

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.

UK:

You can also report side effects directly via the Yellow Card Scheme, website: www.yellowcard.mhra.gov.uk.

Ireland:

You can also report side effects directly via HPRA Pharmacovigilance. 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.

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

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.



Frequently asked questions

Narcolepsy

What are the primary symptoms of narcolepsy?

Excessive Daytime Sleepiness (EDS) is present in all cases, but it is also a frequent symptom in many other medical and sleep disorders. Patients often experience EDS in one of three ways: a constant level of drowsiness, sustained episodes of extreme and unavoidable sleepiness, and brief moments of sleep called Micro Sleep and possible sleep attacks. For a person without Narcolepsy to feel this effect, she or he would have to stay awake for 48 hours without even a brief nap and then try to function normally.

Cataplexy is present in most cases and is exclusive to narcolepsy. These are episodes of bilateral, partial or total, loss of strength or tone to all or part of a person's muscles, starting from head & neck to the buckling of the knees. Cataplexy can be as subtle as a brief facial tic, or as dramatic as a full body collapse. Episodes are usually triggered by strong emotions such as humour, love, joy, surprise, anger, etc. These events can last a brief moment to a few minutes.

Disrupted Night-time Sleep is the inability to maintain sleep for more than a few hours at a time. While the arousals from sleep may be total (coming full awake with awareness and memory of being awake), they are often partial (without awareness or memory of awakening). This prevents restful, adequate, and satisfying sleep, as the sleep is always fragmented.

What are the other symptoms of narcolepsy?

Sleep Paralysis is the inability to speak or control any of the voluntary muscles of the body at the onset of sleep or waking up. This may also include the feeling of inability to breathe. This is always short lasting and has no after effect.

Hallucinations at onset of sleep or at onset of waking up. These vivid, realistic, and often frightening images are experienced at the onset of sleep or waking up from a dream, but the mind believes that the dreams are reality.

How common is narcolepsy?

Narcolepsy is a rare disease. The UK has a prevalence rate of 47 patients per 100,000 inhabitants.

At what age do people get Narcolepsy?

Narcolepsy can appear at any age, with a large peak around 15 years and a smaller peak around 36 years of age. Narcolepsy is a lifelong neurological disorder affecting life-style.

What is the cause of narcolepsy?

Researchers have discovered that, in most cases of narcolepsy with cataplexy, two chemicals in the brain called hypocretins (orexins) are missing. These neurotransmitters are involved in the regulation of the sleep/wake cycle as well as other bodily functions (e.g. blood pressure and metabolism). Further research has shown that the majority of hypocretin-producing cells, located in a specific area of the brain called hypothalamus, have been destroyed in people who develop narcolepsy with cataplexy. The cause of narcolepsy without cataplexy is still under investigation.

Why are narcoleptic patients lacking the hypocretin substance?

Recent studies have shown that the hypocretin-containing cells are missing in the brain of narcoleptic patients. The most likely explanation may be that the cells are destroyed by an autoimmune attack.

What is an autoimmune disorder?

An autoimmune disease is a disorder where the immune system turns against one's own body instead of fighting an external infection.

Is cataplexy dangerous?

Mild cataplexy, while often embarrassing, is not dangerous. However, severe cataplexy, resulting in sudden and progressive body collapse, may cause injury. Partners and friends should be told in advance what to expect and how to help. They should always check for the person's safety and comfort, immediately relieving any unnatural bending of limbs or unusual body positions, assuring complete relaxation and then allowing him or her to recover naturally in a few minutes. To note: vital signs and consciousness are always present. Obviously, potentially life-threatening situations should be avoided unless cataplexy is fully controlled.

I have narcolepsy. Can I drive a car?

Driving should be avoided unless cataplexy is fully controlled. Please discuss this with your treating doctor and check the law in your country.

What is the risk for my child to develop narcolepsy?

Most cases of narcolepsy have no other family members affected with narcolepsy and the risk is very small. If you have narcolepsy-cataplexy, the risk for your child to develop narcolepsy-cataplexy is only 1-2%.

