

Package leaflet: Information for the user
Pifeltro® 100 mg film-coated tablets
doravirine

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 Pifeltro is and what it is used for
2. What you need to know before you take Pifeltro
3. How to take Pifeltro
4. Possible side effects
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1. What Pifeltro is and what it is used for

What Pifeltro is

Pifeltro is used to treat HIV ('human immunodeficiency virus') infection. It belongs to a group of medicines called 'antiretroviral medicines'.

Pifeltro contains the active substance doravirine - a non-nucleoside reverse transcriptase inhibitor (NNRTI).

What Pifeltro is used for

Pifeltro is used to treat HIV infection in adults and adolescents aged 12 years and older weighing at least 35 kg. HIV is the virus that causes AIDS ('acquired immune deficiency syndrome'). You should not take Pifeltro if your doctor has told you that the virus causing your infection is resistant to doravirine.

Pifeltro must be used in combination with other medicines for HIV.

How Pifeltro works

When used with other medicines, Pifeltro works by preventing HIV from making more viruses in your body. This will help by:

- reducing the amount of HIV in your blood (this is called your 'viral load')
- increasing the number of white blood cells called 'CD4⁺ T'. This can make your immune system stronger. This may reduce your risk of early death or catching infections because your immune system is weak.

2. What you need to know before you take Pifeltro

Do not take Pifeltro

- if you are allergic to doravirine or any of the other ingredients of this medicine listed in section 6.
- if you are taking the following medicines:
 - carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for seizures)
 - rifampicin, rifapentine (medicines for tuberculosis)
 - St. John’s wort (*Hypericum perforatum*, a herbal remedy used for depression and anxiety) or products that contain it
 - mitotane (a medicine to treat cancer)
 - enzalutamide (a medicine to treat prostate cancer)
 - lumacaftor (a medicine to treat cystic fibrosis)

Do not take Pifeltro if the above applies to you. If you are not sure, talk to your doctor, pharmacist, or nurse before taking Pifeltro. See also “Other Medicines and Pifeltro” section.

Warnings and precautions

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

Immune reactivation syndrome

This can happen when you start taking any HIV medicine, including this medicine. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor right away if you start having any new symptoms after starting your HIV medicine.

Autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Children and adolescents

Do not give this medicine to children aged less than 12 years or weighing less than 35 kg. The use of Pifeltro in children aged less than 12 years or weighing less than 35 kg has not yet been studied.

Other medicines and Pifeltro

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines. This is because other medicines may affect how Pifeltro works, and Pifeltro might affect the way some other medicines work.

There are some medicines you must not take with Pifeltro. See list under “Do not take Pifeltro” section.

Talk to your doctor before taking the following medicines with Pifeltro, as your doctor may need to change the dose of your medicines:

- bosentan (a medicine to treat lung disease)
- dabrafenib (a medicine to treat skin cancer)
- lesinurad (a medicine to treat gout)
- modafinil (a medicine to treat excessive sleepiness)
- nafcillin (a medicine to treat some bacterial infections)
- rifabutin (a medicine to treat some bacterial infections such as tuberculosis)
- telotristat ethyl (a medicine to treat diarrhoea in people with carcinoid syndrome)

- thioridazine (a medicine to treat psychiatric conditions such as schizophrenia)

If your doctor decides you should take these medicines with Pifeltro, one tablet of doravirine should be taken twice daily (approximately 12 hours apart).

Your doctor may check your blood levels or monitor for side effects if you take the following medicines with Pifeltro:

- sirolimus (a medicine used to control your body's immune response after a transplant)
- tacrolimus (a medicine used to control your body's immune response after a transplant)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, talk to your doctor about the risks and benefits of taking Pifeltro. It is preferable to avoid the use of this medicine during pregnancy. This is because it has not been studied in pregnancy and it is not known if it will harm your baby while you are pregnant.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines

Use caution when driving or riding a bicycle, or operating machines if you feel dizzy, tired, or sleepy after taking this medicine.

Pifeltro tablets contain lactose

If you have been told by your doctor that you have an intolerance to lactose, talk to your doctor before taking this medicine.

