SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aciclovir Vision

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The active substance is aciclovir 3% W/W.

Composition: 1 g of ointment contains 30 mg aciclovir.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
White to almost white ointment with a uniform consistency.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the treatment of herpes simplex keratitis.

4.2 Posology and method of administration

For topical application in the eye.

Posology
Adults: 1 cm ointment strip should be squeezed into the lower conjunctival sac five times a day at approximately 4-hour intervals, except when sleeping. Treatment should continue for at least 3 days after the lesions have healed.

Children: As in adults

Elderly patients: As in adults.

4.3 Contraindications

Aciclovir Vision is contraindicated in patients with known hypersensitivity to aciclovir, valaciclovir or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients should be advised that they may experience a slight transient burning sensation immediately after the application of the eye ointment.

Patients should avoid wearing contact lenses while using Aciclovir Vision eye ointment.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions have been established.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are data from post-marketing pregnancy registry on pregnant women treated with various forms of aciclovir. The reported data do not show an increase in the number of birth defects in children of mothers treated with aciclovir compared to the general population, and the birth defects show no similarity or feature suggesting a common cause.

According to internationally accepted standard tests, embryotoxic or teratogenic effects in rabbits, rats or mice have not been established with systemic administration of aciclovir.

Fetal abnormalities were detected in non-standard studies in rats only after administration of very high maternal toxic doses, subcutaneously. The clinical relevance of these data has not been established.

Aciclovir should be used during pregnancy only when the potential benefits outweigh the potential risks to the fetus.

Breastfeeding

Limited human data suggest that aciclovir passes into breast milk when administered systemically. However, the dose potentially taken by the infant after topical administration of Aciclovir Vision eye ointment would be negligible.

Fertility

There is no information on the effect of aciclovir on female fertility.
In a study of 20 males with normal sperm count, oral aciclovir administered at doses up to 1 g daily for up to six months was shown to have no clinically relevant effect on sperm count, motility or morphology.

See clinical trial data presented in section 5.3.

4.7 Effects on ability to drive and use machines

Eye ointment can temporarily affect the vision, and caution is therefore advised when driving or using machines.

4.8 Undesirable effects

Adverse reactions are listed below according to the MedDRA system organ classification and frequency.

The following terminology is used to classify adverse reactions by frequency: very common (> 1/10), common (> 1/100 to <1/10), uncommon (> 1/1000 to <1/100), rare (> 1 / 10 000 to <1/1000), very rare (<1 / 10 000).

The adverse reactions are presented by frequency based on clinical trial data with aciclovir eye ointment. Due to the nature of the observed adverse reactions, it is not possible to determine unequivocally which reactions are related to drug administration and which are disease related. Data from spontaneous reporting have been used to determine the incidence of adverse reactions observed in the post-marketing period.

Immune system disorders
Very rare: immediate hypersensitivity reactions, incl. angioedema and urticaria.

Eye disorders

Very common: superficial punctate keratopathy
It does not require early cessation of treatment and resolves without complications.

Common: transient mild burning sensation in the eyes immediately after administration, conjunctivitis.
Rare: blepharitis.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il.

4.9 Overdose

No adverse effects are expected even if the entire contents of the package are swallowed.

However, it should be noted that the accidental, repeated overdose of oral aciclovir for several days has resulted in gastrointestinal effects (nausea and vomiting) and neurological effects (headache and confusion). Aciclovir is dialyzed by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, antiinfectives, Antivirals, ATC code: S01AD03

Aciclovir is an antiviral product with high in vitro activity against Herpes simplex virus (HSV), type 1 and type 2, but its toxicity to mammalian cells is low.

After penetrating the herpes-infected cell, aciclovir is phosphorylated to the active metabolite aciclovir triphosphate. The first step of this process depends on the presence of the virus-encoded enzyme thymidine kinase. Aciclovir triphosphate acts as a substrate and inhibitor of herpesvirus DNA polymerase, thereby impeding further viral DNA replication. These reactions do not affect normal cellular processes.

5.2 Pharmacokinetic properties

Aciclovir is rapidly absorbed from eye ointment through the epithelial layer of the cornea and superficial eye tissues, resulting in virotoxic concentrations in the intraocular fluid. After topical administration, it is not possible to detect aciclovir in the blood using existing methods, but trace amounts are detected in the urine. However, these levels are not clinically relevant.

5.3 Preclinical safety data

The results of a large number of in vitro and in vivo mutagenicity studies indicate that aciclovir does not pose a risk to the human genome.

In the studies conducted over a long period of time in mice and rats, no carcinogenic effect of aciclovir was detected.

In experiments in rats and dogs with aciclovir at doses far in excess of therapeutic, reversible effects on spermatogenesis associated with general intoxication were found. No effects on fertility were found in a study of two generations of mice administered oral aciclovir.

Systemic administration of aciclovir in internationally accepted standard tests does not induce embryotoxic or teratogenic effects in rats, rabbits or mice.
Fetal abnormalities were detected in non-standard studies in rats only after administration of very high maternal toxic doses, subcutaneously. The clinical relevance of these data has not been established.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin white soft

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening of the package: 28 days

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Each package contains one Aluminium tube containing 5 g of ointment.
Each tube is packaged in a carton box.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND IMPORTER

RAZ Pharmaceutics Ltd.,31 Gesher haetz st. industrial park, Hemek hefer , Israel.

8. MARKETING AUTHORISATION NUMBER

175-52-37211-99

9. Manufacturer
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