**Package leaflet: Information for the user**

**Aciclovir Agila 25mg/ml Powder for Solution for Infusion**
Aciclovir

**Read all of this leaflet carefully before you start using 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 or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**:



## 1. What Aciclovir Agila is and what it is used for

Aciclovir Agila contains the active substance aciclovir. It belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses.

Aciclovir Agila can be used to:
- treat severe cases of genital herpes
- prevent or treat *Herpes simplex* infections (cold sores and genital herpes) in people whose immune systems work less well, which means their bodies are less able to fight infections
- treat *Herpes* simplex infections in children up to 3 months of age. This can rarely be caused by the virus responsible for cold sore infection and genital herpes.
- treat Herpes encephalitis (inflammation of the brain. This can rarely be caused by the virus responsible for cold sore infection and genital herpes.)
- treat *Varicella zoster* infections (shingles).

## 2. What you need to know before you use Aciclovir Agila

**Do not use Aciclovir Agila:**

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of this medicine (listed in Section 6).

Do not use Aciclovir Agila if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Aciclovir Agila.

**Warnings and precautions**

Talk to your doctor or pharmacist before using Aciclovir Agila if:

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

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

**Other medicines and Aciclovir Agila**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal 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
- tacrolimus, ciclosporin or mycophenolate mofetil, used to stop your body rejecting transplanted organs.
- lithium, used to treat manic-depressive disorders
- theophylline, used to treat some breathing disorders

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor or pharmacist for advice before using any medicine.

**Aciclovir Agila contains sodium**

This medicinal product contains less than 1 mmol sodium (24.5 mg) per dose, i.e. essentially ‘sodium- free.

## 3. How to use Aciclovir Agila

**How your medicine is given**

You will never be expected to give yourself this medicine. It will always be given to you by a person who is trained to do so.

Before the medicine is given to you it will be diluted.

Aciclovir Agila is for intravenous use and 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 1 hour.

Aciclovir Agila is usually given every 8 hours.

You may be given fluids to ensure you do not become dehydrated.

If Aciclovir Agila accidently gets into your eyes or onto your skin, tell your doctor or nurse immediately so that it may be washed away.

The dose you will be given, how often you are given it and the duration of the dose will depend on:

- the type of infection you have
- your weight
- your age
- how well your kidneys are working

If you are overweight, elderly or have kidney problems your doctor may reduce your dose of this medicine.

**Use in children**

The dose of Aciclovir Agila given to:

- children between 3 months and 12 years of age is calculated based on body surface area.
- newborns and infants up to 3 months of age is calculated based on body weight.
- If a child has kidney problems the dose of this medicine may be reduced.
- Treatment with this medicine usually lasts 14-21 days depending on the type of infection.

**Patients with kidney problems**

Your doctor may adjust the dose of Aciclovir Agila if you have kidney problems. If you have kidney problems, it is important you receive plenty of fluids while you are being treated with this medicine to ensure you do not become dehydrated.
Talk to your doctor before using Aciclovir Agila if this applies to you.

**Elderly patients**

If you are elderly your doctor may adjust your dose of Aciclovir Agila to avoid possible kidney problems.

It is important that you receive plenty of fluids to ensure you do not become dehydrated.

**If you are given more Aciclovir Agila than you should**

If you think you have been given too much Aciclovir Agila, talk to your doctor or nurse straight away.

If you have been given too much Aciclovir Agila you may:
- feel confused or agitated
- have hallucinations (seeing or hearing things that aren't there)
- have fits
- become unconscious (coma).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

If you have an allergic reaction, **stop taking Aciclovir Agila and see a doctor straight away**. The signs may include:
- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or trouble breathing
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Allergic reactions caused by using this medicine are very rare and may affect up to 1 in 10,000 users.

Other side effects include:

**Common** (may affect up to 1 in 10 people)
- feeling or being sick
- itchy, hive-like rash
- skin reaction after exposure to light (photosensitivity)
- itching
- swelling, redness and tenderness at the site of injection.

**Uncommon** (may affect up to 1 in 100 people)
- nosebleeds and bruising more easily than usual.

**Very rare** (may affect up to 1 in 10,000 people)
- headache or feeling dizzy
- diarrhoea or stomach pains
- feeling tired
- fever

- effects on some blood urine tests
- feeling weak
- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that aren't there)
- fits
- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination
- difficulty speaking
- inability to think or judge clearly
- unconsciousness (coma)
- paralysis of part or all of your body
- disturbances of behaviour, speech and eye movements
- stiff neck and sensitivity to light
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- kidney problems where you pass little or no urine
- pain in your lower back, the kidney area of your back or just above your hip (renal pain).

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via (See details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

## 5. How to store Aciclovir Agila

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Following dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user

For reconstituted solutions, chemical and physical in-use stability has been demonstrated for at least 12 hours at 25°C.

This medicine should not be used if it has visible particles in it.

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.

## 6. Contents of the pack and other information

### What Aciclovir Agila contains

The active substance is aciclovir.