3. How to take Pifeltro

Always take this medicine exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure. This medicine must be used in combination with other medicines for HIV.

How much to take

The recommended dose is 1 tablet once a day. If you take certain medicines, your doctor may need to change the amount of doravirine you take. See "Other medicines and Pifeltro" section for a list of medicines.

Taking this medicine

- Swallow the tablet whole (do not crush or chew).
- This medicine can be taken with food or between meals.

If you take more Pifeltro than you should

Do not take more than the recommended dose. If you accidentally take more, contact your doctor.

If you forget to take Pifeltro

- It is important that you do not miss or skip doses of this medicine.
- If you forget to take a dose, take it as soon as you remember. But if your next dose is due within 12 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.
- Do not take a double dose to make up for a missed dose.
- If you are not sure what to do, call your doctor or pharmacist.

If you stop taking Pifeltro

Do not run out of this medicine. Refill your prescription or talk to your doctor before it is all gone.

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. Do not stop taking this medicine without first talking to your doctor.

Common: may affect up to 1 in 10 people:

- abnormal dreams, difficulty in sleeping (insomnia)
- headache, dizziness, sleepiness
- feeling sick (nausea), diarrhoea, stomach pain, vomiting, wind (flatulence)
- rash
- feeling tired

Blood tests may also show:

- increased levels of liver enzymes (ALT)

Uncommon: may affect up to 1 in 100 people:

- nightmares, depression, anxiety, irritability, confusion, suicidal thoughts
- trouble concentrating, memory problems, tingling of hands and feet, stiff muscles, poor quality sleep
- high blood pressure
- constipation, stomach discomfort, swollen or bloated stomach (abdominal distension), indigestion, soft stools, stomach spasms
- itchiness
- muscle pain, joint pain
- feeling weak, general feeling of being unwell

Blood tests may also show:

- decreased levels of phosphate
- increased levels of liver enzymes (AST)
- increased levels of lipase
- increased levels of amylase
- decreased levels of haemoglobin

Rare: may affect up to 1 in 1,000 people:

- aggression, hallucinations, difficulty adjusting to changes, mood changes, sleep walking
- difficulty breathing, enlarged tonsils
- feeling of incomplete defecation
- inflammation of the skin due to allergy, redness on the cheeks, nose, chin or forehead, bumps or pimples on the face
- kidney damage, kidney problems, kidney stones
- pain in the chest, feeling cold, pain, thirst

Blood tests may also show:

- decreased levels of magnesium
- increased levels of creatine phosphokinase

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

at: 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 Pifeltro

- 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 bottle after EXP. This medicine should be used within 35 days after first opening of the bottle.
- The bottle contains a desiccant protecting the tablets from moisture. Keep the desiccant inside the bottle and do not throw away until you have finished taking all of the medicine.
- Keep the bottle tightly closed in order to protect from moisture.
- This medicinal product does not require any special temperature 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 Pifeltro contains

- The active substance is doravirine 100 mg.
- The other ingredients are croscarmellose sodium E468; hypromellose acetate succinate; lactose monohydrate; magnesium stearate E470b; microcrystalline cellulose E460; and silica, colloidal anhydrous E551. The tablets are film-coated with a coating material containing the following ingredients: carnauba wax E903; hypromellose E464; lactose monohydrate; titanium dioxide E171; and triacetin E1518.

What Pifeltro looks like and contents of the pack

Pifeltro is available as a white, oval-shaped, film-coated tablet, and is debossed with the corporate logo and 700 on one side and plain on the other side.

The following pack sizes are available:

- 1 bottle with 30 film-coated tablets
- 90 film-coated tablets (3 bottles of 30 film-coated tablets)

Not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Merck Sharp & Dohme (UK) Limited, 120 Moorgate, London, EC2M 6UR, UK.

Manufacturer: Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands.

Other sources of information

For any information about this medicine, please contact:

Merck Sharp & Dohme (UK) Limited
Tel: +44 (0) 208 154 8000
Email: medicalinformationuk@msd.com

This leaflet was last revised in August 2024

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IAIN-017