
- Edible ink Red

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

RYDAPT is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Web site: www.novartis.com.au

RYDAPT is supplied in New Zealand by:

NOVARTIS New Zealand Ltd

PO Box 99102, Newmarket

Auckland 1149

Telephone: 0800 652 422

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