Prescribing Information
STADA Arzneimittel AG, D-61118 Bad Vilbel, Germany
Dear patient,
Please be sure to carefully read this Insert because it contains important information on how to use this medication effectively and safely. If you have any questions or concerns, please do not hesitate to ask your doctor or pharmacist.

Acyclovir 800 Stada®

Product Description
Oblong, White tablet with breaking notch on both sides. Imprint: VS3
Composition
Each tablet contains:
Pharmacologically active ingredient: Acyclovir, 800mg
Other ingredients:
Microcrystalline cellulose, copolyvidon, magnesium stearate, sodium starch glycolate, colloidal anhydrous silica
Presentation and contents
Original package of 35 tablets (7 blisters x 5 tablets)
Acyclovir 800 Stada® is an antiviral drug
Pharmacodynamics
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 (VSV). 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. This relative selectivity minimizes the toxicity of acyclovir to host cells. Normal cellular nucleotidyl phosphotransferases then catalyse the sequential conversion of acyclovir monophosphate to acyclovir triphosphate. 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 nom 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 off 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 VSV-encoded thymidine kinase, but the concentrations required for anti-VSV activity are higher. Acyclovir also inhibits EBV DNA polymerase. Toxicity to the host cell is low because of the drug's affinity for viral enzymes. Acyclovir is also active against Esptein-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 a different mechanism of action may be involved.
Pharmacokinetics
Only part of an [oral] acyclovir does is absorbed from the gastro-intestinal tract. The mean peak plasma concentrations at steady state following repeated oral administration of 200mg, 400mg or 800mg of acyclovir 5 times daily every 4 hours [during the day] were 3.02 + 0.5µmol/l (200mg), 5.21 + 1.32µmol/l (400mg) or 8.16 + 1.98µmol/l (800mg). These values were attained after about 1.5 + 0.6 hours. Plasma trough levels (determined about 4 hours after the last oral acyclovir dose) were 1.61 + 0.3 µmol/l (200mg), 2.59 + 0.53 µmol/l (400mg), or 4.0 + 0.72 µmol/l (800mg). No drug was detectable in the body 24 hours after stopping acyclovir tablets.
Immunocompromised (3 to 11-year-old) children received 400mg of oral acyclovir (equivalent to 300-650mg of acyclovir/m2) 5 times daily and showed mean peak plasma concentrations of 5.7-15.1 µmol/l infants (1-6 weeks old) were administered 600mg of acyclovir/m2 every 6 hours and had peak plasma concentrations of 17.3 or 8.6µmol/l.
The biexponential kinetics of acyclovir suggest that the drug attains high concentrations in tissues and organs and is eliminated from these at a slow rate. The volume of distribution at steady state was 50 + l/1.73 m2 in adults and 28.8 + 9.3 l/1.73 m2 in neonates and infants up to 3 months old. Protein binding ranged between 9 and 33%.
Indications
Shingles (herpes zoster).
Contraindications
When should you not take Acyclovir 800 Stada® ?
You must not take Acyclovir 800 Stada® if you know you are hypersensitive to acyclovir or any other ingredient of Acyclovir 800 Stada®
What should you be aware of if you are pregnant or breast-feeding?
The treating doctor will have to carefully weigh expected benefits against potential risks in pregnant women in whom Acyclovir 800 Stada® therapy proves necessary.
Acyclovir has been detected in breast milk following administration of acyclovir products. Breast-feeding is therefore discouraged while taking Acyclovir 800 Stada®.
What should you be aware if you are elderly?
Elderly patients are more likely to have impaired kidney function than are younger people.
Elderly patients, therefore, are recommended to have their kidney function checked and ensure an adequate fluid intake while taking Acyclovir 800 Stada® tablets.
Also, the treating doctor may want to adjust your dosage (see "Dosage and Administration, duration of therapy").
Precautions for use and warnings:
What should you be aware of?
See "Contraindications" and "Dosage and administration, duration of therapy".
Interactions with other drugs:
What other medicines are known to interfere with the effects of Acyclovir 800 Stada® ?
Probenecid (uricosuric drug for gout) reduces acyclovir excretion via the kidneys, which may increase acyclovir persistence in the body. Please bear in mind that these interactions may also apply to recently used medicines.
Dosage and administration, duration of therapy
The instructions given below apply unless your doctor has prescribed Acyclovir 800 Stada® otherwise for you. Please comply with these and/or your doctor's instructions for effective and safe Acyclovir 800 Stada® therapy.
How many tablets and how often should you take Acyclovir 800 Stada® ?
Recommended dosage:
Adults:
Shingles (herpes zoster)
Take 1 tablet (800mg) of acyclovir 5 times daily every 4 hours during the day.
Patients with impaired kidney function:
(see "Contraindication")
Patients with kidney function impairment, which is particularly prevalent in elderly patients, may need a lower acyclovir dose than indicated above. If you should have kidney problems, your doctor will adjust your dosage to reflect your kidney function (see below).

