SUMMARY OF PRODUCT CHARACTERISTICS

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1. NAME OF THE FINISHED PRODUCT

Virest 400 mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	PER TABLET (MG)
Aciclovir	400.00*

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Aciclovir is used for the treatment of viral infections due to herpes simplex virus (type 1 & 2) and varicella-zoster virus (zoster & chickenpox).

4.2 Posology and Method of administration

Adults

Genital herpes infection

Initial therapy : Oral, 200 mg 5 times a day for 10 days.
- Creatinine clearance >10 ml/min : Oral, 200 mg 5 times a day for 10 days.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day for 10 days.

Intermittent therapy : Oral, 200 mg 5 times a day for 5 days.
- Creatinine clearance >10 ml/min : Oral, 200 mg 5 times a day for 5 days.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day for 5 days.

Chronic suppressive therapy : Oral, 400 mg twice a day; or 200 mg 2 to 5 times a day.
- Creatinine clearance >10 ml/min : Oral, 400 mg twice a day.
- Creatinine clearance 0-10 ml/min : Oral, 200 mg twice a day

Herpes zoster

Oral, 800 mg 5 times a day for 7 to 10 days.
Creatinine clearance >25 ml/min : 800 mg 5 times a day for 7 to 10 days.
Creatinine clearance 10-25 ml/min : 800 mg twice a day for 7 to 10 days.
Creatinine clearance 0-10 ml/min : 800 mg twice a day for 7 to 10 days.

Varicella

Oral, 20 mg per kg of body weight, up to 800 mg per dose, 4 times a day for 5 days. Treatment should be initiated at the earliest sign or symptom of chickenpox.

Herpes simplex
Oral, 200 to 400 mg 5 times a day for 10 days in immunocompromised patients.

Paediatrics
Children < 2 years : Dosage has not been established in children up to 2 years of age. However, no unusual toxicity or paediatric-specific problems have been observed in studies done in children using doses of up to 3000 mg/m2/day and 80 mg/kg/day.
Children 2 to 12 years : Varicella: Oral 20 mg per kg of body weight, up to 800 mg per dose, 4 times a day for 5 days.
Treatment should be initiated at the earliest sign or symptom of chickenpox

Note: The information given here is limited. For further information consult your doctor or pharmacist.

4.3 Contraindication

This medication should not be used when the following medical problems exist:
- Hypersensitivity to aciclovir or ganciclovir

4.4 Warnings and precautions

- Dehydration or renal function impairment - intravenous aciclovir may increase the potential for nephrotoxicity; it is recommended that acyclovir be administered in a reduced dosage to patients with impaired renal function
- Neurological abnormalities or prior neurologic reactions to cytotoxic medications - intravenous aciclovir may increase the potential for neurologic side effects
- Aciclovir should be used with caution to patients with renal impairment and doses should be adjusted according to creatinine clearance
- Women with herpes genitalis may have an increased risk of developing cervical cancer; annual Pap tests may be required. Checking with physician if no improvement within a few days
- Use of aciclovir has not been shown to prevent the transmission of herpes simplex virus to sexual partners
- Aciclovir crosses placenta. No adverse fetal effects have been reported. FDA Pregnancy category C
- Aciclovir passes into breast milk. No toxicity was observed infants

4.5 Drug Interactions

Probenecid reduces excretion of aciclovir when used concurrently, resulting in increased aciclovir plasma concentration and risk of toxicity.

4.6 Pregnancy and lactation

Pregnancy

Aciclovir crosses placenta. No adverse fetal effects have been reported. FDA Pregnancy category C

Lactation

Aciclovir passes into breast milk. No toxicity was observed infants

4.7 Effects on ability to drive and use machines

NOT APPLICABLE

4.8 Main Side/ Adverse Effects

- Acute renal failure
- Gastrointestinal disturbances (nausea or vomiting, diarrhea, abdominal pain)
- Headache
- Increase in blood concentrations of urea and creatinine
- Lightheadedness
- Increase values for liver enzymes
- Skin rashes
- Encephalopathic changes (lethargy, confusion, tremors, seizures)
- Haematological changes

4.9 Overdose

Since there is no specific antidote, treatment of adverse effects and/or overdose should be symptomatic and supportive with possible utilization of the following:

- Adequate hydration to prevent precipitation of aciclovir in the renal tubules
- Hemodialysis to aid in the removal of aciclovir from the blood, especially in patients with acute renal failure and anuria

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aciclovir is converted to aciclovir monophosphate, a nucleotide, by the viral thymidine kinases of herpes simplex virus (HSV) and varicella-zoster virus (VZV). Aciclovir monophosphate is converted to the diphosphate by cellular guanylate kinase and to the triphosphate by a number of cellular enzymes. Aciclovir triphosphate interferes with HSV and VZV DNA polymerase and inhibits viral DNA replication. The triphosphate can be incorporated into growing chains of DNA by viral DNA polymerase, resulting in termination of the DNA chain. Aciclovir is therefore selectively converted to the active triphosphate form by HSV and VZV-infected cells.

5.2 Pharmacokinetic properties

Aciclovir crosses the placenta and are excreted through the kidney and in breast milk. The terminal half-life is reported to be 2-3 hours for adults without renal impairment. The half-life increases in patients with renal impairment. Aciclovir is poorly absorbed from the gastrointestinal tract. Not significantly affected by food.

5.3 Preclinical Safety Data

NOT APPLICABLE

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Polyvinylpyrrolidone K-30
Iron Oxide Red
Microcrystalline Cellulose pH101
Microcrystalline Cellulose pH102
Sodium Starch Glycolate

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture

6.4 Special precaution for storage

Store below 30˚C. Protect from light.

6.5 Nature and contents of container

Immediate Container/Packaging

Primary Packaging

Blister Pack

Type

Push-through blister pack; the package consists of a clear thermoformable plastic (PVDC) material and a heat-sealed, lacquered backing material.

Rigid Polyvinylidenechloride (PVDC) Film

Description	:	PVDC coated Polyvinylchloride(PVC) Film
Appearance	:	Glass clear transparent film

Aluminium blister foil

Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface/Aluminium foil with high slip primer on matt surface and heat seal on bright surface
Appearance	:	Bright surface/Matt surface each side
Heat Seal Lacquer	:	Heat Seal Lacquer surface is present on plain surface

Secondary Packaging Components

Outer Container/Packaging

Type: Unit box

Material: Paper carton

6.6 Instructions for use and handling <and disposal>

NOT APPLICABLE

7. MARKETING AUTHORISATION HOLDER

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer Name :

Name : HOVID Bhd.

Address : Lot 56442, 7 ½ Miles,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak., Malaysia.

8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

HOV/MAL/028

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2016

10. DATE OF REVISION OF THE TEXT

June 2020