

Information for use

WARIVIRON 200 mg

Active ingredient: Aciclovir

COMPOSITION: Active ingredient: 1 tablet contains 200 mg Aciclovir. Inactive ingredients: Starches, cellulose, polyvidone, silica, magnesium stearate.

INDICATIONS: Skin and mucous membrane infections by herpes simplex, especially genital herpes (primary and frequently recurrent infections of the genital region); the preventive treatment of adults suffering from very serious forms of frequently recurrent genital herpes simplex infections is recommended.

CONTRAINDICATIONS: Hypersensitivity to Aciclovir. In case of a limited renal function or a reduced urine production (less than 100 ml / 24 hours) WARIVIRON 200 mg should not be used prophylactically.

If a treatment during pregnancy becomes inevitable, risk and benefit have to be considered carefully by the physician. After taking preparations containing Aciclovir the latter has been detected in mother's milk. Therefore nursing is to be discontinued during the course of treatment with Aciclovir.

The elderly suffer more often from a disturbed renal function than other patients so that its check is recommended and special care should be taken that sufficient liquids are taken during the application of the tablets.

ADVERSE EFFECTS: The following information is also valid for a preparation having been taken recently.

Probenecide reduces the renal excretion of Aciclovir, which may lead to an extended availability of Aciclovir in the body.

ADMINISTRATION, DURATION OF TREATMENT AND DOSAGE: Unless otherwise prescribed adults take in case of infections due to herpes simplex 1 tablet 5 times daily at intervals of 4 hours.

Prophylactically against serious forms and very frequently recurrent genital infections by herpes simplex adults with a healthy immunological system take 1 tablet 4 times daily at intervals of 6 hours. In isolated cases a successful prophylactic treatment is possible with 1 tablet 3 times daily at intervals of 8 hours or 1 tablet 2 times daily at intervals of 12 hours respectively. Adults with an impaired immunological system take prophylactically 1 tablet 4 times daily at intervals of 6 hours and those with a seriously impaired immunological condition (e.g. following organ transplantation) take 2 tablets 4 times daily at intervals of 6 hours.

In case of infections by herpes simplex children over the age of 2 years get the dose for adults while younger children get half of it.

A disturbed renal function may lead to a reduced dosage to be determined by the physician according to the impairment:

In case of a creatinine clearance $< 10 \text{ ml/min./1.73 m}^2$ and a serum creatinine $> 550 \text{ }\mu\text{mol/l}$ ($> 6.22 \text{ mg/dl}$) in women or $> 750 \text{ }\mu\text{mol/l}$ ($> 8.48 \text{ mg/dl}$) in men the dosage is 1 tablet 2 times daily at 12 hours' intervals to treat infections due to herpes simplex.

Take the tablets unchewed with sufficient liquid, preferably after meals. In case of a disturbed renal function special attention has to be paid to an adequate intake of liquid during treatment.

Important note: WARIVIRON 200 mg should be taken as early as possible after first symptoms of an infection have become manifest. Particularly in case of recurrent herpes simplex infections the intake of WARIVIRON 200 mg should be started as soon as the first symptoms (e.g. itching, tension and blistering) have occurred.

Herpes simplex infections are usually treated for 5 days but the medication may be prolonged if necessary. The duration of prophylaxis in patients with a healthy immunological condition depends on the severity of the courses and their tendency to relapse but it should not exceed 6-12 months. In case the immunological system is seriously damaged this period depends on the impairment and is fixed by the physician according to the individual case.

If too large quantities of WARIVIRON 200 have been taken (overdosage), please consult your physician. If you have taken a too small quantity of WARIVIRON 200 or forgotten the intake, do not take more than the prescribed quantity with the next intake and inform your physician accordingly.

SIDE EFFECTS: The following side effects have been observed, disappearing when the application is discontinued. **Occasionally:** Skin rashes and gastro-intestinal disturbances such as nausea, vomiting, diarrhea and abdominal pain; neurological symptoms mainly as vertigo, states of confusion, hallucinations and somnolence, which usually occur with patients suffering from a disturbed renal function or other diseases favouring these side effects; increased loss of hair (diffuse hair loss) in an unclear relation with the intake of Aciclovir. **Seldom:** Temporary changes in certain liver, kidney and blood picture values (increase in bilirubin, liverenzymes, serum urea and creatinine and a slight decrease in the hematological parameters); headache, weariness, sleeplessness and tiredness; respiratory complaints. **In isolated cases:** states of estrangement; temporary attacks of cramp and psychoses especially when Aciclovir is applied intravenously in complicated courses of disease.

Hint: Do not use this medicament after its expiry!

Medicament, to be stored inaccessible to children!