

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEN ACYCLOVIR 250 mg powder for solution for infusion

Acyclovir 250 mg per vial

Sugar free

Read all of this leaflet carefully before ASPEN ACYCLOVIR 250 mg is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What ASPEN ACYCLOVIR 250 mg is and what it is used for
2. What you need to know before ASPEN ACYCLOVIR 250 mg is administered to you
3. How ASPEN ACYCLOVIR 250 mg will be administered to you
4. Possible side effects
5. How to store ASPEN ACYCLOVIR 250 mg
6. Contents of the pack and other information

1. What ASPEN ACYCLOVIR 250 mg is and what it is used for

ASPEN ACYCLOVIR 250 mg belongs to a group of medicines called antiviral agents.

- ASPEN ACYCLOVIR 250 mg is used to treat herpes encephalitis, shingles (only if lesions are not older than 72 hours), and chicken pox.

- ASPEN ACYCLOVIR 250 mg is also used to treat *herpes simplex* infections and to prevent recurrent attacks of *herpes simplex* infections in people whose immune systems are weakened.
- ASPEN ACYCLOVIR 250 mg is also used to treat *herpes simplex* infections in neonates.
- ASPEN ACYCLOVIR 250 mg prevents a virus called cytomegalovirus (CMV) in people who have had a bone marrow transplant.

2. What you need to know before ASPEN ACYCLOVIR 250 mg is administered to you

ASPEN ACYCLOVIR 250 mg should not be administered to you:

- if you are hypersensitive (allergic) to acyclovir or valaciclovir or any of the other ingredients of ASPEN ACYCLOVIR 250 mg (listed in section 6).

Warnings and precautions

Take special care with ASPEN ACYCLOVIR 250 mg:

- you are pregnant or trying to become pregnant (see section on Pregnancy, breastfeeding and fertility).
- you are breastfeeding or planning to breastfeed (see section on Pregnancy, breastfeeding and fertility).
- if you suffer from kidney or liver disease.
- if you are elderly.

If you are elderly or if you have kidney problems, it is important that you drink adequate fluids whilst you are having treatment. The doctor will monitor you closely as there is a risk of experiencing nervous system side effects (see section 4).

- if you develop a skin rash, fever or swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with

Eosinophilia and Systemic Symptoms (DRESS) (see section 4. Possible side effects.). If any of the above happens to you, or any signs that may be suggestive of DRESS, ASPEN ACYCLOVIR 250 mg should be withdrawn immediately and your healthcare provider should consider alternative treatment options. If DRESS has been confirmed, ASPEN ACYCLOVIR 250 mg should not be rechallenged.

- If any of the above applies to you or if you are unsure if they apply to you, and if you have not already discussed with your doctor, tell your doctor or pharmacist before you start receiving ASPEN ACYCLOVIR 250 mg.

Other medicines and ASPEN ACYCLOVIR 250 mg

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Probenecid (used in the treatment for gout).
- Cimetidine (used in the treatment of heartburn, stomach ulcers, reflux disease or any other condition that may cause an increase in stomach acid).
- Mycophenolate mofetil (immunosuppressant medicine used in kidney transplants).
- Lithium (used in bipolar disorder where your mood changes from feeling very high (mania) and very low (depression)).
- Ciclosporin or tacrolimus (immunosuppressant agents used in transplants).

Pregnancy, breastfeeding and fertility

You should not breastfeed your baby if you are on treatment with ASPEN ACYCLOVIR 250 mg (see section 2).

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

Driving and using machines

ASPEN ACYCLOVIR 250 mg will be administered to you in hospital and should therefore not have any affect on your ability to drive or operate any machinery.

It is not always possible to predict to what extent ASPEN ACYCLOVIR 250 mg may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN ACYCLOVIR 250 mg affects you (see section 4).

3. How ASPEN ACYCLOVIR 250 mg will be administered to you

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

You will not be expected to give yourself ASPEN ACYCLOVIR 250 mg. It will be given to you by a person who is qualified to do so.

Your doctor will prescribe a dose to suit you or your child, depending on your condition and your response to this treatment.

ASPEN ACYCLOVIR 250 mg injection will be reconstituted before use and will be given to you by slow intravenous infusion over a one-hour period.

