

Package leaflet: Information for the patient

Sitavig 50 mg, muco-adhesive buccal tablets aciclovir

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sitavig is and what it is used for
2. What you need to know before you use Sitavig
3. How to use Sitavig
4. Possible side effects
5. How to store Sitavig
6. Contents of the pack and other information

1. What Sitavig is and what it is used for

Sitavig contains the active substance aciclovir, and belongs to a group of medicines called antivirals.

Sitavig is used, in adults whose immune system works well, for the treatment of recurrent cold sores on the lips, caused by herpes simplex virus. Sitavig should be taken as soon as first symptoms (burning, tingling, itching), or signs (redness, swelling) occur.

The virus causes blisters or sores, on the lips primarily but sometimes also in other parts of the face. The virus infection can be activated when the immune system is weakened, e.g. by colds or other infections. Strong sun, stress or menstruation can also trigger the symptoms.

Sitavig inhibits the virus ability to reproduce and therefore makes the infection to reverse.

2. What you need to know before you use Sitavig

Do not use Sitavig

- If you are allergic (hypersensitive) to aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- If you are allergic to milk or milk derivatives.

Warnings and precautions

- Accidental ingestion of Sitavig may occur. If Sitavig is accidentally swallowed it is recommended to drink a glass of water.
- Talk to your doctor before using this medicine if you have a weak immune system. Sitavig should not be used in this case.
- We don't know whether Sitavig works or not if used once the blisters or sores have already appeared. Therefore, you should only use Sitavig as soon as you feel the first symptoms of cold sores (itching, redness or tingling).

Children and adolescents

This medicine should not be used in children.

Other medicines and Sitavig

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Sitavig with food and drink

You may eat and drink while using this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Sitavig may be used during pregnancy and breast-feeding.

Driving and using machines

This medicine does not affect your ability to drive or use machines.

Sitavig contains lactose (milk protein concentrate with traces of lactose)

If you have been told by your doctor that you have an intolerance to some sugars (i.e. lactose...), contact your doctor before taking this medicinal product.

3. How to use Sitavig

DO NOT SWALLOW SITAVIG

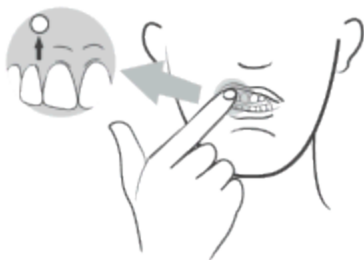
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use

This medicine should be applied to the upper gum, just above a front tooth as soon as the first symptoms or signs of cold sores occur (itching, redness or tingling):

- Before applying the tablet, locate the area on the upper gum, above the front tooth.
- Apply the tablet with a dry finger immediately after taking it out of the blister. You will notice that the tablet has a rounded side and a flat side marked with “AL21”.
- For comfort, place the rounded side on the upper gum, but either side of the tablet can be applied.
- If the mouth is dry, it is recommended to drink some water to humidify your gum before applying the tablet. The tablet may be used if it sticks inside of the lip instead of the gum.

Once applied, the tablet stays in position and gradually dissolves during the day.



How to apply SITAVIG

Hold the tablet in place by applying a slight pressure with your finger on the outside of your upper lip for 30 seconds to ensure adhesion.



Food and drink can be taken normally when Sitavig is in place. The tablet should not be sucked, chewed or swallowed.

All situations that could interfere with adhesion of the tablet should be avoided:

- Touching or pressing the tablet already placed.
- Chewing gum.
- Brushing teeth during the day.

If this medicine does not adhere or falls off within the first 6 hours, the same tablet should be repositioned immediately. If the tablet cannot be repositioned, a new tablet should be applied.

If you accidentally swallow a tablet of Sitavig drink a glass of water.

If the tablet is swallowed within the first 6 hours after application, it should be replaced only once.

If Sitavig falls off or is swallowed accidentally after 6 hours, no replacement of the tablet should be done.

The shape of the tablet may change due to absorbing saliva in order to fit your gum shape.

Dosage

The recommended dose is one tablet of Sitavig applied only once.

Use in children and adolescents

This medicine should not be used in children.

If you use more Sitavig than you should

You should consult your doctor or your pharmacist immediately, although the risk of overdose is low given the low absorption of aciclovir into the blood following the intake of Sitavig.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Common side effects (may affect up to 1 in 10 people):

- Headache
- Pain at the application site

Uncommon side effects (may affect up to 1 in 100 people):

- Dizziness
- Feeling sick (nausea)
- Irritation at the application site
- Canker sore
- Gum pain
- Redness

If you get any side effects, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sitavig

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sitavig contains

- **The active substance is:** aciclovir. Each muco-adhesive buccal tablet contains 50 mg of aciclovir.
- **The other ingredients are:** hypromellose, milk protein concentrate with traces of lactose, sodium laurilsulfate, magnesium stearate, microcrystalline cellulose, Povidone, colloidal silica anhydrous.

What Sitavig looks like and contents of the pack

- This medicine is a mucoadhesive buccal tablet of 8 mm, white to slightly yellow with a rounded side and a flat side marked with “AL21”.
- Each carton box of Sitavig contains 2 unit dose blisters of 1 tablet.

Marketing Authorisation Holder

Onxeo
49 Boulevard du Général Martial Valin
75015 Paris - France
Phone: + 33 (0)1 45 58 76 00
Fax: + 33 (0)1 45 58 08 81

Manufacturer

Farméa
10 rue Bouché Thomas
ZAC d'Orgemont
49 000 Angers - France

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark, Finland, Sweden, United Kingdom, Norway, France: Sitavig
Spain, Italy: Labiriad

This leaflet was last revised in 2017-12-06