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	0022	Fentanyl Transdermal Systemic	0022.xml	14 Apr 2008

PDF

Aciclovir (Topical)

Aciclovir (Topical)

Category: Antiviral (topical).

Indications:

Accepted: Herpes simplex (treatment)—Topical aciclovir is indicated for the treatment of herpes simplex virus infections of the lips (herpes labialis). However, treatment with oral aciclovir is recommended for severely immunocompromised patients with herpes simplex labialis.

Unaccepted: Topical aciclovir is not effective in the treatment of recurrent herpes genitalis or herpes zoster (shingles) in non-immunocompromised patients, although topical aciclovir may cause some reduction in the duration of viral shedding. Also, there is no evidence that topical aciclovir will prevent the transmission of herpes infection to others or that it will prevent recurrent infections in the absence of signs and symptoms of infection.

Pharmacology/Pharmacokinetics:

Physicochemical characteristics: Molecular weight—221.21.

Mechanism of action/Effect: Aciclovir is converted to aciclovir monophosphate, a nucleoside, by herpes simplex virus (HSV)-coded thymidine kinase. Aciclovir monophosphate is converted to the diphosphate by cellular granule 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. Since aciclovir is preferentially taken up and selectively converted to the active triphosphate form by HSV-infected cells, it is much less toxic to normal uninfected cells.

Absorption: Intact skin—Minimal; aciclovir not detected in blood or urine. Dissolved skin (herpes zoster)—Moderate; serum concentrations up to 0.28 microgram per mL have been reported in patients with normal renal function and up to 0.78 microgram per mL in patients with impaired renal function.

Elimination: Renal—Up to approximately 9% of the total daily dose may be excreted in the urine.

Precautions to Consider:

Carcinogenicity: Lifetime bioassays in rats and mice given daily doses of 70, 150, and 450 mg per kg of body weight (mg/kg) for groups have not shown any evidence of carcinogenicity. However, *in vitro* cell transformation assays have given conflicting results, being positive at the highest dose used in one system.

Tumorigenicity: Studies in rats and mice have not shown any statistically significant difference between the incidence of benign tumours produced in drug-treated animals and that produced in control animals.

Mutagenicity: No chromosomal changes were noted at maximum tolerated treatment doses (100 mg/kg in rats) in Chinese hamsters. Higher doses (200 and 1000 mg/kg) were clastogenic in Chinese hamsters. No problems were reported in dominant lethal studies in mice. Also, there was no evidence of mutagenicity in F 0 or F 1 sublethal and maximum cell assays. In 2 of the maximum cell assays, a positive response for mutagenicity and chromosomal damage was noted, but only at concentrations of at least 1000 times the usual plasma concentrations in humans following topical application.

Pregnancy/Reproduction: **Fertility:** Studies in mice given oral doses of up to 450 mg/kg per day have not shown that aciclovir causes infertility or reproductive problems in female rabbits. In rats, aciclovir subcutaneously subsequent to mating have shown a significant decrease in implantation efficiency, but no decrease in litter size at doses of 0-100 mg/kg per day.

Pregnancy: Adequate and well-controlled studies in humans have not been done. Studies in mice and rabbits given subcutaneous doses of up to 10 mg/kg daily and in rats given oral doses of up to 450 mg/kg daily have not shown that aciclovir causes adverse effects on the foetus.

ADSC Pregnancy Category B1.

Breast-feeding: It is not known whether topical aciclovir is distributed into breast milk. However, aciclovir is unlikely to be distributed into breast milk in significant amounts following topical administration, since the total daily dose is small, even though absorption through diseased skin is moderate.

Paediatrics: Appropriate studies on the relationship of age to the effects of topical aciclovir have not been performed in the paediatric population. However, limited data are available about the use of oral aciclovir in the paediatric population, and no unusual toxicity or paediatric-specific problems have been observed in studies done in children using doses of up to 3000 mg per square metre of body surface per day and 80 mg/kg per day.

Geriatrics: Appropriate studies on the relationship of age to the effects of topical aciclovir have not been performed in the geriatric population. However, no geriatric-specific problems have been documented to date.

Medical considerations/Contraindications: The medical considerations/contraindications included here have been selected on the basis of their potential clinical significance (adverse effects or interactions where appropriate)—not necessarily include (i.e. major clinical significance).

Risk-benefit should be considered when the following medical problem exists:

Patient monitoring: The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition, — if severely recommended):

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Aciclovir (Topical)

Drug ID: 0001
Revision Date: 08/18/04 16:23 PM

Category: Antiviral (topical).

Indications:

Accepted: Herpes simplex (treatment)—Topical aciclovir is indicated for the treatment of herpes simplex virus infections of the lips (herpes labialis). However, treatment with oral aciclovir is recommended for severely immunocompromised patients with herpes simplex labialis.

Unaccepted: [Herpes zoster (treatment adjunct)]—Topical aciclovir is used as adjunctive therapy to improve cutaneous healing of localised herpes zoster in immunosuppressed persons being treated systemically with other treatment regimens for herpes zoster.

Resistance to aciclovir, although currently of minor clinical significance, has been reported to develop with prolonged treatment in immunocompromised patients. Resistance does not appear to be significant in patients with normal immune function.

Web

Aciclovir (Systemic)

Category: Enzyme replenisher.

Indications:

Accepted: Glucocerebrosidase deficiency (treatment)—Imiglucerase is indicated as long-term enzyme replacement therapy to treat one or more of a number of conditions (anaemia, bone disease, hepatomegaly or splenomegaly, or thrombocytopenia) caused by confirmed Type 1 Gaucher disease.

There is insufficient evidence to prove that imiglucerase treatment will improve neurologic symptoms in Type 2 or 3 Gaucher disease.

There are no data regarding use of imiglucerase for acute management of bone crises associated with Gaucher disease.

Pharmacology/Pharmacokinetics:

Physicochemical characteristics: Source—Synthetic, by recombinant technology, in Chinese hamster ovary cells. Chemical group—Recombinant, marzobaga-targeted, variant of human.

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Name: Ringo Chan Email: rchan@aliette.com.au

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Monograph Title

Category: Indications

Pharmacology / Pharmacokinetics

Precautions to Consider

Side / Adverse Effects

Overdose

Counselling Information

General Dosing Information

Special Dosage Form

INDICATIONS

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[Herpes zoster (treatment adjunct)]—Topical aciclovir is used as adjunctive therapy to improve cutaneous healing of localised herpes zoster in immunosuppressed persons being treated systemically with other treatment regimens for herpes zoster.

Resistance to aciclovir, although currently of minor clinical significance, has been reported to develop with prolonged treatment in immunocompromised patients. Resistance does not appear to be significant in patients with normal immune function.