

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Rydapt?

Rydapt contains the active ingredient midostaurin. Rydapt is used to treat acute myeloid leukemia (AML) in adults who have a defect in a gene called FLT3. It is also used to treat a disease called advanced systemic mastocytosis in adults. For more information, see Section [1. Why am I using Rydapt?](#) in the full CMI.

### 2. What should I know before I use Rydapt?

Do not use if you have ever had an allergic reaction to Rydapt or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Rydapt?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Rydapt and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Rydapt?

- The usual daily dose for AML is 50 mg (2 capsules) twice daily (4 capsules per day).
- The usual daily dose for advanced systemic mastocytosis is 100 mg (4 capsules) twice daily (8 capsules per day).
- Rydapt should be taken twice a day with food at approximately 12 hours apart (for example during breakfast and during dinner).

More instructions can be found in Section [4. How do I use Rydapt?](#) in the full CMI.

### 5. What should I know while using Rydapt?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Rydapt.</li><li>• Keep all your doctor's appointments so that your progress can be checked.</li><li>• Have the blood tests your doctor tells you to have.</li><li>• Use additional contraception for both men and women to avoid pregnancy while taking Rydapt and do this for 4 months after stopping.</li><li>• If you become pregnant while taking Rydapt, tell your doctor immediately.</li><li>• Have your heart and lungs checked regularly.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Rydapt may cause dizziness, light-headedness or tiredness in some people.</li><li>• Be careful before you drive or use any machines or tools until you know how Rydapt affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• There are no known interactions between Rydapt and alcohol</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your capsules in the pack until it is time to take them. Store below 30°C.</li></ul>

For more information, see Section [5. What should I know while using Rydapt?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include headache, feeling unwell, vomiting, tummy pain, joint pain, cough, sleeping difficulty, infections. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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](http://www.tga.gov.au/reporting-problems).

# Rydapt®

Active ingredient(s): *midostaurin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Rydapt. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rydapt.**

Where to find information in this leaflet:

1. [Why am I using Rydapt?](#)
2. [What should I know before I use Rydapt?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Rydapt?](#)
5. [What should I know while using Rydapt?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using Rydapt?

**Rydapt contains the active ingredient midostaurin.**

Rydapt is used to treat certain types of white blood cell diseases.

**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).

It is also used to treat a disease called advanced systemic mastocytosis in adults. This is a disease in which the body produces too many mast cells, a type of white blood cell.

## 2. What should I know before I use Rydapt?

### Warnings

**Do not take Rydapt if:**

- you are allergic to midostaurin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are taking any of the following medicines: rifampicin (used to treat tuberculosis), carbamazepine or phenytoin (used to treat epilepsy), enzalutamide (used to treat prostate cancer), St. John's Wort (also known as *Hypericum perforatum*, a herbal medicine used to treat depression).

**Check with your doctor if you have:**

- any infection at the time of being prescribed Rydapt

- heart issues
- problems with your lungs or problems breathing.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**You should avoid becoming pregnant while taking Rydapt and for 4 months after you stop taking it.**

### Contraception

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

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 Rydapt.

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.

For men on 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 Rydapt.

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

### Fertility protection

Rydapt may cause problems with fertility in men and women. Discuss with your doctor fertility protection

before starting treatment with Rydapt if you plan to have children in the future.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with Rydapt and affect how it works such as:**

- medicines used to treat infections, such as ketoconazole or clarithromycin
- medicines used to treat epilepsy, such as carbamazepine which should not be taken
- rifampicin, a medicine used to treat tuberculosis which should not be taken
- some medicines used to treat depression such as nefazodone or the herbal medicine St. John's Wort (also known as hypericum perforatum) which should not be taken
- medicines used to treat high blood cholesterol, such as rosuvastatin
- bupropion, a medicine used to quit smoking
- medicines used to treat HIV, such as ritonavir.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rydapt.**

### 4. How do I use Rydapt?

#### How much to take

Acute Myeloid Leukemia (AML)

- The usual daily dose is 50 mg (2 capsules) twice daily (4 capsules per day)
- Advanced Systemic Mastocytosis
- The usual daily dose is 100 mg (4 capsules) twice daily (8 capsules per day).
- Follow the instructions provided and take Rydapt until your doctor tells you to stop.

