

## Package leaflet: Information for the patient

**Pyrukynd 5 mg film-coated tablets**  
**Pyrukynd 20 mg film-coated tablets**  
**Pyrukynd 50 mg film-coated tablets**  
mitapivat

▼ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Pyrukynd is and what it is used for
2. What you need to know before you take Pyrukynd
3. How to take Pyrukynd
4. Possible side effects
5. How to store Pyrukynd
6. Contents of the pack and other information

#### **1. What Pyrukynd is and what it is used for**

Pyrukynd contains the active substance mitapivat.

Pyrukynd is used to treat adults with an inherited condition called pyruvate kinase deficiency. Patients with pyruvate kinase deficiency have changes to an enzyme in their red blood cells called pyruvate kinase, which result in it not working properly. This leads to the red blood cells being broken down too fast, a process known as haemolytic anaemia.

Pyrukynd helps the pyruvate kinase enzyme to work better. It increases the energy in your red blood cells and stops them from being broken down too fast.

Talk to your doctor, pharmacist or nurse if you have any questions about how Pyrukynd works or why this medicine has been prescribed for you.

#### **2. What you need to know before you take Pyrukynd**

##### **Do not take Pyrukynd**

- if you are allergic to mitapivat or any of the other ingredients of this medicine (listed in section 6).

## **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Pyrukynd.

It is important that you do not stop taking this medicine suddenly because this may lead to worsening of your anaemia, with sudden breakdown of red blood cells (acute haemolysis).

- If you want to stop taking Pyrukynd, talk to your doctor first.
- Your doctor will tell you how to stop taking this medicine – usually by reducing the dose gradually. This is to prevent any side effects caused by sudden breakdown of the red blood cells.

See section 4 below for more information about these side effects.

## **Children and adolescents**

Do not give this medicine to children and adolescents under 18 years of age. This is because it is not known if mitapivat is safe and effective for them.

## **Other medicines and Pyrukynd**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular:

Tell your doctor or pharmacist if you take any of the following medicines because they may increase the risk of side effects of Pyrukynd (such as not sleeping) or they may stop Pyrukynd from working properly:

- certain medicines for fungal infections - such as itraconazole
- certain medicines for tuberculosis - such as rifampicin
- certain medicines for stomach ulcers, heartburn or acid reflux - such as famotidine

Tell your doctor or pharmacist if you take any of the following medicines because Pyrukynd may stop these medicines from working properly:

- certain sedatives - such as midazolam
- certain birth control (contraceptive) medicines containing hormones - such as ethinylestradiol
- certain chemotherapy medicines for cancer treatment - such as irinotecan, cyclophosphamide, paclitaxel
- certain medicines to help you stop smoking - such as bupropion
- certain medicines for stomach ulcers, heartburn or acid reflux - such as omeprazole
- certain medicines for type 2 diabetes - such as repaglinide
- certain blood thinners - such as warfarin, dabigatran etexilate
- certain medicines for heart problems - such as digoxin
- certain medicines to treat epilepsy - such as carbamazepine, phenytoin, valproic acid
- certain medicines used for strong pain relief - such as alfentanil
- certain medicines used to prevent organ rejection after an organ transplant - such as cyclosporine, sirolimus, tacrolimus
- certain medicines used to treat an abnormal heart rhythm - such as quinidine
- certain medicines used to treat migraines - such as ergotamine
- certain medicines used to treat chronic pain - such as fentanyl
- certain medicines used to control involuntary movements or sounds - such as pimozide
- certain medicines used to treat or prevent gout flares - such as colchicine

## **Pregnancy, breast-feeding and fertility**

### Pregnancy

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.

You should avoid becoming pregnant during treatment with Pyrukynd.

- This is because it may cause harm to your unborn baby.
- Talk to your doctor straight away if you become pregnant while taking this medicine.

### Breast-feeding

If you plan to breast feed, ask your doctor or pharmacist for advice before taking this medicine. This is because it is not known whether the medicine passes into human breast milk or what the effects might be on the baby.

### Fertility

While taking Pyrukynd, there may be an impact on the ability of a woman and a man to conceive. Talk to your doctor or pharmacist for advice if you are planning to have a child.

## **Contraception for women**

If you could become pregnant, you must use reliable contraception while taking Pyrukynd. You must also do this for at least 1 month after taking your last dose.

While you are taking Pyrukynd, some birth control medicines containing hormones (such as pills) may not work as well as expected, meaning you might be at risk of becoming pregnant. Talk to your doctor, pharmacist or nurse about contraception methods that may be right for you while you are using this medicine.

## **Driving and using machines**

You may experience difficulty sleeping (insomnia) during treatment with Pyrukynd. If this happens to you, be careful when driving or using machines.

## **Pyrukynd contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

## **3. How to take Pyrukynd**

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 starting dose of Pyrukynd is one 5 mg tablet taken twice a day. Your doctor may gradually increase the dose every few weeks based on the results of your blood tests (haemoglobin levels) and how well your condition responds, up to a maximum of one 50 mg tablet taken twice a day.

You should keep taking the medicine unless your doctor tells you to stop.

### How to take

Pyrukynd is taken by mouth.

- Swallow the tablet whole.
- You can take it with or without food.
- Do not split, crush, chew or dissolve the tablets.

### Elderly

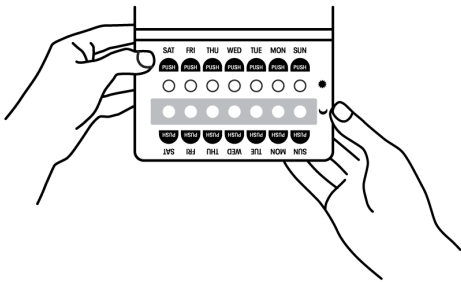
Pyrukynd has been used in a limited number of patients aged 65 years and older. There is no evidence to suggest that elderly patients need a different dose compared to younger adults.

