ONE AND DONE DOSING

HOW TO USE SITAVIG:



Step 1: Peel back the cover of the blister pack. Do NOT push the blister through the packet. Take 1 Sitavig out of the blister pack. When removed from the blister pack, Sitavig must be used right away. Sitavig is round on one side and flat on the other side.



Step 2: When you apply Sitavig, find the area on your upper gum, just above either the left or the right incisor. The incisor tooth is the tooth just to the right or left of your two front teeth. This is where you should apply Sitavig.



Step 3: Place the flat side of Sitavig on your dry fingertip. Apply the round side of Sitavig to your upper gum. The flat side will be facing the inside of your lip.



Step 4: Hold Sitavig in place by applying a slight pressure with your finger on the outside of your upper lip, over the area where Sitavig is placed, for 30 seconds. This will help Sitavig stick to your gum.

Step 5: Leave the Sitavig tablet in place until it dissolves (tablet can take up to 6-12 hours to dissolve).

See package insert for instructions for use.

HOW MUCH DOES SITAVIG COST?

Your cost for Sitavig depends on your specific insurance coverage, any prescription deductibles you might have, and your prescription copay. Be sure to ask your doctor for the Sitavig Patient Access Card to reduce your out-of-pocket copay.

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 (3%), dizziness (1%), lethargy (1%), gingival pain (1%), aphthous stomatitis (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. Visit www.fda.gov/medwatch.com or call 1-800-FDA-1088.

ADDITIONAL RESOURCES:

- http://www.mayoclinic.org/diseases-conditions/cold-sore/ basics/definition/con-20021310. Accessed 5/19/2014
- http://www.mckinley.illinois.edu/handouts/herpes_ simplex/herpes_simplex.html. Accessed 5/19/2014
- http://www.merckmanuals.com/professional/ infectious_diseases/herpesviruses/herpes_ simplex_virus_hsv_infections.html. Accessed 5/19/2014
- 4. http://www.ncbi.nlm.nih.gov/pmc/articles/ PMC2602638/. Accessed 5/19/2014

REFERENCES:

- 1. Bieber T, et al. J Drugs Dermatol 2014; In Press.
- 2. Lemarchand C, et al. J Clin Pharmacol & Clin Pharmacokinet. 2014; 1(1):000001.

See Accompanying Full Prescribing Information.



SIT-PFR-081





HOW DOES SITAVIG WORK?1

Stops some cold sores before they develop.*

35% of patients did not develop a blister, when Sitavig was applied soon after symptoms emerged.¹

Helps prevent the next episode for longer periods of time.*

Half of patients treated with Sitavig went an additional 40 days longer before having another cold sore episode (the average was 105 days).¹

36% of patients who were treated with Sitavig were still free from another outbreak 10 months after their single dose treatment.¹

Eases symptoms of cold sores.*

Patients treated with Sitavig had significant relief from symptoms in an average of just 3 ½ days.¹

Helps cold sores resolve faster.*

Patients treated with Sitavig had complete healing of their cold sores in an average of just 5 ½ days.¹

IS SITAVIG SAFE?

In clinical studies, Sitavig was shown to be safe when applied properly for the treatment of cold sores. Because the medication in Sitavig has minimum systemic absorption, safety risks with the use of Sitavig are considered low.²

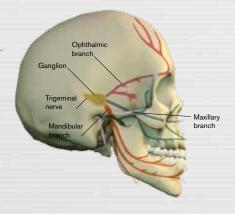
*Sitavig was evaluated in a clinical study of 775 patients with recurrent herpes labialis (cold sores). Treatment outcomes in patients treated with Sitavig were statistically superior to outcomes in patients who received placebo (P<.05 for all).

WHAT CAUSES COLD SORES?

Cold sores (Herpes labialis, sometimes called fever blisters) are caused by the herpes virus (HSV-1 or HSV-2) and are contagious not only during the cold sore outbreak, but also during a process called "viral shedding", which can occur even when no blister is present. For this reason, up to 80% of the adult population has been exposed to HSV. The virus is most commonly spread by kissing or by sharing food or drink items with an infected person.

WHY DO MY COLD SORES KEEP COMING BACK?

Once infected with the herpes virus, a person remains infected for the remainder of his/her life. The virus cycles through inactive (asymptomatic) and active periods (presence of cold sores). During the inactive periods, the virus lives in a dormant state in the trigeminal ganglia (nerve cells) and in the oral mucosal region. A triggering factor such as sun exposure, stress or trauma to the lip region can result in the activation of the virus and the development of a cold sore. Most cold sores develop in the same place as in previous outbreaks.



IS THERE A TREATMENT FOR MY COLD SORES?

Yes! Sitavig, a new treatment for cold sores, has been shown to stop the cold sore from developing in some patients when taken soon after symptoms emerge. Cold sores can be treated, however treatment must be started during the small window of time after symptoms emerge (8-12 hours) in order to yield therapeutic benefit. You may feel a tingling, itching, or burning sensation around the mouth before the cold sore appears. You may also experience tiredness or fever. This is the optimal time to treat an outbreak in order to maximize your therapeutic benefits.

DISEASE PROGRESSION OF A HERPES EPISODE

Tingling 1 day Redness 1-2 days Bumps 1-2 days Blisters 2-3 days Scabs 5-7 days Redness 1-2 days









TREATMENT OPTIONS FOR COLD SORES



New! Sitavig Muco-adhesive buccal tablet

- Single dose dissolves on the gum
- Medication stays at the site of infection

Topical Antiviral Creams

- Apply 5 times for 5 days
- Medication stays at the site of infection

Systemic Treatments (Pills)

- 1 pill every 12 hours for 1-5 days
- Medication is absorbed throughout the body