Applicant: MSD (Pty) Ltd
APPROVED PATIENT INFORMATION LEAFLET
PIFELTRO 100 mg Film-coated Tablet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PIFELTRO® 100 mg Film-coated Tablet

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.
- PIFELTRO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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
5. How to store PIFELTRO
6. Contents of the pack and other information

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 without past or present evidence of resistance to other antiretroviral medicines within the same class as doravirine (NNRTI class). 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 PIFELTRO listed in section 6.

- if you are taking the following medicines:
  - carbamazepine, oxcarbazepine, phenobarbitone, phenytoin (medicines for seizures)
  - rifampicin, rifapentine (medicines for tuberculosis)
  - St. John's wort (*Hypericum perforatum*, an 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 or pharmacist before taking PIFELTRO. See also the list in section "Taking other medicines and PIFELTRO".

Warnings and precautions

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

Passing HIV to others

HIV is spread by contact with blood or through sexual contact with a person with HIV. You can still pass on HIV when taking PIFELTRO, although effective therapy lowers the risk. Talk to your doctor about what you can do to avoid infecting other people.

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.

Children and adolescents

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

Taking other medicines and PIFELTRO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional 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).

Human reproduction

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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.
Women with HIV should not breastfeed because HIV can be passed on to their babies through breast milk. Talk with your doctor about the best way to feed your baby.

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.

Important information about some of the ingredients of PIFELTRO

PIFELTRO Tablets contain 222 mg lactose (as monohydrate)

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

3. How to take PIFELTRO

Always take PIFELTRO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. PIFELTRO is a complete regimen taken as a single tablet for the treatment of HIV infection.

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 PIFELTRO

- Swallow the tablet whole (do not crush or chew).
- PIFELTRO 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 take more, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

PIFELTRO can cause side effects.

Should your general health worsen or if you experience any untoward effects while taking PIFELTRO, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PIFELTRO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty in breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to PIFELTRO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you have any of the following:

- pain in the chest
- kidney damage, kidney problems, kidney stones.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- 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).

Less frequent:

- 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
- imbalance in levels of immune cells (CD4/CD8 ratio)
- aggression, hallucinations, difficulty adjusting to changes, mood changes, sleep walking
- 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
- feeling cold, pain, thirst.

Blood tests may also show:

- decreased levels of magnesium
- increased levels of creatine phosphokinase.

If you notice any side effects not mentioned in this leaflet, please inform you doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PIFELTRO.

5. How to store PIFELTRO

- Store at or below 30 °C. Keep the bottle tightly closed in order to protect from moisture.
- Do not use PIFELTRO after the expiry date which is stated on the bottle after EXP.
- 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.
- 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.
- Store all medicines out of reach of children.

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; silica and 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.

Each carton contains a white, high density polyethylene (HDPE) bottle with a white polypropylene child-resistant closure with silica gel desiccant.

The following pack size is available: 1 bottle with 30 film-coated tablets

Holder of Certificate of Registration

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