SITAVIG is a buccal tablet containing 50 mg of acyclovir. SITAVIG is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

**INDICATIONS AND USAGE**

SITAVIG is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. The tablets are round, off-white tablets, with a rounded side and a flat side. The tablets are marked with an “AL21” on the flat side.

**DOSE AND ADMINISTRATION**

**SITAVIG** should be applied to the lesion(s) when pain begins or within 24 hours of the appearance of signs and symptoms of herpes labialis lesions. The tablet should be applied with a dry finger directly to the active lesion(s). The tablet should be applied with a slight pressure over the upper lip for 30 seconds. The tablet cannot be repositioned, a new tablet should be used if the tablet comes out of the blister or cannot be repositioned.

**CLINICAL STUDIES**

Clinical studies of SITAVIG did not include sufficient subjects with renal impairment to determine whether they respond differently from patients with normal renal function.

**PATIENT COUNSELING INFORMATION**

The safety of SITAVIG has not been studied in immunocompromised subjects.
Patients may experience adverse reactions including headache, nausea, vomiting, and musculoskeletal pain. See the end of this section for a complete list of adverse reactions in HSV-1 and HSV-2.

Do not store SITAVIG if you are allergic to acyclovir, ganciclovir, or foscarnet (FOS).

Before using SITAVIG, tell your healthcare provider about all of your medical conditions, including if you:

• are allergic to acyclovir, ganciclovir, or foscarnet (FOS).
• have or have had a weakened immune system (immune deficiency or immune dysfunction).
• are breastfeeding or plan to breastfeed. It is not known if SITAVIG is safe and effective in breastfeeding women.
• are pregnant or plan to become pregnant. It is not known if SITAVIG will harm your unborn baby.
• have or have had a cold sore or a problem with your immune system.

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The efficacy and safety of SITAVIG were evaluated in a randomized, double-blind, placebo-controlled trial involving 376 SITAVIG and 395 placebo-treated patients. The study was conducted over 12 weeks (range: 18-80 years) and the majority of patients were female (59%). Patients were included in the intent-to-treat (ITT) efficacy population, which included all patients who were randomized and received at least one dose of study drug and had a follow-up visit at least 1 day after treatment initiation (except the mean age was 41 years and the median age was 35 years. In the previous 12 months, 75% of patients had at least one herpes labialis lesion, 72% had 1 or more cold sores, and 62% had 1 or more oral blisters. Patients were instructed to initiate treatment within 1 hour after one of a cold sore or oral blister appeared. The study was a double-blind, placebo-controlled, patient-initiated, multicenter trial designed to evaluate the efficacy of SITAVIG in reducing the duration of cold sores.

The mean and median durations of the recurrent herpes labialis event were 5.6 days and 3.8 days, respectively, in patients treated with SITAVIG compared with patients treated with placebo. Treatment with SITAVIG (mean duration 4.2 days) shortened the duration of recurrent herpes labialis event compared with placebo (mean duration 5.0 days). The mean duration of the recurrent herpes labialis event was also shorter in patients treated with SITAVIG compared with patients treated with placebo (mean duration 4.2 days) than in patients treated with placebo (mean duration 5.0 days). The mean and median durations of the recurrent herpes labialis event were 5.6 days and 3.8 days, respectively, in patients treated with SITAVIG compared with patients treated with placebo. Treatment with SITAVIG (mean duration 4.2 days) shortened the duration of recurrent herpes labialis event compared with placebo (mean duration 5.0 days).

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