#### When to take Rydapt

- Rydapt should be taken twice a day at approximately 12 hours apart (for example during breakfast and during dinner)
- Take Rydapt at about the same time each day.
- Take Rydapt with food

#### How to take Rydapt

- Swallow Rydapt capsules whole with a glass of water.

#### If you forget to take Rydapt

Rydapt should be taken regularly at the same time each day. If you miss your dose at the usual time, take as soon as you remember.

**If you miss a dose and it is almost time for your next 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 you missed.**

#### If you take too much Rydapt

If you think that you have taken too much Rydapt, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26 (Australia) or telephone 0800 POISON or 0800 764 766 (New Zealand)), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using Rydapt?

#### Things you should do

- Use additional contraception for both men and women to avoid pregnancy while taking Rydapt and do this for 4 months after stopping Rydapt
- If you become pregnant while taking Rydapt, tell your doctor immediately
- Keep all your doctor's appointments so that your progress can be checked
- Have the blood tests your doctor tells you to have
- Have your heart and lungs checked regularly.

Remind any doctor, dentist or pharmacist you visit that you are taking Rydapt.

#### Things you should not do

- Do not stop taking this medicine suddenly.

#### Additional Tests

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

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Rydapt affects you.**

Rydapt may cause dizziness, light-headedness or tiredness in some people

## Looking after your medicine

- Keep your capsules in the pack until it is time to take them
- Store below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Infections such as:</b></p> <ul style="list-style-type: none"> <li>• Upper chest infection (sore throat, runny nose)</li> <li>• Kidney infection</li> </ul> <p><b>Tummy problems such as:</b></p> <ul style="list-style-type: none"> <li>• Feeling sick</li> <li>• Vomiting</li> <li>• Tummy pain</li> <li>• Diarrhoea</li> <li>• Constipation</li> <li>• Indigestion</li> </ul> <p><b>General issues such as:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Dizziness</li> <li>• Excessive sweating</li> <li>• Back pain</li> <li>• Joint pain</li> <li>• Rapid weight gain</li> <li>• Tiredness</li> <li>• Swelling of calves/ankles</li> <li>• Thirsty</li> <li>• Muscle weakness</li> <li>• Muscle spasms</li> <li>• Neck pain</li> <li>• Difficulty sleeping</li> <li>• Skin rash with flaking or peeling</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.</b></p>

<ul style="list-style-type: none"> <li>• Nose bleeding</li> </ul> <p><b>Heart problems such as:</b></p> <ul style="list-style-type: none"> <li>• Fast heart beat</li> <li>• Chest pain</li> <li>• Fainting or Dizziness</li> </ul> <p><b>Eye problems such as:</b></p> <ul style="list-style-type: none"> <li>• Eye pain or blurred eyesight</li> <li>• Swelling of the eyelid</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Infections such as:</b></p> <ul style="list-style-type: none"> <li>• Fever, sore throat or mouth ulcers.</li> <li>• Fever, cough with or without mucous, chest pain, trouble breathing or shortness of breath, or wheezing.</li> <li>• Fever, decreased wee, fast pulse, fast breathing.</li> </ul> <p><b>Breathing problems such as:</b></p> <ul style="list-style-type: none"> <li>• Painful or troubled breathing, feeling breathless or tired</li> <li>• Rapid breathing</li> </ul> <p><b>General issues such as:</b></p> <ul style="list-style-type: none"> <li>• Weakness, sudden bleeding or bruising, with fever, chills, sore throat or mouth ulcers</li> <li>• Vomiting of blood, black or bloody poo</li> <li>• Raised, painful, red to dark reddish-purple skin patches or sores that appear mainly on the arms &amp; legs, face and neck, with a fever</li> </ul>	<p><b>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.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration (for Australia) online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). or to your doctor or Novartis (for New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Rydapt contains

<b>Active ingredient (main ingredient)</b>	midostaurin
<b>Other ingredients (inactive ingredients)</b>	PEG40 hydrogenated castor oil macrogol 400 Glycerol ethanol anhydrous Corn oil PEG6 esters titanium dioxide (E171) dl-alpha-tocopherol carmines (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
<b>Potential allergens</b>	traces of sulfites in gelatin alcohol

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Rydapt looks like

Rydapt capsules are pale orange oblong capsules with red imprint "PKC NVR" (AUST R 287013).

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

### Who distributes Rydapt

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](http://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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