Indication	Creatinine clearance	Serum creatinine (µmol/l) respectively (mg/dl)		Dosage
	(ml/min/1.73 m^2)	Women	Men	
Herpes zoster	25 – 10	280-550/ 3.17-6.22	370-750/ 4.18-8.48	1 tablet (800 mg of acyclovir) 3 times daily (every 8 hours)
	<10	>550/ >6.22	>750/ >8.48	1 tablet (800 mg of acyclovir) twice daily (every 12 hours)

How and when should you take Acyclovir 800 Stada® ?
Swallow the tablets whole with a sufficient amount of liquid (eg a glass of water) after meals. An adequate fluid intake must be ensured during Acyclovir 800 Stada® therapy, especially in patients with impaired kidney function.
Please note:
For best response, Acyclovir 800 Stada® therapy should be started as early as possible, ie as soon as you notice the first signs on your skin.
For how long should you take Acyclovir 800 Stada® ?
Your doctor will determine for how long you should continue Acyclovir 800 Stada® therapy.
The duration of therapy of herpes zoster is 7 days.
Violations of dosing schedule and overdose action
What should you do in the event of a (deliberate or inadvertent) Acyclovir 800 Stada® overdose?
Intoxication is unlikely after an Acyclovir 800 Stada® overdose. A single dose of 5 g of acyclovir produced no signs or symptoms of intoxication. However, no data are available for higher single over doses.
If you suspect an overdose, should experience pronounced side effects or are in doubt, be sure to discuss with your doctor any concerns you may have.
Treatment of overdose
Acyclovir is effectively eliminated by haemodialysis.
What should you do if you took less than the prescribed dose of Acyclovir 800 Stada® or missed dose?
Continue therapy as prescribed (so do not take your Acyclovir 800 Stada® tablets more often or in larger doses). If you missed several doses, discuss with your doctor.
What should you bear in mind if you wish to interrupt or stop Acyclovir 800 Stada® early?
Even as your well-being may improve appreciably, you should complete Acyclovir 800 Stada® therapy as prescribed by your doctor so as not to jeopardise outcome. Should you be in doubt – because of side effects for example – discuss with your doctor before interrupting or stopping treatment.
Side effects
What adverse reactions could you experience while using Acyclovir 800 Stada® ?
To date, Acyclovir 800 Stada® has occasionally been associated with the following side effects:
Skin rashes disappearing upon discontinuation of the medicinal product, gastro-intestinal symptoms including nausea, vomiting, diarrhoea, and abdominal pain.
There have also been occasional reports of neurological (affecting the nervous system) side effects, mainly dizziness, confusion, hallucinations and drowsiness.
These side effects disappeared upon discontinuation of the medicinal product and were typically seen in patients with impaired kidney function or other conditions pre-disposing to this sort of adverse reactions.
Moreover, there have been isolated reports or depersonalisation experiences disappearing upon discontinuation of the medicinal product. Transient convulsions and psychoses have need observed, especially with acyclovir administered by intravenous infusion to patients with complicated clinical courses.
There have been rare reports of transient laboratory adverse effects relating to liver and kidney function as well as the blood (bilirubin, liver enzyme, serum urea nitrogen and/or serum creatinine elevations, and/or serum creatinine elevations, and/or slight reductions in haematological parameters). There have also been rare reports of head-ache, exhaustion, insomnia or fatigue.

The rare patient has experienced difficulty breathing. There have been occasional reports of diffuse loss of hair associated with the use of Acyclovir 800 Stada®, but a causal relationship is unclear.
Should you experience any adverse effects not described in this insert, please be sure to inform your doctor or pharmacist.

Shelf life and stability of this medicine

The expiry date of this medicinal product is shown on the box and blister foil. Do not use this product after this expiry date.
Do not store above 30°C

Specification: In house

Sold only by prescription

Keep drugs out of reach of children

STADA

Produkt/Product: **ACYCLOVIR 800MG TAB SD MY:PIL**
STADA Mat.-Nr./Mat.-No.: **9299559** DZ: **2012**
STADA Art.-Nr./Art.-No.: **167988**
Hersteller/Manufacturer: **STADA AG**
Hersteller Art.-Nr./ Manufacturer Art.-No.: **-**
Format/Size: **148 x 420 mm**
Schriftgröße/Font-size: **7 pt - 13 pt**
NTIN/GTIN: **-**
PZN/EAN: **-**
Pharma-Code: **122**
Flattermarke/Collating mark: **-**
1. Farbe/Colour: **Black**
2. Farbe/Colour: -
3. Farbe/Colour: -
4. Farbe/Colour: -
5. Farbe/Colour: -
6. Farbe/Colour: -
7. Farbe/Colour: -
8. Farbe/Colour: -
Version: **2. Loop** Datum/Date: **01.02.2021**
Agentur/Agency: **STADA Agency**
Grafik erstellt von/Graphic made by: **S.R.**
Aktueller Umlauf/Current loop: **S.R.**
Genehmigt/Approved

9299559
2012 MY