Can I be cured?

Currently no cure for narcolepsy exists, nor any way to replace the missing hypocretin. Treatment of narcolepsy is available and aims to relieve the severity and the frequency of the symptoms.

What is Xyrem®?

Xyrem® (sodium oxybate) oral solution is a medicine indicated to treat narcolepsy with cataplexy in paediatric (from 7 years old), adolescent and adult patients.

Xyrem® has been shown to be effective on all key symptoms of this disease i.e. controlling cataplexy attacks, reducing excessive daytime sleepiness and improving quality of sleep.

Xyrem® was approved in Europe in 2005. In the USA, Xyrem® has been available since 2002.

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.

May I drink soft drinks while I'm taking Xyrem®?

Yes, you can take any soft drinks if you are certain that they don't contain any alcohol, and if you respect at least two hours before Xyrem® intake.

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, have suicidal ideation, homicidal ideation, and became more aggressive whilst taking Xyrem®, you should tell your doctor straight away. You should also inform your doctor if you have suffered in the past from any of the following conditions; depressive illness, suicide attempt, bipolar disorder, anxiety, psychosis, affective disorder and abnormal thinking.

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®.

Seizures

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

Dependency/abuse/misuse

The active ingredient of Xyrem® is Sodium Oxybate, a form of gamma-hydroxybutyrate (GHB). Your doctor will therefore ask you specifically if you have any history of drug abuse.

Abuse and misuse 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.

Can Xyrem® be abused? Is it addictive?

Xyrem® contains sodium oxybate, a form of gamma-hydroxybutyrate (GHB). Abuse of Xyrem® can cause serious medical problems, including trouble in breathing, seizures (convulsions), loss of consciousness, coma, and death; and could also lead to dependence, craving for the drug, and severe withdrawal symptoms (following illicit use at frequent repeated doses in excess of the therapeutic dose range).

Xyrem®, an approved pharmaceutical product, should not be equated with illicit substance purchased from any other source. The potency and purity of Xyrem® is highly controlled and regulated to ensure you receive a correct and consistent dose that will be defined by your doctor for correct use.

Will my dose change?

It could take time to identify the dose that works best for you, perhaps up to several weeks. During that time, your doctor may gradually increase or decrease your dose, based on your response to treatment.

During this time, inform your doctor about any significant body weight change, and, if you experience any breathing trouble, or if you feel depressed. Never adjust or change your Xyrem® dose without consulting your doctor!

Why do I have to be in bed, ready to sleep, before taking Xyrem®?

Xyrem® rapidly induces sleep; therefore, as a safety precaution, it is best to be in bed as its effects begin to take place.

Why there are two different scales on the Xyrem® syringe?

The Xyrem® syringe has two different measurement scales, one scale may be more helpful for you than the other depending on which dose your doctor has prescribed. By looking at each scale you will see which one provides the exact mark for your dose. So, it is important that you only use the syringe provided in the box when preparing doses of Xyrem®.

Why do I need to take a second dose at night?

The active ingredient in Xyrem® is short acting and the beneficial effects of a single dose of Xyrem® will not last for the entire night. Therefore, it is required that you take a second dose of Xyrem® 2.5 to 4 hours after the first dose, for the desired therapeutic effect.

How will I wake up to take the second dose of Xyrem®?

You should set an alarm clock to wake yourself 2.5 to 4 hours after taking the first dose. It is not uncommon to wake up before the alarm. If you do wake up before the alarm and it has been at least 2.5 hours after the first dose, take your second dose, turn off the alarm, and go back to sleep. For more information please refer to the package information leaflet. For children who sleep more than 8 hours per night, sodium oxybate may be given after bedtime, while the child is in bed, in two equally divided doses 2.5 to 4 hours apart.

Would I wake up in an urgent situation or emergency after having taken Xyrem®?

