**INDICATION**

Sitavig® (acyclovir), 50mg Muco-Adhesive Buccal Tablet is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

**IMPORTANT SAFETY INFORMATION**

- Sitavig should not be used in patients with known hypersensitivity to acyclovir, milk protein concentrate, or other components of the product.
- Sitavig has not been studied in pregnant women or in immunocompromised patients and no interaction studies have been performed. Sitavig’s safety and efficacy have not been established in pediatric patients.
- Sitavig is a **Pregnancy Category B product**; therefore it should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. It is not known if Sitavig is excreted in breast milk; however, systemic absorption is minimal.
- In a controlled clinical trial, Sitavig’s most common side effects (greater than or equal to 1%) were: headache (9%), dizziness (1%), lethargy (1%), gingival (gum) pain (1%), aphthous stomatitis (canker sore) (1%), application site pain (1%), application site irritation (1%), erythema (1%), and rash (1%). In the same trial, these side effects ranged from 0%-3% for placebo.

You are encouraged to report negative side effects of prescription drugs to the FDA. Call 1-800-FDA-1088 or visit www.fda.gov/medwatch.

*Data on the incidence and delay of the next recurrence need further confirmation as they were obtained on a subset of patients.*

**REFERENCE**


See accompanying Full Prescribing Information.
Cold sores are caused by the herpes simplex virus (HSV-1), which lies dormant until awakened by a triggering event. When the virus first starts replicating, you may experience a tingling, itching or burning sensation. At this stage, if you act immediately with the right treatment, you can potentially prevent a blister from forming. This may also reduce the severity of your cold sore, not to mention the time it takes to heal. Immediate treatment may also delay your next outbreak.

Even if you have no signs of a cold sore, it’s smart to see your healthcare provider and ask for Sitavig. Go ahead and get your prescription filled and keep your Sitavig tablet with you at all times.

**INJURY OR TRAUMA**
- Cosmetic, surgical, or dental procedures
- Sports injuries
- Cuts from shaving

**HORMONAL CHANGES**
- PMS
- Pregnancy
- Menopause

**MAJOR EVENT STRESSORS**
- Weddings/divorces
- Reunions
- Family vacations
- Graduations

**DAILY LIFE STRESSORS**
- Job pressure
- Fatigue
- Finances
- Exams

**SUN EXPOSURE**

**ILLNESS**

Patients also experienced significant relief from cold sore symptoms in just 3½ days and completely healed in 5½ days when Sitavig was applied within 1 hour of feeling the tingling sensation and before the blister appeared.

When you understand the things that can trigger a cold sore, you have a better chance of stopping an outbreak. Here are a few common triggers:

**KNOW YOUR TRIGGERS**

- Cosmetic, surgical, or dental procedures
- Sports injuries
- Cuts from shaving
- PMS
- Pregnancy
- Menopause
- Weddings/divorces
- Reunions
- Family vacations
- Graduations
- Job pressure
- Fatigue
- Finances
- Exams
- Sun exposure
- Illness

**KNOW MORE, WORRY LESS**

The virus begins to multiply in the mouth
You may experience itching, burning or tingling sensations
A blister may form in 2–3 days

**FEWER COLD SORES**

Sitavig delivers concentrated medication that is localized at the site of viral replication in the mouth.

Patients treated with a single dose of Sitavig went an average of 304 days before their next cold sore outbreak compared with an average of 199 days for patients treated with a placebo.

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Please see additional Important Safety Information on back and accompanying Full Prescribing Information.