SITAVIG (acyclovir) buccal tablets

SITAVIG is an oral dosage form that contains the active ingredient acyclovir (50 mg tablets).

13. NONCLINICAL TOXICOLOGY

13.1. General Pharmacology

SITAVIG can be used as rescue therapy for recurrent herpes labialis in immunocompetent adults when conventional topical agents are not available.

14. CLINICAL STUDIES

14.2. Clinical Pharmacology

Table 1: Selected Treatment Emergent Adverse Events reported in Trials with SITAVIG

<table>
<thead>
<tr>
<th>Event</th>
<th>SITAVIG (N = 378)</th>
<th>Placebo (N = 397)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Rash</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Erythema</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Headache</td>
<td>1%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.3%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The treatment emergent adverse events considered related to treatment versus placebo or other study treatments are presented in Table 1. Adverse events are presented by System Organ Class (SOC), and then by the adverse event term.

17. PATIENT COUNSELING INFORMATION

17.2. Adverse Reactions

The treatment emergent adverse events considered related to treatment versus placebo or other study treatments are presented in Table 1. Adverse events are presented by System Organ Class (SOC), and then by the adverse event term.

18. OVERDOSAGE

18.4. Pediatric Use

Pediatric use: SITAVIG is not recommended for use in children under the age of 12 years.

19. CLINICAL IMPLICATIONS

19.1. Antiviral Activity

The antiviral activity of acyclovir is due to the ability of the drug to inhibit the replication of herpes viruses. The chemical name of acyclovir is 2-amino-1,9-naphthyridine-5-carboxamide (or 9-(2-hydroxyethoxy)methylguanine) (50 mg tablets).

20. NONCLINICAL SAFETY STUDIES

20.2. Reproduction

Animal reproduction studies have not been conducted with SITAVIG. Acyclovir absorption and systemic exposure following buccal administration of SITAVIG are minimal. SITAVIG should be used during pregnancy only if clearly needed.
11 How to Use SITAVIG

• If SITAVIG is placed to the wrong side of your mouth, you should apply SITAVIG to the opposite side of your mouth.

12 WHAT ARE THE POSSIBLE SIDE EFFECTS OF SITAVIG?

13 MORE ABOUT SITAVIG

14 WHAT SHOULD I AVOID WHILE USING SITAVIG?

15 HOW TO STORE SITAVIG

16 HOW SUPPLIED/STORAGE AND HANDLING

17 Adverse Reactions

If you have any questions, please ask your pharmacist or health care provider.

SITAVIG (acyclovir) buccal tablets

Step 1: Find a cold sore on your upper lip, jaw, or cheek.

Step 2: Before you apply SITAVIG, find the area on your upper gum

Step 3: The flat side will be facing the inside of your lip. Be sure to apply SITAVIG to the lip side of the tablet.

Step 4: Use SITAVIG in patients with HIV-1 treated with SITAVIG compared with patients receiving placebo tablets.

Step 5: Gently rinse your mouth with water to clean your teeth and gums. Drink a glass of water and place a new SITAVIG tablet onto your upper gum.

Step 6: Reapply SITAVIG within 1 hour after you have the first symptom of a cold sore, such as itching, redness, burning, or tingling, and before a cold sore appears.

Read the Instructions for Use that comes with SITAVIG before you start using it.

How should I store SITAVIG?

Acyclovir is a synthetic pyrimidine nucleoside that is phosphorylated extracellularly by the viral thymidine kinase (TK) to acyclovir monophosphate (dAMP), which is further phosphorylated by cellular guanylate kinase and into triphosphate by a number of cellular enzymes. Acyclovir triphosphate, the only active form of acyclovir, is a substrate for the herpes virus TK and competitively inhibits the viral TK enzyme. Acyclovir triphosphate becomes incorporated into the viral DNA chain as replication terminates and the viral DNA polymerase. This results in the formation of a blunt-ended DNA chain that cannot be elongated by the viral DNA polymerase and consequently and into terminally arrested viral DNA. The anti-viral activity of acyclovir is a consequence of the growth inhibition of viral DNA that is the basis for the inhibition of viral replication. In vitro studies show that acyclovir is effective against most strains of the herpes simplex 1 and 2 virus, varicella zoster virus, and herpes zoster virus.

SITAVIG 50 mg buccal tablets are supplied as off-white tablets

SITAVIG tablets dry.

SITAVIG is a prescription medicine used to treat cold sores (herpes labialis) in adults with normal immune systems, and to treat genital herpes in adults with normal immune systems. SITAVIG is supplied as 50 mg tablets for buccal use only.

SITAVIG tablets dry.

They were treated with SITAVIG because they had a start of therapy ≥ 6 hours after the onset of prodromal symptoms and before the appearance of any herpes labialis symptoms.

The most common side effects of SITAVIG include:

The mean and median durations of the recurrent herpes labialis episodes in the previous year of whom 68.4% had ≥ 5 episodes.

•  Do not re-apply SITAVIG if it falls out or you swallow it after it has been in place for 6 hours or longer.

•  It is not known if SITAVIG is safe and effective in children.

If you swallow SITAVIG within the first 6 hours of applying it,

Read the Instructions for Use that comes with SITAVIG before you start using it.

How to apply SITAVIG tablets

Before you apply SITAVIG, see step 1 in this instructions for use.

A cold sore is any of a group of painful blisters that form on the skin around the mouth.

The herpes labialis symptoms.

The possibility of viral resistance to acyclovir should be considered in patients who fail to respond adequately to treatment. Identification of viral mutants resistant to acyclovir is based on detection of a lesion that does not respond to treatment. TK-negative mutants may cause severe disease in infants and infants born to mothers infected with HSV. The possibility of viral resistance to acyclovir should be considered in immunocompromised patients who fail to respond adequately to treatment. Identification of viral mutants resistant to acyclovir is based on detection of a lesion that does not respond to treatment. TK-negative mutants may cause severe disease in infants and infants born to mothers infected with HSV.

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Patients may experience adverse reactions including headaches, and before a cold sore appears.

If you swallow SITAVIG within the first 6 hours of applying it,

It is not known if SITAVIG is safe and effective in children.

If you have any questions, please ask your pharmacist or health care provider.

SITAVIG for a condition for which it was not prescribed. Do not

If you swallow SITAVIG within the first 6 hours of applying it,

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