

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

MYLAN VALACICLOVIR 250 mg (film-coated tablet)

MYLAN VALACICLOVIR 500 mg (film-coated tablet)

Valaciclovir hydrochloride monohydrate 250 mg & 500 mg film-coated tablets.

Sugar free.

Read all of this leaflet carefully before you start taking MYLAN VALACICLOVIR

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.

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

1. What MYLAN VALACICLOVIR is and what it is used for

What MYLAN VALACICLOVIR is:

MYLAN VALACICLOVIR contains a medicine called valaciclovir. This belongs to a group of medicines called antivirals. It works by slowing or stopping the growth of viruses.

MYLAN VALACICLOVIR is used to:

- Treat shingles.
- Treat cold sores and genital herpes.
- Stop these problems returning after you have had them.
- Stop you from being infected with CMV (Cytomegalovirus). This is a rare virus that can complicate kidney transplants.

2. What you need to know before you take MYLAN VALACICLOVIR

Do not take MYLAN VALACICLOVIR:

- If you are hypersensitive (allergic) to valaciclovir, aciclovir or any of the other ingredients of MYLAN VALACICLOVIR (listed in section 6).
- If you are pregnant or breastfeeding (see Pregnancy and breastfeeding and fertility).

Do not take MYLAN VALACICLOVIR if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking MYLAN VALACICLOVIR.

Warnings and precautions

Take special care with MYLAN VALACICLOVIR:

- If you have or had blood disorders, a bone marrow transplant, a kidney transplant or have advanced HIV disease.
- If you have kidney problems.
- If you have liver problems.
- If you are an elderly patient.
- If you have a weak immune system.
- If you are dehydrated.

- If you develop signs of nervous system side-effects, you will be closely monitored by your doctor. This might include feeling confused or agitated, or feeling unusually sleepy or drowsy.
- If you currently have or have had genital herpes in the past. Even if you are taking MYLAN VALACICLOVIR, you should still practice safe sex, including the use of condoms. You should not have sex if you have sores or blisters.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking MYLAN VALACICLOVIR.

Other medicines and MYLAN VALACICLOVIR

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of MYLAN VALACICLOVIR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription (including herbal medicines). This is because MYLAN VALACICLOVIR can affect the way some other medicines work. Also some medicines can affect the way MYLAN VALACICLOVIR works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Probenecid, used to treat gout.
- Cimetidine, used to treat stomach ulcers.
- Tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body from rejecting transplanted organs.
- Aminoglycosides, antibiotics used to treat infections.
- Organoplatinum compounds, medicines that may be used to treat cancer.
- Medicines containing iodine (which are often injected into the body during radiography).
- Methotrexate, used to treat certain types of cancer and to suppress your immune system.
- Pentamidine, an antifungal medicine used to treat infections.
- Foscarnet, an antiviral medicine.

MYLAN VALACICLOVIR with food and drink and alcohol

You may take MYLAN VALACICLOVIR with your food or drinks.

Pregnancy and breastfeeding and fertility

You should not take MYLAN VALACICLOVIR if you are pregnant or breastfeeding your baby, because it may harm your baby.

Before taking MYLAN VALACICLOVIR, tell your doctor if you are pregnant or trying to get pregnant.

If you are pregnant or breastfeeding your baby while taking MYLAN VALACICLOVIR, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

- MYLAN VALACICLOVIR may cause dizziness.
- You must make sure how you react before driving or using machinery.

MYLAN VALACICLOVIR is sugar free.

3. How to take MYLAN VALACICLOVIR

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

Always take MYLAN VALACICLOVIR exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the correct dose for you. The usual dose is:

Treatment of shingles:

Adults: Take 1000 mg (2 (two) MYLAN VALACICLOVIR 500 mg tablets) three times a day for 7 days.

Treatment to stop the problems of genital herpes returning after you have had them:

Adults: Take 500 mg (1 (one) MYLAN VALACICLOVIR 500 mg tablet twice daily for 5 days, beginning as soon as possible.

Treatment or prevention of cold sores returning after you have had them:

Adults: Take 500 mg (1 (one) MYLAN VALACICLOVIR 500 mg tablet) once daily. If you have more than 10 episodes per year, take 250 mg (1 (one) MYLAN VALACICLOVIR 250 mg tablet) twice daily.

If necessary, your healthcare professional may increase the dosage.

Treatment when your immune system is weak:

Take 500 mg (1 (one) MYLAN VALACICLOVIR 500 mg tablet) twice daily.

To stop you from being infected with CMV (Cytomegalovirus):

This is a rare virus that can complicate kidney transplants.

Adults and children of 12 years and older: You must start treatment as soon as possible.

Starting treatment after you have had a transplant:

You must take 2000 mg (4 (four) MYLAN VALACICLOVIR 500 mg tablets) four times daily for 90 days. Your treatment may be for longer, depending on your condition. Your doctor may change the dosage depending on how well your kidneys are working.

Your doctor will tell you how long your treatment with MYLAN VALACICLOVIR will last.

If you take more MYLAN VALACICLOVIR than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you take too many MYLAN VALACICLOVIR tablets you may feel sick, vomit or be confused, dizzy or unusually sleepy.

If you forget to take / missed a dose of MYLAN VALACICLOVIR

- If you forget to take MYLAN VALACICLOVIR, take it as soon as you remember.
However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten individual dose.
- If you have the impression that the effect of MYLAN VALACICLOVIR is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects

MYLAN VALACICLOVIR can have side effects.

