

## 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. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using PEMAZYRE?

PEMAZYRE contains the active ingredient pemigatinib. PEMAZYRE has **provisional approval** in Australia, and it is used to treat adults with bile duct cancer (also known as cholangiocarcinoma) whose cancer cells have an abnormal form of the FGFR2 protein, and when the cancer has spread to other parts of the body or cannot be removed by surgery, and when treatment with other medicines is no longer working.

For more information, see Section [1. Why am I using PEMAZYRE?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to pemigatinib 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 PEMAZYRE?](#) in the full CMI.

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

Some medicines may interfere with PEMAZYRE 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 PEMAZYRE?

- The recommended dose is 1 tablet of PEMAZYRE 13.5 mg taken once daily for 14 days, followed by 7 days without taking PEMAZYRE.

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

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

<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 PEMAZYRE.</li><li>• Use lubricating or hydrating eye drops or gels to help prevent or treat dry eyes.</li><li>• If you become pregnant while being given this medicine, tell your doctor immediately.</li><li>• If you experience any changes in your vision, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not take this medicine if you are pregnant or breastfeeding.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• PEMAZYRE can cause side effects such as fatigue or visual disturbances. Do not drive or operate machinery if this happens.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• The effects of alcohol on this medicine were not assessed as part of its registration.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C</li></ul>

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

### 6. Are there any side effects?

Common side effects include high or low phosphate levels seen in blood tests, hair loss, diarrhoea, fatigue, nail toxicity, taste disturbance, nausea, constipation, inflammation of the inner lining of the mouth, dry mouth, dry eye, joint pain, dry skin and hand-foot syndrome.

Serious side effects include low sodium in blood, increase of creatinine in blood tests, and fatigue. The symptoms of these side effects can be located in Section 6.

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).

# PEMAZYRE®

## Active ingredient(s): (*pemigatinib*)

This medicine has **provisional approval** in Australia, and it is used to treat adults with bile duct cancer (also known as cholangiocarcinoma) whose cancer cells have an abnormal form of the FGFR2 protein, and when the cancer has spread to other parts of the body or cannot be removed by surgery, and when treatment with other medicines is no longer working. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PEMAZYRE. **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 PEMAZYRE.**

### Where to find information in this leaflet:

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

## 1. Why am I using PEMAZYRE?

**PEMAZYRE contains the active ingredient pemigatinib.** PEMAZYRE belongs to a group of cancer medicines called tyrosine kinase inhibitors. It blocks the action of proteins in the cell called fibroblast growth factor receptor types 1, 2 and 3 (FGFR1, FGFR2, and FGFR3) that help regulate cell growth. Cancer cells may have an abnormal form of this protein. By blocking FGFR, pemigatinib can prevent the growth of such cancer cells.

### PEMAZYRE is used:

- to treat adults with bile duct cancer (also known as cholangiocarcinoma) whose cancer cells have an abnormal form of the FGFR2 protein, and
- when the cancer has spread to other parts of the body or cannot be removed by surgery, and
- when treatment with other medicines is no longer working.

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

### Warnings

#### Do not use PEMAZYRE if:

- you are allergic to pemigatinib, 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 using St John's wort, a medicine to treat depression.

#### Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have severely reduced liver function. Your treatment may need to be adjusted.
- have severely reduced kidney function. Your treatment may need to be adjusted.
- have cancer cells that have spread into the brain or spinal cord.
- have been told you have an increase or decrease of a mineral in your blood called phosphorus.
- vision or eye problems.
- have trouble swallowing pills.

#### Eye examinations are recommended:

- before starting treatment with PEMAZYRE.
- every 2 months for the first 6 months of treatment.
- every 3 months thereafter or immediately if any visual symptoms occur, including blurred vision, flashes of light, visual disturbances, or dark spots.

Tell your doctor straight away if you experience any changes in your vision.

You should also use lubricating or hydrating eye drops or gels to help prevent or treat dry eyes.

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. PEMAZYRE may harm the unborn baby and should not be used during pregnancy unless you are told otherwise by your doctor.

A pregnancy test should be performed before initiating treatment.

An effective contraception must be used during treatment and for at least 1 week after the last dose of PEMAZYRE in

women of childbearing age and in men with women partners of childbearing age.

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

Do not breastfeed during treatment with PEMAZYRE and for at least 1 week after the last dose.

## Children and adolescents

PEMAZYRE should not be given to children or adolescents under 18 years. It is not known whether it is safe and effective in this age group.

## 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.

You should tell your doctor if you are taking any of the following medicines so that the doctor can decide if your treatment needs to change:

- **St John's wort:** a medicine to treat depression. You **must not** take St John's wort during treatment with PEMAZYRE.
- **itraconazole:** a medicine to treat fungal infections.
- **rifampicin:** a medicine to treat tuberculosis or certain other infections.
- **carbamazepine, phenytoin, phenobarbital, primidone:** medicines to treat epilepsy.
- **efavirenz:** medicine to treat HIV infection.
- **cyclophosphamide, ifosfamide:** other medicines to treat cancer.
- **methadone:** a medicine to treat severe pain or for managing addiction.
- **digoxin:** a medicine to treat heart disease.
- **dabigatran:** a medicine to prevent blood clots.
- **colchicine:** a medicine to treat gout attacks.

## PEMAZYRE with food and drink

Avoid eating grapefruit or drinking grapefruit juice while using this medication.

