SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name
VIREST CREAM 5%

1.2 International Non-Proprietary Name
ACICLOVIR CREAM 5%

1.3 Strength
Each gram contains Aciclovir 50 mg.

1.4 Pharmaceutical Dosage Form
Cream

2. Quality and Quantitative Composition:

No.	Name of Ingredient	mg/tablet	Function	Reference monograph
Active ingredient				
1	Aciclovir	*5.30	Active ingredient	BP

Kindly refer to 6.1 for the list of excipients.

3. Pharmaceutical Form
Virest 5% Cream is a white opaque cream which contains 5.00 %w/w Aciclovir. It is available in 5g in aluminium tube.

4. Clinical Particulars

4.1 Therapeutic Indications
It is used for the treatment of herpes simplex viral infections of the skin including initial and recurrent genital herpes and herpes labialis.

4.2 Contraindications
Hypersensitivity to aciclovir or ganciclovir.

4.3 Posology and Method of Administration

Usual adult, adolescent, paediatric and geriatric dose:
Topical, apply to the skin, every three hours, six times a day, for seven days. Apply a sufficient quantity to cover all lesions adequately.

Therapy should begin as early as possible after the start of an infection, and for recurrent episodes, this should preferably be during the prodromal period or when the lesions first appear.

To help clear up the herpes infection, continue using the medicine for the full time of treatment, even if the symptoms begin to clear up after a few days. However, patients should not use this medicine more often or for a longer time than the physician ordered.

4.4 Special Warning and Precautions for Use

- 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.
- Avoiding contact with eyes.
- Do not apply to mucous membranes eg. in the mouth, eyes or vagina, as it may be irritant.

4.5 Drug Interaction

Probenecid is reported to block the renal clearance of aciclovir.

4.6 Pregnancy and lactation

Adequate and well-controlled studies in human pregnancy have not been done. It is not whether topical acyclovir is distributed into breast milk.

4.7 Effects on ability to drive and use machine

None known

4.8 Undesirable effects

Mild pain, burning, stinging, pruritus (itching), skin rash. Erythema or mild drying and flaking of the skin have been reported in a small proportion of patients.

4.9 Overdose

Not applicable

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Aciclovir is converted to acyclovir monophosphate, a nucleotide, by the viral thymidine kinases of herpes simplex virus (HSV). 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 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-infected cells and it is much less toxic to normal uninfected cells.

5.2 Pharmacokinetic Properties

- **Absorption:**
  - Intact skin: Minimal; acyclovir not detected in blood or urine.
  - Diseased skin (herpes zoster): Moderate; serum concentrations up to 0.28 mcg per mL have not been reported in patients with normal renal function and up to 0.78 mcg per mL in patients with impaired renal function.
- **Elimination:**
  - Renal: Up to 9.4% of the total daily dose may be excreted in the urine.

5.3 Preclinical Safety Data

None known

6. Pharmaceutical Particulars

6.1 List of Excipients

Oleic Acid
Sorbitan Monooleate
Propylene Glycol
Cetyl Alcohol
Liquid Paraffin
Propyl Hydroxybenzaote
Methyl Hydroxybenzaote
Sodium Lauryl Sulphate
(Dodecyl Sulphate Sodium)
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store below 30°C. Protect from freezing.

6.5 Nature and Contents of Container

Descriptions of packaging material for Virest 5% Cream is as below:

Primary Packaging Components

Name of Packing Material : Collapsible Aluminium Tube

Package Size	:	Body – 99.7% Aluminium Purity Internal Lacquered – Epoxy Phenolic External Lacquered – Polyester Enamel Cap – High Density Polyethylene
Specification	:	Cap – White Screw Cap Finishing (Body) – Internally lacquered, external preprinted and fitted with caps as per approved design Diameter – about 15.88mm Length – 80 ± 1 mm

Secondary Packaging Components

Virest 5% Cream (5g) Unit Box

7. Marketing Authorization Holder

Name **:** Hovid Bhd.
Address **:**121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30100 Ipoh, Perak, Malaysia.

8. Manufacturer and Manufacturing Site

Name **:** Hovid Bhd.
Address **:** 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar), 30100 Ipoh, Perak, Malaysia.

9. Date of First Authorization / Renewal of the Authorization

NIL

10. Date of Revision of Text

April 2023