

Seizures

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

Dependancy/abuse/misuse

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

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

Is Xyrem® 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. Xyrem® 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).

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



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

Here are some questions you may have about taking Xyrem®. 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.

What is Xyrem®?

Xyrem® (sodium oxybate) is an oral prescription brand 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)

May I drink alcohol while I'm taking Xyrem®?

No, you must not drink alcohol while taking Xyrem®. Xyrem®'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.

What are the serious side effects of Xyrem®?

Trouble breathing (respiratory depression)

Xyrem® can affect breathing. If you have any breathing or lung problems you should tell your doctor before taking Xyrem®. 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 Xyrem®, 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 Xyrem® 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 Xyrem®. 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 Xyrem®.

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

Get emergency help right away if you take too much Xyrem® (overdose).

Taking too much Xyrem® 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.

What if I stop taking Xyrem® suddenly?

If you suddenly stop taking Xyrem®, 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.

What are other important things I need to know about taking Xyrem®?

- Do not share your Xyrem® 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 Xyrem®
- Always keep Xyrem® in its original package, in a safe location.
- Keep Xyrem® 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 Xyrem®, inform your doctor straight away.

Reporting of side effects

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, if in UK, via the Yellow Card Scheme, website: <http://yellowcard.mhra.gov.uk/> or, if in Republic of Ireland, via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Please also report to UCB Pharma Ltd at UCBCares: +44(0) 1753 777100; Email: UCBCares.UK@ucb.com (UK) or +353 1463 2371; Email: UCBCares.IE@ucb.com (Ireland).

By reporting side effects you can help provide more information on the safety of this medicine.