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

## 4. How do I use PEMAZYRE?

PEMAZYRE treatment should be started by a doctor who is experienced in the diagnosis and treatment of bile duct cancer. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

## How much to take

- The recommended dose is 1 tablet of PEMAZYRE 13.5 mg taken once daily for 14 days, followed by 7 days without taking PEMAZYRE.
- Treatment is continued with the same pattern of 14 days of PEMAZYRE once daily, followed by 7 days off therapy. Do not take PEMAZYRE during the 7 days off therapy. Your doctor will adjust the dose or stop treatment if needed.
- Follow the instructions provided and use PEMAZYRE until your doctor tells you to stop.

## How to take it

- Swallow the tablet whole with one glass of water.
- Do not crush, chew, split or dissolve the tablets.

## When to take PEMAZYRE

- PEMAZYRE should be taken at the same time every day.
- PEMAZYRE may be taken with food or between meals.

## If you forget to use PEMAZYRE

PEMAZYRE should be used regularly at the same time each day. If you miss your dose of PEMAZYRE by 4 hours or more, or if you vomit after taking PEMAZYRE, do not take another PEMAZYRE tablet to make up for the missed dose. Take your next dose of PEMAZYRE at the scheduled time.

**If 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 use too much PEMAZYRE

If you think that you have used too much PEMAZYRE, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), 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 PEMAZYRE?

### Things you should do

- Use lubricating or hydrating eye drops or gels to help prevent or treat dry eyes.
- Remind any doctor, dentist or pharmacist you visit that you are using PEMAZYRE.

**Call your doctor straight away if you:**

- Experience any changes in your vision.

- Become pregnant while being given this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using PEMAZYRE.

### Things you should not do

- Do not stop using this medicine suddenly without discussing it with your doctor, as this could reduce the success of therapy.
- Do not take this medicine if you are pregnant or breastfeeding.

### Driving or using machines

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

PEMAZYRE can cause side effects such as fatigue or visual disturbances. Do not drive or operate machinery if this happens.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Store below 25°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 which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

## 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
<b>General or affecting different parts of the body:</b> <ul style="list-style-type: none"> <li>• Dry skin</li> </ul>	<b>Speak to your doctor if you have any of these less serious side</b>

<ul style="list-style-type: none"> <li>• Skin reactions with redness, swelling and pain on palms of the hands and soles of the feet, called hand-foot syndrome</li> <li>• Nail toxicity, including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, colour or texture changes in your nails, infected skin around the nail</li> <li>• Hair loss</li> <li>• Joint pain</li> <li>• Abnormal hair growth</li> </ul>	<b>effects and they worry you.</b>
<b>Stomach and digestive system related:</b> <ul style="list-style-type: none"> <li>• Taste disturbance</li> <li>• Nausea</li> <li>• Inflammation of the inner lining of the mouth</li> <li>• Diarrhoea</li> <li>• Constipation</li> <li>• Dry mouth</li> </ul>	
<b>Eye related:</b> <ul style="list-style-type: none"> <li>• Dry eye</li> <li>• Inflammation of the cornea (the clear outer layer of the eye)</li> <li>• Reduced vision</li> <li>• Eyelash changes including abnormally long eyelashes, ingrown eyelashes</li> </ul>	
<b>General or affecting different parts of the body:</b> <ul style="list-style-type: none"> <li>• Fatigue</li> </ul>	

### Serious side effects

Serious side effects	What to do
<b>Metabolism and nutrition related:</b> <ul style="list-style-type: none"> <li>• High or low phosphate levels seen in blood tests (symptoms include muscle cramps, numbness or tingling around the mouth)</li> <li>• Low sodium in blood (symptoms include decreased ability to think, headache, nausea, poor balance, confusion, seizures, coma)</li> </ul>	<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>
<b>Kidney related:</b> <ul style="list-style-type: none"> <li>• Blood tests showing increase of creatinine, which can suggest kidney problems; usually raised creatinine does not cause symptoms, but symptoms of kidney problems may include nausea and changes in urination</li> </ul>	

<b>Eye related:</b> <ul style="list-style-type: none"> <li>Fluid build-up under the retina (the light-sensitive layer at the back of the eye) (symptoms include blurred vision, flashes of light, or see black spots)</li> </ul>	
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**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 online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 PEMAZYRE contains

<b>Active ingredient (main ingredient)</b>	Pemigatinib
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Sodium starch glycollate (Type A) Magnesium stearate
<b>Potential allergens</b>	Not applicable

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

### What PEMAZYRE looks like

PEMAZYRE 4.5 mg tablets are round, white to off-white, debossed on one side with "I" and "4.5" on the reverse (AUST R 375309)

PEMAZYRE 9 mg tablets are oval, white to off-white, debossed on one side with "I" and "9" on the reverse (AUST R 373031)

PEMAZYRE 13.5 mg tablets are round, white to off-white, debossed on one side with "I" and "13.5" on the reverse (AUST R 375314)

The tablets are provided in blisters containing 14 tablets. The carton contains 14 or 28 tablets.

Not all pack sizes may be marketed.

### Who distributes PEMAZYRE

Specialised Therapeutics Alim Pty Ltd  
Level 2, 17 Cotham Road  
Kew, Victoria 3101

Ph: 1300 798 820  
Fax: 1800 798 829  
[www.stbiopharma.com](http://www.stbiopharma.com)

This leaflet was prepared in November 2022.