AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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LEAFLET

AGOVIR-400

(Aciclovir Tablets BP 400mg)

Composition:
Each uncoated tablet contains:
Aciclovir BP 400mg
Excipients q.s

Therapeutic indications:
Aciclovir tablet 400 mg are indicated for the treatment of varicella (chickenpox) and herpes zoster (shingles) infections (excluding neonatal HSV and severe HSV infections in immune compromised children).
Aciclovir400mg tablet is recommended in children over the age of 6.

Posology and method of administration:
Dosage:
Varicella zoster (chickenpox), treatment / Herpes zoster (shringles), treatment:
400 mg Aciclovir should be taken
By mouth
- Child 1-23 months: 200 mg 4 times a day for 5 days
- Child 2-5 years 400 mg 4 times a day for 5 days
- Child 6-11 years: 800 mg 4 times a day for 5 days
- Child 12-17 years : 800 mg 5 times a day for 7 days
- Adult: 800 mg 5 times a day for 7 days

By INTRAVENOUS INFUSION
- Adult: 5 mg/kg every 8 hours usually for 5 days.

Herpes simplex, suppression:
By mouth
- Child 12-17 years : 400 mg twice daily, alternatively 200 mg 4 times a day; increased to 400 mg 3 times a day, dose may be increased if recurrences occur on standard suppressive therapy or for suppression of genital herpes during late pregnancy (from 36 weeks gestation),therapy interrupted every 6-12 months to reassess recurrence frequency-consider restarting after two or more recurrences.
- Adults: 400 mg twice daily, alternatively 200 mg 4 times a day; increased to 400 mg 3 times a day, dose may be increased if recurrences occur on standard suppressive therapy or for suppression of genital herpes during late pregnancy (from 36 weeks gestation), therapy interrupted every 6-12 months to reassess recurrence frequency – consider restarting after two or more recurrences.

Administration:
Aciclovir 400 BP tablets are for oral administration and may be dispersed in a minimum of 50 ml of water or swallowed whole with a little water. Ensure that patients on high doses of aciclovir are adequately hydrated.

Contraindications:
Hypersensitivity to aciclovir or valaciclovir.

Use in patients with renal impairment and in elderly patients:
Aciclovir is eliminated by renal clearance, therefore the dose must be adjusted in patients with renal impairment. Elderly patients are likely to have reduced renal function and therefore the need for dose adjustment must be considered in this group of patients. Both elderly patients and patients with renal impairment are at increased risk of developing neurological side effects and should be closely monitored for evidence of these effects. In the reported cases, these reactions were generally reversible on discontinuation of treatment. Prolonged or repeated courses of aciclovir in severely immune-compromised individuals may result in the selection of virus strains with reduced sensitivity, which may not respond to continued acyclovir treatment..*Hydration status:* Care should be taken to maintain adequate hydration in patients receiving high doses of aciclovir. The risk of renal impairment is increased by use with other nephrotoxic drugs. The data currently available from clinical studies is not sufficient to conclude that treatment with aciclovir reduces the incidence of chickenpox-associated complications in immune competent patients.

Interaction with other medicinal products and other forms of interaction:
Aciclovir is eliminated primarily unchanged in the urine via active renal tubular secretion. Any drugs administered concurrently that compete with this mechanism may increase aciclovir plasma concentrations. Probenecid and cimetidine increase the AUC of aciclovir by this mechanism, and reduce aciclovir renal clearance. Similarly increases in plasma AUCs of aciclovir and of the inactive metabolite of mycophenolatemofetil, an immune suppresant agent used in transplant patients have been shown when the drugs are co-administered. However no dosage adjustment is necessary because of the wide therapeutic index of aciclovir.

An experimental study on five male subjects indicates that concomitant therapy with aciclovir increases AUC of totally administered theophylline with approximately 50%. It is recommended to measure plasma concentrations during concomitant therapy with aciclovir.

Fertility, pregnancy and lactation
Pregnancy:
The use of aciclovir should be considered only when the potential benefits outweigh the possibility of unknown risks.
A post-marketing aciclovir pregnancy registry has documented pregnancy outcomes in women exposed to any formulation of Aciclovir. The registry findings have not shown an increase in the number of birth defects amongst Aciclovir exposed subjects compared with the general population, and any birth defects showed no uniqueness or consistent pattern to suggest a common cause. Systemic administration of aciclovir in internationally accepted standard tests did not produce embryotoxic or teratogenic effects in rabbits, rats or mice.

Side Effects:
Nausea, vomiting, headache, abdominal pain, diarrhoea, fatiguerash, urticaria pruritus, rarely dyspnoea, angioedema, epatitis, jaundice, acute renal failure, fever, anaphylaxis, tremors.

STORAGE:
Store under normal storage condition (15°C to 30°C).
Keep all medicines out of reach of children.
Protect from light.

PRESENTATION:
A bulk pack of 100 tablets
A bulk pack of 1000 tablets
Blister pack of 10 X 10 tablets

I205/01/01

Manufactured in India by:
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl.Co-op. Estate Ltd.,
Vasai (E), Dist. Thane. INDIA