Manufactured by:
STADA Arzneimittel AG, Stadastraβe 2-18, D-61118 Bad Vilbel, Germany

Acyclovir Stada® Cream

Composition
1 g of cream contains:
Pharmacologically active ingredient: Acyclovir 50mg
Other Ingredients: Steaoryl macrogolglycerides, Dimeticone, Cetyl alcohol, Liquid paraffin, White soft paraffin, Propylene glycol, Purified water
Presentation and contents:
White to off-white homogenous cream
Original packages of 2g or 5g of cream
Acyclovir Stada® is an anti-viral drug For external use only
Indications
Treatment of herpes simplex virus infection of the skin including initial and recurrent genital herpes and herpes labialis.
Mode of Action
Acyclovir is a guanine derivative whose activity is essentially confined to viral thymidine kinase-producing human pathogenic herpes viruses, i.e. herpes simplex virus types 1 and 2 (HSV-1 and HSV-2), and varicella-zoster virus (VZV). Acyclovir is not pharmacologically active until it has been converted by viral thymidine kinase inside virally infected cells along the following pathway:
Phosphorylation of acyclovir (the substrate) to acyclovir monophosphate is faster by viral thymidine kinase than by host cell thymidine kinase. The relative selectivity minimizes the toxicity of acyclovir to host cells. Normal cellular nucleotidyl phosphotransferases then catalyse the sequential conversion of acyclovir monophosphate to acyclovir triphosphoate. Acyclovir triphosphate (the active form of the drug) selectively inhibits viral DNA polymerase and is incorporated into viral DNA. Acyclovir triphosphate competitively displaces deoxyguanosine triphosphate from DNA polymerases. Acyclovir triphosphate has higher affinity for HSV-encoded DNA polymerase than cellular DNA polymerase (10 to 20 times greater). It acts as a substrate for HSV-encoded DNA polymerase and, cleaving of diphosphate is incorporated into viral DNA. However, as acyclovir lacks a 3-hydroxyl group, nucleotides can no longer be added by 3',5'-linkage, causing chain termination. Moreover, the DNA-viral polymerase complex remain intact, inactivating the enzyme. Acyclovir activity is greatest against HSV-1 and HSV-2 because these depend on their own thymidine kinase for replication. Acyclovir is also a substrate for VZV-encoded thymidine kinase, but the concentrations required for anti-VZV activity are higher. Acyclovir also inhibits EBV DNA polymerase. Toxicity to the host cell is low because of the drug's high affinity for viral enzymes. Acyclovir is also active against the Epstein-Barr virus (EBV), cytomegalovirus (CMV) and other herpes viruses (varicella-like simian virus, DHV 1, neurotropic and tumour viruses pseudorabies virus, PDV), but to a lesser extent and may act via a different mechanism of action.
Pharmacokinetics Absorption
Percutaneus drug absorption from topical dosage forms depends on the ability of the drug (active ingredient) to penetrate the skin as well as on the vehicle.
An in-vitro study on the penetration capacity of acyclovir using PEG (polypropylene glycol) modified aqueous base and DMSO (dimethylsulphoxide) demonstrated an increase of 8- and 60 fold-fold increase in the release of acyclovir from the modified aqueous vehicle and DMSO compared to PEG ointment. The composition of Acyclovir Stada® Cream is essentially identical with the composition of hydrophilic [poly]propylene glyco-based acyclovir cream, but it was improved by using substances with a lower potential for skin irritancy, while maintaining the dermal penetration profile of the former formulation. Hence the vehicle formulation used in Acyclovir Stada® Cream shows good percutaneous absorption.
Bioavailability
Systemic absorption of topical acyclovir is minimal and the resulting blood levels are below the limit of detection. It is therefore impossible to characterize the kinetics of bioavailability of topical acyclovir. Toxic effects are unlikely with topical acyclovir because the drug does not reach the systemic circulation.
Contraindications
You must not use Acyclovir Stada® if you know you are hypersensitive to acyclovir or any other ingredient of Acyclovir Stada®. You should not apply Acyclovir Stada® to mucous membranes (e.g. oral cavity, eye or vagina to avoid local irritation.
The situations described here relate to certain conditions in which Acyclovir Stada® should be used only with particular caution. Discuss with your doctor, also if any of these conditions applied to you previously. Be sure to inform your doctor before starting therapy if you are severely immunocompromised (i.e. if your body's immune system is severely impaired.)
Precautions for use and warning:
Warning:
When using Acyclovir Stada® in the genital or anal region and a latex condom at the same time, the condom's resistance to tear may be reduced by the paraffin and petroleum jelly contained in Acyclovir Stada®, compromising condom reliability.
Use in Pregnancy
No information is available on the effects of administration of Acyclovir cream during human pregnancy.
Interactions with other drugs
No interactions with other drugs are known to date.
Dosage and administration, duration of therapy
The instructions given below apply unless your doctor has prescribed Acyclovir Stada® otherwise for you. Please comply with these and/or your doctor's instructions for effective and safe Acyclovir Stada® therapy.

Apply a thin film of cream to infected skin areas 5 times daily every4 hours.

Use a cotton swab to take up as much cream as is necessary to cover the infected skin area(s). As you apply Acyclovir Stada®, be sure to cover not only the areas with visible signs of herpes infection (vesicles, swelling, reddening) but adjacent areas as well. Should you be applying Acyclovir Stada® with your hand(s), be sure to wash these thoroughly both before and after cream application to prevent additional infection of the compromised skin area(s) (with bacteria etc.) and/ or viral carry over to other, as yet uninfected mucosal or skin areas.
Please note:
For best response, Acyclovir Stada® therapy should be started as early as possible, i.e. as soon as you notice the first signs of herpes (burning, itching, discomfort, reddening).

Your doctor will determine how long you should continue Acyclovir Stada® therapy. Treatment is usually continued for 5 days but therapy should be individualized and continued until vesicular crusting or healing has been achieved. However, the duration of therapy should not exceed 10 days.
Violations of dosing schedule and overdosage action
If you used less than the prescribed dose of Acyclovir Stada® or missed dose, continue therapy as prescribed (so do not apply the cream more often and do not apply a thicker film or cream.)
Please bear in mind if you wish to interrupt or stop Acyclovir Stada® early that you should use Acyclovir Stada® sufficiently long to ensure best results (see "Dosage and Administration, duration of therapy").
Side effects
Should you experience any adverse effects not described in this Insert, please be sure to inform your doctor or pharmacist. Application of Acyclovir Stada® may produce transient burning or stinging of the treated skin areas. Reddening, drying and scaling of Acyclovir Stada®- treated skin have occasionally been observed.
There have been rare reports of allergic skin reactions contact dermatitis following the use of Acyclovir Stada®. In most cases where allergological testing was performed, the pharmaceutical aids of the cream base rather than the active ingredient Acyclovir proved the cause of the skin reaction. You may be suffering from contact dermatitis if the above side effects are pronounced and involve also skin areas beyond those treated with the cream. Discuss with your doctor.

Shelf life and stability of this medicine
The expiry date of this medical products is shown on the tube and box.
Do not use this product after this expiry date.
Do not use this product after 12 months after opening.
Do not store above 30°C
Keep drugs out of reach of children
Date of revision
05 November 2020