Not all side effects reported for MYLAN VALACICLOVIR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYLAN VALACICLOVIR, please consult your healthcare professional for advice.

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

If you have a severe allergic reaction (anaphylaxis), stop taking MYLAN VALACICLOVIR and see a doctor urgently or go to the casualty department at your nearest hospital immediately. The signs may include:

- A rash, itching or hives on your skin (urticaria).
- Severe widespread rash with blisters and peeling of the skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Swelling of your hands, feet, ankles, face, lips, mouth, tongue and throat, causing difficulty swallowing or breathing, or swelling of other parts of your body.
- Fainting.

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

Tell your doctor immediately or as soon as possible to go to the casualty department at your nearest hospital if you notice the following:

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

- Shortness of breath, wheezing or trouble breathing (angioedema).
- Fall in blood pressure and passing out (fainting).
- Inflammation of the liver, yellow eyes or skin (jaundice).
- Confusion, tiredness and dizziness may occur if you have kidney disease.
- Kidney problems where you pass little or no urine.
- Pain in the kidney area of your back (renal pain).
- Increased rate of heartbeat.

- Coma.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Headache.
- High doses for CMV prophylaxis may cause confusion and hallucinations (seeing or hearing things that are not there).
- Nausea.
- Diarrhoea.

The following side effects have been reported less frequently:

- Blood disorders may occur which may make you feel weak, tired or drowsy. You may also experience fainting, seeing spots or have bruising/bleeding into the skin and bleeding of your nose.
- Confusion, tiredness and dizziness may occur if you have kidney disease.
- Elated mood (mania) and psychosis, a mental illness where you hear and see things that are not there.
- Aggressive behaviour.
- Confused or disturbed thoughts (delirium).
- Psychotic symptoms (psychosis is a condition that affects the way your brain processes information which may cause you to lose touch with reality).
- Feeling agitated.
- Unsteadiness when walking and lack of co-ordination (ataxia).
- Decreased consciousness.
- Tremor.

- Slow, slurred speech (dysarthria).
- Fits (convulsions).
- Altered brain function (encephalopathy).
- Skin reactions after exposure to sunlight (photosensitivity).
- Loss of hair (alopecia).
- Visual abnormalities.
- High blood pressure.
- Increased rate of heartbeat.
- Shortness of breath (dyspnoea).
- Vomiting.
- Stomach discomfort.
- Pain in the joints.
- Inflammation of the liver, yellow eyes or skin (jaundice).
- Kidney problems where you pass little or no urine.
- Pain in the kidney area of your back (renal pain).
- Blood in urine (haematuria).
- Painful menstruation, abdominal cramps.

The following side effects have been reported but the frequency is unknown:

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug reaction hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs. See also section 2.
- An inflammation of the kidneys (tubulointerstitial nephritis).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA on the SAHPRA website at:

<https://medsafety.sahpra.org.za/#download>, via email at: adr@sahpra.org.za or via

telephone at: 0125010311

By reporting side effects, you can help provide more information on the safety of MYLAN VALACICLOVIR.

5. How to store MYLAN VALACICLOVIR

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

The bottles must be kept tightly closed.

Do not remove from the carton until required for use.

Do not use after the expiry date stated on the label/carton.

Do not store in a bathroom.

Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLAN VALACICLOVIR contains:

The active substance is valaciclovir hydrochloride monohydrate.

Each MYLAN VALACICLOVIR 250 mg film-coated tablet contains valaciclovir hydrochloride monohydrate equivalent to 250 mg valaciclovir.

Each MYLAN VALACICLOVIR 500 mg film-coated tablet contains valaciclovir hydrochloride monohydrate equivalent to 500 mg valaciclovir.

The other ingredients are: Magnesium stearate, microcrystalline cellulose (Avicel PH 101) {coating: Opadry white OY-58900 - composition: HPMC 2910/Hypromellose 5cp (E484), macrogol/PEG 400, titanium dioxide (E171)}.

What MYLAN VALACICLOVIR looks like and contents of the pack:

What MYLAN VALACICLOVIR looks like:

MYLAN VALACICLOVIR 250 mg: White coloured, oval shaped, biconvex film-coated tablet.

MYLAN VALACICLOVIR 500 mg: White coloured, oval shaped, biconvex film-coated tablet with breakline on one side and plain on the other side.

MYLAN VALACICLOVIR contents of the pack:

The tablets are packed in a PVC High density polyethylene (HDPE) bottle pack (marketable pack) that comprises of a round, wide-mouth white HDPE bottle with a white opaque polypropylene (PP) screw closure with an aluminium induction sealing liner and is packed in a cardboard carton (100's).

Cold form blister pack (marketable pack) comprises of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side (blisters of 10's), packed in a carton.

Pack sizes of 30 and 42 may also be marketed.

Holder of Certificate of Registration and Manufacturer

Mylan (Pty) Ltd

4 Brewery Street, Isando,

Johannesburg

1600, Gauteng, South Africa

This leaflet was last revised in

Date of publication: 04 October 2014

Date of revision of text: 16 August 2023

Registration number

MYLAN VALACICLOVIR 250 mg: 45/20.2.8/0604

MYLAN VALACICLOVIR 500 mg: 45/20.2.8/0605

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website