

APPROVED PACKAGE INSERT: FENIVIR Cold Sore Cream

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

FENIVIR Cold Sore Cream

COMPOSITION

Each 1 g of cream contains 0,01 g penciclovir.

Contains 41.68 % *m/m* propylene glycol as preservative.

PHARMACOLOGICAL CLASSIFICATION

A 20.2.8 Antiviral agents

PHARMACOLOGICAL ACTION

Penciclovir has demonstrable *in-vitro* activity against herpes simplex viruses (types 1 and 2), varicella-zoster virus and Epstein-Barr virus. Some activity against cytomegalovirus has been demonstrated *in-vitro* and against herpes simplex virus (types 1 and 2) infections in animals. Penciclovir targets virus-infected cells where it is converted to a triphosphate (mediated via virus-induced thymidine kinase). This triphosphate persists in infected cells in excess of 12 hours and inhibits replication of viral DNA. In uninfected cells treated with penciclovir, concentrations of penciclovir triphosphate are only barely detectable. Accordingly, uninfected cells are unlikely to be affected by therapeutic concentrations of penciclovir.

INDICATIONS

FENIVIR Cold Sore Cream is indicated for the treatment of cold sores (herpes labialis).

FENIVIR Cold Sore Cream shortens healing time, reduces lesion-associated pain and shortens the duration of viral shedding.

CONTRAINDICATIONS

Known hypersensitivity to penciclovir, famciclovir, or any of the constituents, e.g. propylene glycol.

DOSAGE AND DIRECTIONS FOR USE

FOR EXTERNAL USE ONLY.

Adults (over 18 years of age, including the elderly):

FENIVIR Cold Sore Cream should be applied at approximately 2 hourly intervals during waking hours. Treatments should be continued for 4 days. **FENIVIR Cold Sore Cream** should be applied to the lesions or impending lesions as early as possible after the start of an infection. It is particularly important to start treatment of recurrent episodes during the prodromal period or when the lesions first appear.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Transient burning, stinging and numbness has occurred infrequently on application.

Special precautions

FENIVIR Cold Sore Cream should only be used on cold sores on the lips and face.

Not recommended for application to mucous membranes.

Particular care should be taken to avoid application in or near the eye.

PREGNANCY AND LACTATION

Systemic absorption of penciclovir following topical administration of **FENIVIR Cold Sore Cream** has been shown to be minimal. However, since the safety of penciclovir in human pregnancy has not been established, **FENIVIR Cold Sore Cream** should not be used during pregnancy or in nursing mothers.

IDENTIFICATION

A smooth, white, homogenous cream.

PRESENTATION

2 g and 5 g aluminium tubes.

2 g plastic airless pump dispenser.

STORAGE INSTRUCTIONS

Store at or below temperatures not exceeding 30 °C.

DO NOT FREEZE.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

31/20.2.8/0077

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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