CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Read all of this leaflet carefully before you are given ACYCLOVIR 25 mg/ml ACCORD

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

What is in this leaflet

1. What **ACYCLOVIR 25 mg/ml ACCORD** is and what it is used for

2. What you need to know before you use **ACYCLOVIR 25 mg/ml ACCORD**

3. How to use **ACYCLOVIR 25 mg/ml ACCORD**

4. Possible side effects

5. How to store **ACYCLOVIR 25 mg/ml ACCORD**

6. Contents of the pack and other information

1. What ACYCLOVIR 25 mg/ml ACCORD is and what it is used for

ACYCLOVIR 25 mg/ml ACCORD contains a medicine called acyclovir.

This belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

ACYCLOVIR 25 mg/ml ACCORD can be used to:

- Treat chickenpox.
- Treat severe cases of genital herpes.
- Treat and stop cold sores and genital herpes in people whose immune systems work less well, which means their bodies are less able to fight infections.
- Treat serious virus infections in children up to 3 months. This can be caused by the virus responsible for cold sore infection and genital herpes.
- Treat inflammation of the brain. This can be caused by the virus responsible for cold sore infection and genital herpes.

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2. What you need to know before you use ACYCLOVIR 25 mg/ml ACCORD

Do not use ACYCLOVIR 25 mg/ml ACCORD.

ACYCLOVIR 25 mg/ml ACCORD should not be administered to you

- if you are hypersensitive (allergic) to acyclovir or valacyclovir or any of the other ingredients of ACYCLOVIR 25 mg/ml ACCORD.

Warnings and precautions

Drug reaction with eosinophilia and systemic symptoms (DRESS) and Acute generalised exanthematous pustulosis (AGEP)

Your doctor will inform you on the risks of DRESS and AGEP.

Signs and symptoms that you need to look out for include the following:

Extensive skin rash, enlarged lymph nodes and a high fever (DRESS).

Rapid appearance of pin-head sized pustules typically starting on the face and skin flexures before becoming more widespread and fever (AGEP).

Please stop taking ACYCLOVIR 25 mg/ml ACCORD immediately and contact your doctor or seek medical attention if you notice any of these signs and symptoms mentioned above.

Your doctor will stop treatment and consider an alternative treatment.

Tell your doctor or healthcare provider before being given the injection:

- if you have kidney problems
- if you are over 65 years of age.

It is important that you drink plenty of water while taking ACYCLOVIR 25 mg/ml ACCORD.

Children and adolescents

ACYCLOVIR 25mg/ml ACCORD is given in children from 3 months and older.

Other medicines and ACYCLOVIR 25 mg/ml ACCORD

Always tell your healthcare provider if you are taking any other medicine.

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(This includes complementary or traditional medicines).

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
- lithium, used to treat mood disorders
- tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking ACYCLOVIR 25 mg/ml ACCORD

Driving and using machines:

It is not always possible to predict to what extent ACYCLOVIR 25 mg/ml ACCORD 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 ACCORD ACYCLOVIR 25 mg/ml affects you.

ACYCLOVIR 25 mg/ml ACCORD contains sodium.

ACYCLOVIR 25 mg/ml ACCORD contains 26 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. How ACYCLOVIR 25 mg/ml ACCORD will be administered to you:

You will not be expected to give yourself ACYCLOVIR 25 mg/ml ACCORD.

It will be given to you by a person who is qualified to do so.

ACYCLOVIR 25 mg/ml ACCORD will be given to you as a continuous infusion into your vein. This is where the medicine is slowly given to you over a period of time.

The dose you will be given, the frequency and the duration of the dose will depend on:

- the type of infection you have
- your weight
- your age.

Your doctor may adjust the dose of ACYCLOVIR 25 mg/ml ACCORD if:

- you have kidney problems. If you have kidney problems, it is important you receive plenty of fluids while you are being treated with ACYCLOVIR 25 mg/ml ACCORD.

Talk to your doctor before having ACYCLOVIR 25 mg/ml ACCORD if any of the above apply.

If you are given more ACYCLOVIR 25 mg/ml ACCORD than you should:

If you have been given too much ACYCLOVIR 25 mg/ml ACCORD you may:

- feel confused or agitated
- have hallucinations (seeing or hearing things that aren't there)
- have fits
- become unconscious (coma).

Since a healthcare professional will administer ACYCLOVIR 25 mg/ml ACCORD, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

If you forget to use ACYCLOVIR 25 mg/ml ACCORD:

Since a healthcare professional will administer ACYCLOVIR 25 mg/ml ACCORD, it is unlikely that the dose will be missed.

4. Possible side effects

ACYCLOVIR 25 mg/ml ACCORD can have side effects.

Not all side effects reported for ACYCLOVIR 25 mg/ml ACCORD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACYCLOVIR 25 mg/ml ACCORD, please consult your health care provider for advice.

If any of the following happens, stop using ACYCLOVIR 25 mg/ml ACCORD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- extensive skin rash or itching accompanied by fever, swollen lymph nodes and swelling of the face ((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 ACYCLOVIR 25 mg/ml ACCORD. You may need urgent medical attention or hospitalisation.

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

- yellowing of your skin and whites of your eyes (jaundice)

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:

- nausea (feeling sick),
- vomiting,
- increase in liver enzymes,
- skin reaction after exposure to light (photosensitivity),
- swelling, redness and tenderness at the site of injection,
- effects on some blood urine tests,
- fever

Less frequent side effects:

- reduced numbers of red blood cells (anaemia),
- reduced numbers of white blood cells (leukopenia),
- reduced numbers of blood platelets (cells that help the blood to clot) (thrombocytopenia),
- headache,
- feeling dizzy,
- diarrhoea,

- feeling tired,
- feeling weak,
- feeling agitated or confused,
- shaking or tremors,
- fits,
- hallucinations (seeing or hearing things that are not there),
- feeling unusually sleepy or drowsy,
- unsteadiness when walking or lack of coordination,
- difficulty speaking,
- inability to think or judge clearly,
- unconsciousness,
- Disturbances of behaviour, speech and eye movements,
- Inflammation of the liver,
- Kidney problems when you pass little or no urine,
- Pain in your lower back, the kidney area of your back or just above your hip (renal pain),
- paralysis of part or whole body.

Frequency unknown

- skin rash
- enlarged lymph nodes at two sites
- pin-head sized pustules.

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 or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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.

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By reporting side effects, you can help provide more information on the safety of ACYCLOVIR 25 mg/ml ACCORD.

5. How to store ACYCLOVIR 25 mg/ml ACCORD

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

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

Discard unused solution.

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

6. Contents of the pack and other information

What ACYCLOVIR 25 mg/ml ACCORD contains

The active substance is acyclovir.

The other ingredients are sodium hydroxide, hydrochloric acid and water for injection.

What ACYCLOVIR 25 mg/ml ACCORD looks like and contents of the pack

A clear, colourless or almost colourless solution, filled in a glass vial.

10, 20 or 50 ml clear glass vials (with filling volumes of 10, 20 and 40 ml respectively), rubber stopper and aluminium flip off seal.

It is supplied in pack size of 1 vial, 5 vials or 10 vials pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

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ACYCLOVIR 25 MG/ML – 10 ML VIAL ACCORD – 55/20.2.8/0369

ACYCLOVIR 25 MG/ML – 20 ML VIAL ACCORD – 55/20.2.8/0370

ACYCLOVIR 25 MG/ML – 40 ML VIAL ACCORD – 55/20.2.8/0371