

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MACLEODS FAMCICLOVIR TABLETS 125 mg (film-coated tablet) Contains sugar (2,550 mg lactose anhydrous).

MACLEODS FAMCICLOVIR TABLETS 250 mg (film-coated tablet)

Contains sugar (5,100 mg lactose anhydrous).

Read all of this leaflet carefully before you start taking MACLEODS FAMCICLOVIR TABLETS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **MACLEODS FAMCICLOVIR TABLETS** 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 **MACLEODS FAMCICLOVIR TABLETS** is and what it is used for
2. What you need to know before you take **MACLEODS FAMCICLOVIR TABLETS**
3. How to take **MACLEODS FAMCICLOVIR TABLETS**
4. Possible side effects
5. How to store **MACLEODS FAMCICLOVIR TABLETS**
6. Contents of the pack and other information

1. What MACLEODS FAMCICLOVIR TABLETS is and what it is used for

MACLEODS FAMCICLOVIR TABLETS belongs to a group of medicines called antivirals.

MACLEODS FAMCICLOVIR TABLETS is used to treat various infections caused by herpes virus.

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2. What you need to know before you take MACLEODS FAMCICLOVIR TABLETS

Do not take MACLEODS FAMCICLOVIR TABLETS

- If you are hypersensitive (allergic) to famciclovir or penciclovir or to any of the other ingredients of **MACLEODS FAMCICLOVIR TABLETS** (listed in section 6).
- If you are pregnant or breastfeeding your infant.

Warnings and precautions

Take special care with **MACLEODS FAMCICLOVIR TABLETS**

- Tell your doctor if you have any kidney problems. Your doctor may give you a lower dose of **MACLEODS FAMCICLOVIR TABLETS**.
- Tell your doctor if you have liver disease.
- If you have a severe form of herpes zoster infection with complications such as the infection spreading to the internal organs of the body (e.g. heart, liver, kidneys) or the infection has spread throughout the body or the motor nerves controlling muscle movement become damaged or the brain becomes infected and inflamed or the blood supply to the brain is affected or if you have a shingles outbreak that occurs on the face, scalp, forehead, nose, eye, or combination of any of those parts or if you have problems with your body's immune system, your doctor will treat you in hospital with an intravenous (iv) form of the medicine.

Other medicines and MACLEODS FAMCICLOVIR TABLETS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

MACLEODS FAMCICLOVIR TABLETS may change the effect of other medicines and other medicines may change the effect of **MACLEODS FAMCICLOVIR TABLETS**.

When you are taking **MACLEODS FAMCICLOVIR TABLETS**, it is especially important to tell your doctor or healthcare professional if you are taking any of the following medicines:

- Probenecid (for gout) or any other medicine that can affect your kidneys.
- Raloxifen (used to prevent and treat osteoporosis).

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MACLEODS FAMCICLOVIR TABLETS with food or drink

MACLEODS FAMCICLOVIR TABLETS can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety and efficacy of **MACLEODS FAMCICLOVIR TABLETS** during pregnancy and breastfeeding has not been established. You should not use **MACLEODS FAMCICLOVIR TABLETS** when you are pregnant or breastfeeding.

Driving and using machines

MACLEODS FAMCICLOVIR TABLETS may cause dizziness, sleepiness or confusion and hallucinations (seeing or hearing things which are actually not there). If you experience these side effects while taking **MACLEODS FAMCICLOVIR TABLETS** do not drive and do not use any tools or machines.

MACLEODS FAMCICLOVIR TABLETS contains lactose

MACLEODS FAMCICLOVIR TABLETS contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **MACLEODS FAMCICLOVIR TABLETS**.

MACLEODS FAMCICLOVIR TABLETS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take MACLEODS FAMCICLOVIR TABLETS

Do not share medicines prescribed for you with any other person.

Always take or give **MACLEODS FAMCICLOVIR TABLETS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Your dose of **MACLEODS FAMCICLOVIR TABLETS** and length of treatment will depend on the type of herpes infection that you have and any other medical problems that you have (e.g. kidney disease).