One ml of the reconstituted solution for infusion contains aciclovir sodium dihydrate equivalent to 25 mg of aciclovir.

Each 10 ml vial contains aciclovir sodium dihydrate equivalent to 250 mg of aciclovir.

Each 20 ml vial contains aciclovir sodium dihydrate equivalent to 500 mg of aciclovir.

This medicinal product contains 24.5 mg sodium per dose.

### What Aciclovir Agila looks like and contents of the pack

Aciclovir Agila 25mg/ml powder for solution for infusion is supplied in glass vials, containing white to off white lyophilized powder.

It is available in 10 ml and 20ml vials, and supplied in a box containing either 1, 5 or 10 vials.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation holder**
<To be completed nationally>

**Manufacturer**
<To be completed nationally>

**This medicinal product is authorised in the Member States of the EEA under the following names:**
AT: Aciclovir Agila 25mg/ml Pulver zur Herstellung einer Infusionslösung
BE: Aciclovir Agila 250mg poeder voor oplossing voor infusie
Aciclovir Agila 500mg poeder voor oplossing voor infusie
DE: Aciclovir Agila 25mg/ml Pulver zur Herstellung einer Infusionslösung
DK: Aciclovir Agila
ES: Aciclovir Agila 25mg/ml polvo para solución para perfusion
FI: Aciclovir Agila 25mg/ml infuusiokuiva-aine, liuosta varten
FR: ACICLOVIR AGILA 25 mg/ml, poudre pour solution pour perfusion
IT: Aciclovir Agila Specialties UK

PL: Aciclovir Agila
SE: Aciclovir Agila 25mg/ml Pulver till infusionsvätska, lösning
UK: Aciclovir 25 mg/ml powder for solution for infusion

**The leaflet was last revised in {MM/YYYY}**
<To be completed nationally>

**The following information is intended for healthcare professionals only.**

**TECHNICAL LEAFLET**

**Aciclovir Agila 25mg/ml powder for solution for infusion**

## Special precautions for disposal and other handling

Reconstitution: Aciclovir Agila should be reconstituted using the following volumes of either Water for Injections or Sodium Chloride 9 mg/ml (0.9% w/v) *solution for infusion* to provide a solution containing 25 mg aciclovir per ml:

| *Formulation* | *Volume of solution for reconstitution* |
|---|---|
| 250 mg vial | 10 ml |
| 500 mg vial | 20 ml |

From the calculated dose, determine the appropriate number and size of vials to be used. To reconstitute each vial add the recommended volume of infusion solution and shake gently until the contents of the vial have dissolved completely.

**Administration:**

After reconstitution Aciclovir Agila may be administered by a controlled-rate infusion pump.

Alternatively, the reconstituted solution may be further diluted to give an aciclovir concentration of not greater than 5 mg/ml (0.5% w/v) for administration by infusion:

Add the required volume of reconstituted solution to the chosen infusion solution, as recommended below, and shake well to ensure adequate mixing occurs.

For children and neonates, where it is advisable to keep the volume of infusion solution to a minimum, it is recommended that dilution is on the basis of 4 ml reconstituted solution (100 mg aciclovir) added to 20 ml of infusion solution.

For adults, it is recommended that infusion bags containing 100 ml of infusion solution are used, even when this would give an aciclovir concentration substantially below 0.5% w/v. Thus one 100 ml infusion bag may be used for any dose between 250 mg and 500 mg aciclovir (10 and 20 ml of reconstituted solution) but a second bag must be used for doses between 500 mg and 1000 mg.

When diluted in accordance with the recommended schedules, Aciclovir Agila is known to be compatible with the following infusion solutions and stable for up to 24 hours at room temperature (25°C):

Sodium Chloride 4.5 mg/ml (0.45%) and 9 mg/ml (0.9% w/v) *solution for infusion*

Sodium Chloride 1.8 mg/ml (0.18% w/v) and Glucose (4% w/v) *solution for infusion*

Sodium Chloride 4.5 mg/ml (0.45% w/v) and Glucose (2.5% w/v) *solution for infusion*

Compound Sodium Lactate (Hartmann's Solution) *solution for infusion*.

Aciclovir Agila when diluted in accordance with the above schedule will give an aciclovir concentration not greater than 0.5% w/v.

This medicinal product is for single use only.

Aciclovir Agila contains no antimicrobial preservative. Reconstitution and dilution should therefore be carried out under full aseptic conditions immediately before use and any unused solution discarded. The reconstituted or diluted solutions should not be refrigerated.

The medicinal product is to be visually inspected prior to use (also after dilution). *Only clear solutions practically free from particles should be used*. Should any visible turbidity or crystallisation appear in the solution before or during infusion, the preparation should be discarded.

Displacement value for the powder is 0.50mL and the final volume in the container after reconstitution is 10.50mL

**Shelf life**
2 years

Following dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
For reconstituted solutions, chemical and physical in-use stability has been demonstrated for at least 12 hours at 25°C.

**Special precautions for storage**
This medicinal product does not require any special storage conditions.