**Package leaflet: Information for the patient**

**Pemazyre 4.5 mg tablets**
**Pemazyre 9 mg tablets**
**Pemazyre 13.5 mg tablets**
pemigatinib

▼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. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Pemazyre is and what it is used for

Pemazyre contains the active substance pemigatinib, which 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 you need to know before you take Pemazyre

**Do not take Pemazyre if you are**
- allergic to pemigatinib or any of the other ingredients of this medicine (listed in section 6)
- using St John's wort, a medicine to treat depression

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Pemazyre if you have:
- been told you have an increase or decrease of a mineral in your blood called phosphorus
- vision or eye problems
- severely reduced liver function. Your treatment may need to be adjusted
- severely reduced kidney function. Your treatment may need to be adjusted

- cancer cells that have spread into the brain or spinal cord

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 flashes of light, visual disturbances or dark spots.

Tell your doctor straight away if you get any symptoms with your vision.

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

Pemazyre may harm the unborn baby. 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.

**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.

**Other medicines and Pemazyre**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, 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.
- medicines with active substance names ending with "**prazole**": they are used to reduce the release of stomach acid. Avoid using these medicines 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

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

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Pregnancy**
  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.
- **Contraception advice for men and women**
  Women being treated with Pemazyre should not become pregnant. Therefore, women who could become pregnant must use effective contraception during treatment and for at least 1 week after the last dose of Pemazyre. Talk to your doctor about the most suitable contraception for you.
  Men should avoid fathering a child. They must use effective contraception during treatment and for at least 1 week after the last dose of Pemazyre.
- **Breast-feeding**
  Do not breast-feed during treatment with Pemazyre and for at least 1 week after the last dose.

**Driving and using machines**
Pemazyre can cause side effects such as fatigue or visual disturbances. Do not drive or operate machinery if this happens.

## 3. How to take 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.

**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.

**Method of use**
Swallow the tablet whole with one glass of water at the same time every day. Pemazyre may be taken with food or between meals.
Do not crush, chew, split or dissolve the tablets.

**Duration of use**
Take Pemazyre for as long as it is prescribed by the doctor.

**If you take more Pemazyre than you should**
Tell your doctor if you have taken more Pemazyre than you should have.

**If you forget to take Pemazyre**
If you miss a 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 you stop taking Pemazyre**
Do not stop taking Pemazyre without discussing it with your doctor, as this could reduce the success of therapy.

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

## 4. Possible side effects

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

**Tell your doctor immediately** if you have any of the serious side effects below. These side effects may occur with the following frequency:

**Very common** (may affect more than 1 in 10 people):
- low sodium in blood; symptoms include decreased ability to think, headache, nausea, poor balance, confusion, seizures, coma
- 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

**Other side effects** may occur with the following frequencies**:**

**Very common** (may affect more than 1 in 10 people)
- high or low phosphate levels seen in blood tests
- taste disturbance
- dry eye
- nausea
- inflammation of the inner lining of the mouth
- diarrhoea
- constipation
- dry mouth
- skin reactions with redness, swelling and pain on palms of the hands and soles of the feet, called hand-foot syndrome
- 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
- hair loss
- dry skin
- joint pain
- fatigue

**Common** (may affect up to 1 in 10 people)
- fluid build-up under the retina (the light-sensitive layer at the back of the eye)
- inflammation of the cornea (the clear outer layer of the eye)
- reduced vision
- eyelash changes including abnormally long eyelashes, ingrown eyelashes
- abnormal hair growth

**Uncommon** (may affect up to 1 in 100 people)
- deposition of calcium salts that appears as hard papules, nodules, or plaques in or under the skin in any area of the body and can cause pain and ulcers

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Pemazyre

Keep this medicine out of the sight and reach of children.

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.

This medicine does not require any special storage conditions.

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.

## 6. Contents of the pack and other information

**What Pemazyre contains**

- The active substance is pemigatinib.
  Each 4.5 mg tablet contains 4.5 mg pemigatinib.
  Each 9 mg tablet contains 9 mg pemigatinib.
  Each 13.5 mg tablet contains 13.5 mg pemigatinib.
- The other ingredients are microcrystalline cellulose, sodium starch glycolate (Type A), magnesium stearate.

**What Pemazyre looks like and contents of the pack**

Pemazyre 4.5 mg tablets are round, white to off-white, debossed on one side with “I” and “4.5” on the reverse.

Pemazyre 9 mg tablets are oval, white to off-white, debossed on one side with “I” and “9” on the reverse.

Pemazyre 13.5 mg tablets are round, white to off-white, debossed on one side with “I” and “13.5” on the reverse.

The tablets are provided in blisters containing 14 tablets. The carton contains 14 or 28 tablets.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Incyte Biosciences UK Ltd
First Floor Q1, The Square
Randalls Way, Leatherhead
KT22 7TW, UK

**Manufacturer**
Incyte Biosciences Distribution B.V.
Paasheuvelweg 25
1105 BP Amsterdam
Netherlands

Tjoapack Netherlands B.V.
Nieuwe Donk 9
4879 AC Etten-Leur
Netherlands

**This leaflet was last revised in 10/2024**.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

**Other sources of information**

Detailed information on this medicine is available on the website of the Medicines and Healthcare products Regulatory Agency http://www.mhra.gov.uk