If you receive more ASPEN ACYCLOVIR 250 mg than you should:

Since a healthcare provider will administer ASPEN ACYCLOVIR 250 mg, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have been given too much ASPEN ACYCLOVIR 250 mg, you may:

- feel confused and agitated,
- see or hear things that are really not there, (hallucinations),
- have fits (seizures),
- become unconscious (coma).

If you do not receive ASPEN ACYCLOVIR 250 mg:

Since a healthcare provider will administer ASPEN ACYCLOVIR 250 mg, it is unlikely that the dose will be missed.

4. Possible side effects

ASPEN ACYCLOVIR 250 mg can have side effects.

Not all side effects reported for ASPEN ACYCLOVIR 250 mg are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while ASPEN ACYCLOVIR 250 mg is being administered to you, please consult your healthcare provider for advice.

If any of the following happens, while ASPEN ACYCLOVIR 250 mg is administered to you, ASPEN ACYCLOVIR 250 mg administration should be stopped and the adverse event should be managed by your treating healthcare provider:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.
- if you develop a skin rash, fever or swelling of lymph nodes and an increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

These are all very serious side effects. If you have them, you may have had a serious reaction to ASPEN ACYCLOVIR 250 mg. You may need urgent medical attention within the facility where you are being treated.

You (or a nurse) should tell your doctor immediately or you should go to the casualty department if you have been discharged at your nearest hospital if you notice any of the following:

- Symptoms such as, but not limited to, hypertension (high blood pressure), night-time urination, changes in how your urine looks (such as frothy or foamy),
- haematuria (blood in your urine) as these may be symptoms of kidney malfunction (impaired kidney function) or kidney failure.
- Kidney pain which is usually felt in your back, under the ribs, to either side of your spine.
- Confusion, memory loss, personality changes, and loss of consciousness where you may be unresponsive (encephalopathy),
- psychotic symptoms (mental disorder which features loss of contact with reality),
- fits (convulsions),
- liver problems, or yellowing of the skin and the whites of the eyes (jaundice),
- weakness, tiredness, feeling faint or shortness of breath. These symptoms may mean you have reduced number of red blood cells (anaemia),
- bruising or nose bleeds. These symptoms mean you have a low number of platelets, a type of white blood cell which helps blood to clot (thrombocytopenia).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Feeling or being sick (nausea or vomiting),
- itching and mild skin reactions e.g. hives/nettle rash or skin rashes (including a skin reaction after exposure to sunlight),
- redness, warmth and pain in the affected area (inflammation of a vein/phlebitis),
- increases in blood urea and creatinine levels detected during blood tests.

Less frequent side effects:

- Although you may not notice any symptoms, ASPEN ACYCLOVIR 250 mg may cause a decrease in your white blood cells.

Side effects reported with an unknown frequency:

- Headache, dizziness, agitation, shakiness, irregular body movements, difficulties with speech, hallucinations, sleepiness during the day,
- hair loss (evenly across the scalp),
- an increase in liver-related enzymes and bilirubin as detected on blood tests
- difficulty breathing,
- diarrhoea and stomach pains,
- fatigue, fever, localised swelling and redness which may lead to ulcerations at the injection site.

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** 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 ASPEN ACYCLOVIR 250 mg.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

5. How to store ASPEN ACYCLOVIR 250 mg

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

The reconstituted solution is stable at 15 °C to 25 °C for up to 12 hours.

The reconstituted and diluted solution is stable at 15 °C to 25 °C for up to 24 hours.

The reconstituted or diluted solution should not be refrigerated.

Do not store in a bathroom.

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

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 ASPEN ACYCLOVIR 250 mg contains

The active substance is 250 mg of acyclovir as the lyophilised sodium salt.

The other ingredients are sodium hydroxide (for pH-adjustment).

Sugar free

What ASPEN ACYCLOVIR 250 mg looks like and contents of the pack

ASPEN ACYCLOVIR 250 mg is a white to off-white lyophilised cake.

1 x 20 ml clear, colourless, glass vial with an aluminium seal, dark grey bromobutyl rubber stopper and a light blue polypropylene flip-top cover. 5 vials are packed in an outer cardboard carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

This leaflet was last revised in

18 February 2025

Registration number

32/20.2.8/0257



Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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