

Cyclovex® Tablets

Acyclovir

DESCRIPTION

Cyclovex® (Acyclovir) is an antiviral agent active against the Herpes simplex and Chickenpox-Zoster viruses. Cyclovex® (Acyclovir) is available as 200 and 400 mg scored tablets for oral administration.

Inactive ingredients:

- For the 200 mg tablets: Lactose, microcrystalline cellulose, sodium starch glycolate, polyvinylpyrrolidone, magnesium stearate.
- For the 400 mg tablets: Microcrystalline cellulose, sodium starch glycolate, polyvinylpyrrolidone, red ferrous oxide (E172), magnesium stearate.

INDICATIONS

- Cyclovex® tablets are indicated:
- for the treatment of Herpes simplex infections of the skin and mucosa, including primary and recurring Herpes genitalis.
 - for the suppression of Herpes simplex recurrences in patients with normal immune function.
 - for the prophylaxis of Herpes simplex infections in patients with compromised immune function.
 - for the treatment of Chickenpox and Herpes zoster.

CONTRAINDICATIONS

The oral formulations of the product are contraindicated in patients with known hypersensitivity to Acyclovir.

PRECAUTIONS

Pregnancy: As the clinical data on administration during pregnancy are limited, the drug should be administered in this condition only in cases of absolute necessity, and under the direct supervision of the doctor.

Breastfeeding: Cyclovex® should not be used during breastfeeding.

For children, elderly patients and patients with specific clinical conditions: See "Dosage and Administration".

DRUG INTERACTIONS

Probenecid increases the retention time and concentration of Acyclovir in the blood. Other drugs that interfere with the kidney functions could modify certain Acyclovir indices in the blood. However, in clinical practice, no other interactions with Acyclovir have been observed.

WARNINGS

No negative effects caused by Cyclovex® tablets on the ability to drive or operate machinery are known.

DOSE AND ADMINISTRATION

Adults

Treatment of Herpes simplex infections: One 200 mg tablet, taken 5 times a day at intervals of 4 hours, with no nocturnal dose. The treatment should be continued for 5 days, but in the case of severe primary infections may have to be extended.

In patients with severely compromised immune function (e.g. after a bone marrow transplant), or in patients with reduced intestinal absorption, the dosage may be doubled.

The therapy should begin as soon as possible and, in the case of recurring infections, preferably on the occurrence of the first symptoms or when the first lesions appear.

For suppressive therapy of recurring infections from Herpes simplex in patients with normal immune function:

One 200 mg tablet 4 times a day, at 6 hour intervals.

Many patients can be successfully treated with the administration of 400 mg in tablet form twice a day at 12 hour intervals.

Also doses of 200 mg in tablet form 3 times a day at 8 hour intervals or twice a day at 12 hour intervals, may be effective.

In some patients, relapses of the infection may take place with a total daily dosage of 800 mg of Cyclovex® tablets.

The therapy should be periodically suspended at intervals of 6 to 12 months, to observe any changes in the natural progress of the illness.

For the prophylaxis of the infections from Herpes simplex in patients with compromised immune function:

One 200 mg tablet 4 times a day at 6 hour intervals. In patients with severely compromised immune function (e.g. after a bone marrow transplant) or in patients with reduced intestinal absorption dosage may be doubled.

The duration of the prophylaxis should be considered in relation to the risk period.

Treatment of Herpes zoster and Chickenpox

Tablets administration times in the course of the day

Time	11:00	15:00	19:00	23:00
breakfast	late morning	early afternoon	late afternoon	evening

800 mg in tablet form 5 times a day at 4 hour intervals, with no nocturnal dose.

The treatment should be continued for 7 days. The therapy should begin immediately after the emergence of the infection, as the best results are obtained if treatment starts at the appearance of the first lesions.

Children

For treatment of infections caused by Herpes simplex and the prophylaxis of these in children over two years of age with normal or compromised immune function, the dosage is similar to that of adults. For children under two years of age, a half dose should be administered.

For the treatment of chickenpox in children over 6 years old, the dosage is 800 mg in tablet form, 4 times a day. In children aged between 2 and 6, the dosage is 400 mg in tablet form 4 times a day. The product should not be taken by children under 2 years of age, as its efficacy and safety in this age range have not been established. A more precise dosage is obtained with the administration of 20 mg/Kg of body weight 4 times a day (without exceeding 800 mg). The treatment should be continued for 5 days.

Specific data on the suppression of infections caused by Herpes simplex or the treatment of Herpes zoster in children with normal immune function are not available.

Elderly patients

In elderly patients, the total elimination of Acyclovir decreases with the reduction of certain kidney function indices associated with aging. In patients who take large quantities of Acyclovir orally, a sufficient liquid intake should be maintained.

Special care should be taken to assess the possibility of reducing the dose in elderly patients with compromised kidney functions.

Patients with compromised kidney functions

In the treatment of infections caused by Herpes simplex in patients with compromised kidney functions, the recommended oral dosage should not cause an accumulation of Acyclovir beyond the tolerable levels, determined after the intravenous administration of the drug. However, in patients with severe kidney malfunction (creatinine clearance below 10 ml/min), we recommend adjusting the dosage to 200 mg, administered twice a day at 12 hour intervals.

In the treatment of Chickenpox and Herpes zoster, we recommend modifying the dosage to 800 mg in tablet form, to be taken twice a day at 12 hour intervals in patients with severe kidney malfunction (creatinine clearance below 10 ml/min), and to 800 mg in tablet form 3 times a day, at 8 hour intervals in patients with moderate kidney malfunction (creatinine clearance between 10 and 25 ml/min).

OVERDOSAGE

Acyclovir is only partially absorbed at intestinal level. It is therefore improbable that there will be severe toxic effects when 5g of Acyclovir are taken in a single dose.

Data on the consumption of greater quantities are unavailable.

Single intravenous doses up to 80 mg/Kg have been administered accidentally without causing side effects.

Treatment: Patients who have taken doses of Acyclovir greater than 5g should be kept under close observation. Acyclovir can be dialysed.

SIDE EFFECTS

In some patients, after oral administration of Cyclovex®, cutaneous eruptions have been observed, but these disappear quickly after the suspension of the therapy.

In the digestive system, symptoms such as nausea, vomiting, diarrhea and abdominal pain have been observed.

Occasionally, reversible neurological reactions have been noted, such as dizziness, states of confusion, hallucinations and sleepiness, usually in patients with kidney malfunction or other inducing factors.

Occasionally, rapid and widespread hair loss has been noted. As this condition is associated with a wide number of illnesses and drugs, its correlation with Acyclovir is uncertain. Rarely, after oral consumption of Cyclovex®, a modest and transitory increase in the bilirubin values and the enzymes in the liver and kidneys has been observed. Moderate urea and creatinine increases have also been reported, together with slight decreases in blood indices, headache and fatigue.

Inform the doctor or pharmacist of the emergence of any side effects not described in this instruction leaflet.

IMPORTANT: Do not use the drug after the expiry date shown on the pack.

PACKAGING QUANTITIES

Tablet 200 mg - blister pack of 30's

Tablet 400 mg - blister pack of 40's

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICAMENT OUT OF CHILDREN'S REACH

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