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- Take **MACLEODS FAMCICLOVIR TABLETS** according to instructions from your doctor or pharmacist.
- Take **MACLEODS FAMCICLOVIR TABLETS** by mouth.
- Swallow the tablets whole with a drink of water.
- Take **MACLEODS FAMCICLOVIR TABLETS** at the same time each day.

If you have the impression that the effect of **MACLEODS FAMCICLOVIR TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MACLEODS FAMCICLOVIR TABLETS than you should

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

If you forget to take MACLEODS FAMCICLOVIR TABLETS

If you have missed a dose of **MACLEODS FAMCICLOVIR TABLETS** take it as soon as you remember. However if it is almost time for the next dose, skip the missed dose and go back to your regular scheduling. Never double the dose.

4. Possible side effects

MACLEODS FAMCICLOVIR TABLETS can have side effects.

Not all side effects reported for **MACLEODS FAMCICLOVIR TABLETS** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **MACLEODS FAMCICLOVIR TABLETS**, please consult your doctor, pharmacist or other health care professional provider for advice.

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

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

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These are all very serious side effects. If you have them you may have had a serious allergic reaction to **MACLEODS FAMCICLOVIR TABLETS**. You may need urgent medical attention or hospitalisation.

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

- Severe blistering of the skin or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (these could be signs of a serious allergic skin reaction).
- Red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. You may have fever, sore throat, headache and/or diarrhoea
- Unexplained bruising, reddish or purplish patches on the skin or unexplained bleeding or nosebleeds (these could be signs of a decrease in the number of blood platelets).
- Swelling below the surface of the skin (e.g. facial swelling, swelling around the eye, eyelid swelling, swelling of the throat).
- Yellowing of the skin and/or eyes (signs of jaundice).
- Purple skin patches, itching, burning (signs of inflamed blood vessels).

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

Tell your doctor if you notice any of the following :

- Confusion, hallucinations (seeing and hearing things that are actually not there).
- Headache, dizziness, sleepiness.
- Palpitations (fast or irregular heartbeats)
- Nausea, vomiting, diarrhoea or stomach discomfort or cramps.
- Liver functions tests showing abnormal results.
- Rash, itching, itchy rash (hives).

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

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **MACLEODS FAMCICLOVIR TABLETS**.

5. How to store MACLEODS FAMCICLOVIR TABLETS

Store at or below 30 °C in a cool and dry place. The bottles must be kept tightly closed.

Any expired or outdated medicines and unused medicines can be returned to your nearest pharmacy.

Do not use **MACLEODS FAMCICLOVIR TABLETS** if you notice discoloration or swelling of tablets.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.

Do not dispose of unused medicines in drains or sewerage systems e.g. toilets

6. Contents of the pack and other information

What MACLEODS FAMCICLOVIR TABLETS contains

The active substance is famciclovir.

The other ingredients are: Lactose anhydrous, low substituted hydroxy propyl cellulose, sodium starch glycolate, hydroxy propyl cellulose, magnesium stearate, hypromellose 5 cps, titanium dioxide, polyethylene glycol 400.

What MACLEODS FAMCICLOVIR TABLETS looks like and contents of the pack

MACLEODS FAMCICLOVIR TABLETS 125 mg : A white to off white, round shaped, biconvex, film coated tablet engraved with “ML 67” on one side and plain on the other side.

MACLEODS FAMCICLOVIR TABLETS 250 mg : A white to off white, round shaped, biconvex, film coated tablet engraved with “ML 70” on one side and plain on the other side.

MACLEODS FAMCICLOVIR TABLETS 125 mg and 250 mg:

30’s HDPE bottle pack with child resistant closure:

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High density polyethylene (HDPE) bottle pack comprises of white opaque HDPE bottle provided along with a white, polypropylene (PP) screw cap with pulp and heat seal liner packed in an outer carton.

Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD.

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Alberton, South Africa.

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MACLEODS FAMCICLOVIR TABLETS 125 mg: 45/20.2.8/1157

MACLEODS FAMCICLOVIR TABLETS 250 mg: 45/20.2.8/1158

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