SCHEDULING STATUS: **S4**

and

S1

when intended for topical application to lips

PROPRIETARY NAME AND DOSAGE FORM:

ADCO-ACYCLOVIR® TOPICAL CREAM

COMPOSITION:

Each 1 g contains acyclovir 0,05 g

Preservative: Benzyl alcohol 0,75 % m/m

List of excipients: Cetomacrogol 1000 (Volpo CS 20), cetostearyl alcohol, hydrochloric acid AR, liquid paraffin, propylene glycol, self-emulsifying glyceryl monostearate and white soft paraffin.

PHARMACOLOGICAL CLASSIFICATION:

A 20.2.8 Antiviral agents

PHARMACOLOGICAL ACTION:

Aciclovir has antiviral activity that is essentially confined to the herpes viruses. It is particularly active in *vitro* against *Herpes simplex* type 1 and herpes simplex type 2. Aciclovir inhibits viral replication by inhibiting DNA

synthesis. This inhibition is due to intracellular conversion of acyclovir by viral thymidine kinase to the monophosphate with subsequent conversion to the diphosphate and the active triphosphate. This active form inhibits the herpes virus DNA polymerase enzyme as well as being incorporated into viral DNA.

INDICATIONS:

S4

Aciclovir is effective in the treatment of viral infections due to *Herpes simplex* type 1 and type 2 of the

skin and genitalia in the initial and recurrent situation.

S1

Application to the lips in the early treatment of recurrent *Herpes simplex* virus infection.

CONTRAINDICATIONS:

Aciclovir is contraindicated in patients known to be allergic to aciclovir and propylene glycol.

Safety of **ADCO-ACYCLOVIR TOPICAL CREAM** in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

Topical applications of acyclovir may sometimes produce burning or erythema.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children:

The topical cream may be applied five or six times daily every three or four hours for periods of five to ten days. Topical treatment of lesions caused by *Herpes simplex* should be initiated as early as possible. It is particularly important to start treatment of recurrent episodes during the prodromal period or when the lesions first appear.

SIDE EFFECTS:

Aciclovir may sometimes cause transient burning or stinging. Erythema or mild drying and flaking of the skin have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See '**SIDE EFFECTS**'. Should aciclovir need to be removed, then haemodialysis would be effective. Further treatment is symptomatic and supportive.

IDENTIFICATION:

Smooth, white soft cream.

PRESENTATION:

Collapsible tubes of 2 g and 10 g.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

28/20.2.8/0369

NAME AND BUSINESS ADDRESS OF HOLDER OF THE

CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

08 October 1997

18288 01/2008