In this regard, Xyrem® is not different than any other sleep medication you might take and your ability to wake up may depend on the following: how soon after taking Xyrem® the urgent situation occurs, the size of the Xyrem® dose being taken, the nature of the urgent situation, and your individual response to Xyrem®.

What do I do if I forget to take Xyrem®?

If you forget to take the first dose before going to bed, take it as soon as you remember that night and then continue as before (take your second dose after the same interval as usual 2.5 to 4 hrs). However, do not take the second dose if you have to get up less than about 7 hours after the first one. If you miss the second dose, skip that dose and do not take Xyrem® again until the next night. Do not take a double dose to make up for any individual doses you have forgotten.

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

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.

If you take more Xyrem® than you were told to take, or take it by accident, get emergency medical help right away.

Taking the labelled medicine bottle with you, even if it is empty, will help medical staff to manage your symptoms.

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. Tell your doctor or pharmacist if you are taking any of the following types of medicines: antidepressants, sodium valporate, topiramate, phenytoin, or ethosuximide.

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.

What does Xyrem® taste like? Can I mix it with liquids other than water?

Because Xyrem® contains sodium, it has a salty taste. Xyrem® should be mixed with water as instructed in the package leaflet. Using cold tap water rather than warm water can minimize the salty taste. Xyrem® should not be mixed with any other liquids, such as soft drinks or fruit juice because mixing Xyrem® with any other beverage can change the chemical properties of the drug which may affect how it works.

Can I use Xyrem® if I am pregnant or breastfeeding?

There are no adequate data on the use of Xyrem® during pregnancy. Xyrem® is therefore not recommended during pregnancy. Xyrem® is excreted into breast milk, so you should not breastfeed when on Xyrem®. Tell your doctor if you are pregnant or plan to become pregnant before starting Xyrem®, or at any point during your treatment.

How soon might I see a change in my symptoms?

Most patients can expect to see some improvements within the first weeks of Xyrem® therapy. However, it may take up to several weeks after you begin using Xyrem® to find the dose that is best for you. During this time, you should discuss your response to treatment with your doctor to make sure you and your doctor work together to find the optimal dose.

May I take Xyrem® with food?

Food will decrease the amount of Xyrem® that your body absorbs, and will significantly slow its absorption, so you should wait several hours after eating to take your first dose. It is also best to

eat your evening meal at a regular time 2 to 3 hours prior to taking the first nightly Xyrem® dose to ensure consistent effects from the medication.

For how long will I need to take Xyrem®?

Although Xyrem® is taken to treat your disease symptoms, it is not a cure and you should continue taking Xyrem® for as long as your doctor determines it is necessary. If you believe you don't require it anymore, or want to stop taking Xyrem® for any other reason, be sure to discuss this with your doctor first.

Are there any precautions I should take while on Xyrem®?

- Do not drive a car, operate heavy machinery, or perform any activity that is dangerous or requires mental alertness, for at least six hours after taking Xyrem®.
- When you first start taking Xyrem®, until you know whether it makes you sleepy the next day, use extreme care while driving a car, operating heavy machinery or doing anything else that could be dangerous or needs you to be fully mentally alert.

How often should I see my doctor?

You should see your doctor as often as she/he requires it.

Will Xyrem® become less effective the longer I take it?

Some medications lose their benefit after they have been taken for a long time. Long-term clinical trials (treatment period up to 44 months) with Xyrem® did not demonstrate a decrease in effectiveness.

What if I stop taking Xyrem® abruptly?

Some medications can have addicting properties or cause psychological or physical dependence. When patients stop taking their medications, they may experience withdrawal symptoms, particularly if taken in a way other than prescribed. Upon abrupt discontinuation of Xyrem®, you may find that cataplexy attacks return and in rare cases experience insomnia, headache, anxiety, dizziness, sleeping problems, sleepiness, hallucination and abnormal thinking.

General requirements for the safe and responsible use of 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.
- Don't take Xyrem® if you are less than 7 years old.
- Always respect a 2-hour interval between the last meal and the intake of Xyrem®.
- Always keep Xyrem® and its syringe, 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.

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