

7. What are other important things I need to know about taking Sodium oxybate?

- Do not share your Sodium oxybate with anyone.
- Use only the dose your doctor prescribed. If you believe the dose needs to be changed, contact your doctor.
- Always respect a 2-hour interval between the last meal and the intake of Sodium oxybate
- Always keep Sodium oxybate in its original package, in a safe location.
- Keep Sodium oxybate out of the reach of children.
- Return any unused product to your pharmacy.
- If you experience any unusual symptoms, like strange thoughts, including thoughts of hurting others, whilst taking Sodium oxybate, inform your doctor straight away.

Ask your healthcare professional for the Sodium oxybate Patient Alert Card to keep with you to remind you about the use of Sodium oxybate. Show this card to all your doctors so they know you are taking Sodium oxybate, especially if they prescribe other medications for you.

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie.
Please also report to AS Kalceks, e-mail: vigilance@grindeks.lv.
By reporting side effects you can help provide more information on the safety of this medicine.

Important risk minimisation information for Patients: Sodium oxybate Frequently Asked Questions (FAQ) Information Sheet

Here are some questions you may have about taking Sodium oxybate. Be sure to speak with your healthcare professional about any other questions you may have, and review the Package Leaflet included with your medicine bottle.

1. What is Sodium oxybate?

Sodium oxybate is an oral prescription medicine used to treat adults who:

- fall asleep frequently during the day, and at unexpected times (narcolepsy)
- have sudden weakness or paralyzed muscles when they feel strong emotions (cataplexy)

2. May I drink alcohol while I'm taking Sodium oxybate?

No, you must not drink alcohol while taking Sodium oxybate. Sodium oxybate's effects can be increased and you may experience impaired breathing (respiratory depression) that can be fatal. You may also experience impaired thinking or confusion.

3. What are the serious side effects of Sodium oxybate?

Trouble breathing (respiratory depression)

Sodium oxybate can affect breathing. If you have any breathing or lung problems you should tell your doctor before taking Sodium oxybate. If you are overweight, you are also at increased risk of respiratory depression. You should not take alcohol as this can increase the risk of respiratory depression also. Respiratory depression can be serious and even fatal.

Depression and suicidal thoughts

If you feel depressed or have any thoughts of harming yourself whilst taking Sodium oxybate, you should tell your doctor straight away. You should also inform your doctor if you have suffered with depression in the past.

Reduced level of consciousness

Because Sodium oxybate acts directly on the brain it causes drowsiness and can impair your level of consciousness. This can lead to coma and can be fatal. It is important that you do not take alcohol whilst taking Sodium oxybate. You should not take any other drugs that cause drowsiness. You should also not drive or operate machinery for at least 6 hours after taking Sodium oxybate.

Seizures

Sodium oxybate can cause seizures. You should tell your doctor before you take Sodium oxybate if you have any history of seizures.

Dependancy/abuse/misuse

The active ingredient of Sodium oxybate is gamma-hydroxybutyrate (GHB). GHB is a chemical that has been abused and mis-used. Your doctor will therefore ask you specifically if you have any history of drug abuse. Abuse and mis-use of Sodium oxybate is dangerous and can lead to fatal consequences.

These are not all the side effects of Sodium oxybate. Talk to your doctor for medical advice about side effects.

4. Is Sodium oxybate safe to use with other medications?

As with all medications, it is very important to tell your doctor about any other medications you are taking, including medicines you get without a prescription. Sodium oxybate should not be used in combination with medications that cause drowsiness, or with drugs like narcotic analgesics that can cause central nervous system depression. Be sure to tell your doctor if you are taking any sleep inducing medicines and medicines that impact central nervous system activity.

Tell your doctor or pharmacist if you are taking any of the following types of medicines:

- Medicines that increase central nervous system activity and antidepressants;
- Medicines that may be processed in a similar way by the body (e.g. valproate, phenytoin or ethosuximide which are used for the treatment of fits);
- Topiramate (used for the treatment of epilepsy).

5. What do I do if I take accidentally more than the prescribed dose?

Get emergency help right away if you take too much Sodium oxybate (overdose). Taking too much Sodium oxybate may cause symptoms such as agitation, confusion, impaired movement, impaired breathing, blurred vision, profuse sweating, headache, vomiting and decreased consciousness leading to coma and seizures. Taking the labelled medicine bottle with you, even if it is empty, will help medical staff to manage your symptoms.

6. What if I stop taking Sodium oxybate suddenly?

If you suddenly stop taking Sodium oxybate, you may experience withdrawal symptoms. You may find that cataplexy attacks return and, in rare cases, you may experience insomnia, headache, anxiety, dizziness, sleeping problems, sleepiness, hallucination and abnormal thinking.