### Instructions for opening the blisters

The following pictures show how to take the tablet out of the blister.

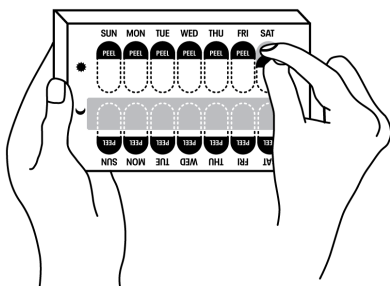
Find the correct blister pocket indicated by the day of the week and, if applicable, time of the day (morning or evening dose, as shown on the blister by sun and moon symbols). At the corresponding tab:

1. Use thumb to PUSH.



The image above shows the inside of the blister wallet.

2. Turn package over, PEEL the raised tab on the back.



The image above shows the back of the blister wallet.

3. Push tablet through the foil.

### **If you take more Pyrukynd than you should**

If you have taken more Pyrukynd than you should, talk to a doctor straight away, or contact your nearest accident and emergency department. Take the medicine pack with you so that you can show the doctor what you have taken.

### **If you forget to take Pyrukynd**

- If you miss a dose by 4 hours or less, take it as soon as possible.
- If you miss a dose by more than 4 hours, do not take a replacement dose. Take your next scheduled dose as you normally would.

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Pyrukynd**

Do not suddenly stop taking this medicine.

- If you want to stop taking Pyrukynd, talk to your doctor first.
- Your doctor will tell you how to stop taking this medicine – usually by reducing the dose gradually.

This is to prevent any side effects caused by sudden breakdown of the red blood cells. See section 4 below for more information about these side effects.

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

## **4. Possible side effects**

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

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

- Difficulty sleeping (insomnia)
- Decreased levels of the hormone oestrone - seen in blood tests in men
- Nausea

**Common** (may affect up to 1 in 10 people):

- Hot flush
- Increased levels of the hormone testosterone – seen in blood tests in men
- Decreased levels of the hormone oestradiol – seen in blood tests in men

### **Side effects that may occur if you suddenly stop taking Pyrukynd**

If you stop taking Pyrukynd suddenly, symptoms may include:

- being very tired
- your skin and whites of the eyes going yellow (jaundice)
- back pain
- dark urine.

Talk to your doctor straight away if you have any of these symptoms after stopping this medicine.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Pyrukynd

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, blister wallet and blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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 Pyrukynd contains

The active substance is mitapivat.

#### Pyrukynd 5 mg film-coated tablets

Each film-coated tablet contains 5 mg of mitapivat (as sulfate).

#### Pyrukynd 20 mg film-coated tablets

Each film-coated tablet contains 20 mg of mitapivat (as sulfate).

#### Pyrukynd 50 mg film-coated tablets

Each film-coated tablet contains 50 mg of mitapivat (as sulfate).

#### Pyrukynd 5 mg, 20 mg and 50 mg film-coated tablets

The other ingredients are:

- *Tablet core*: microcrystalline cellulose, croscarmellose sodium, mannitol (E421) and sodium stearyl fumarate.

- *Film-coating*: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, triacetin, indigo carmine aluminium lake (E132).

- *Printing ink*: shellac (E904), black iron oxide (E172) and ammonium hydroxide (E527).

See section 2 “Pyrukynd contains lactose and sodium”.

### What Pyrukynd looks like and contents of the pack

Pyrukynd 5 mg film-coated tablets are round, blue, film-coated tablets of approximately 5 mm in diameter with “M5” printed in black ink on one side and plain on the reverse.

Pyrukynd 20 mg film-coated tablets are round, blue, film-coated tablets of approximately 8 mm in diameter with “M20” printed in black ink on one side and plain on the reverse.

Pyrukynd 50 mg film-coated tablets are oblong shaped, blue, film-coated tablets of approximately 16 mm x 6.8 mm size with “M50” printed in black ink on one side and plain on the reverse.

#### Packs for starting and continuing treatment

Pyrukynd 5 mg, 20 mg and 50 mg film-coated tablets are available in 4 blister wallets, each containing 14 film-coated tablets. Each carton contains 56 film-coated tablets.

### Packs for reducing or discontinuing treatment

Pyrukynd 5 mg film-coated tablets are also available in blister wallets containing 7 film-coated tablets.

Pyrukynd 20 mg film-coated tablets + Pyrukynd 5 mg film-coated tablets are available in blister wallets containing 14 film-coated tablets (7 film-coated tablets of 20 mg + 7 film-coated tablets of 5 mg).

Pyrukynd 50 mg film-coated tablets + Pyrukynd 20 mg film-coated tablets are available in blister wallets containing 14 film-coated tablets (7 film-coated tablets of 50 mg + 7 film-coated tablets of 20 mg).

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Agios Netherlands B.V.  
Zuidplein 36  
Regus Amsterdam WTC  
1077XV Amsterdam  
The Netherlands

### **Manufacturer**

Almac Pharma Services Limited  
Seagoe Industrial Estate  
Portadown  
Craigavon, County Armagh  
BT63 5UA  
United Kingdom (Northern Ireland)

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### **Other sources of information**

Detailed information on this medicine is available on the Medicines and Healthcare Products Regulatory Agency website: <https://products.mhra.gov.uk>. There are also links to other websites about rare diseases and treatments.