



Important risk minimisation information for Patients and Caregivers:

Sodium Oxybate 500 mg/ml oral solution (sodium oxybate)

Frequently Asked Questions (FAQ)

Here are some questions you might have about taking Sodium Oxybate 500 mg/ml oral solution. 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.

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Frequently asked questions

Narcolepsy

1. What are the primary symptoms of narcolepsy?

Excessive Daytime Sleepiness (EDS) is present in all cases, but 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 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.

2. 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.

3. How common is narcolepsy?

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

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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%.

1.1. 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 symptoms.

What is Sodium Oxybate 500 mg/ml oral solution?

Sodium Oxybate 500 mg/ml oral solution (sodium oxybate) is a medicine indicated to treat narcolepsy with cataplexy in paediatric (from 7 years old), adolescent and adult patients.

Sodium Oxybate 500 mg/ml oral solution 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.

Sodium oxybate was approved in Europe in 2005. In the USA, sodium oxybate has been available since 2002.

1. May I drink alcohol while I'm taking Sodium Oxybate 500 mg/ml oral solution?

No, you must not drink alcohol while taking Sodium Oxybate 500 mg/ml oral solution. Sodium Oxybate 500 mg/ml oral solution'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.

2. May I drink soft drinks while I'm taking Sodium Oxybate 500 mg/ml oral solution?

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 Sodium Oxybate 500 mg/ml oral solution intake.

3. What are the serious side effects of Sodium Oxybate 500 mg/ml oral solution?

Trouble breathing (respiratory depression)

Sodium Oxybate 500 mg/ml oral solution can affect breathing. If you have any breathing or lung problems, you should tell your doctor before taking Sodium Oxybate 500 mg/ml oral solution. 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 become more aggressive, whilst taking Sodium Oxybate 500 mg/ml oral solution, 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 Sodium Oxybate 500 mg/ml oral solution 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 500 mg/ml oral solution. 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 500 mg/ml oral solution.

Seizures

Sodium Oxybate 500 mg/ml oral solution can cause seizures. You should tell your doctor before you take Sodium Oxybate 500 mg/ml oral solution if you have any history of seizures.

Psychosis

Sodium Oxybate 500 mg/ml oral solution can cause psychosis (a mental disorder that may involve hallucinations, incoherent speech, or disorganised and agitated behaviour). You should tell your doctor before you take Sodium Oxybate 500 mg/ml oral solution if you have any history of psychosis.

Dependency/abuse/misuse

The active ingredient of Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution is dangerous and can lead to fatal consequences.

These are not all the side effects of Sodium Oxybate 500 mg/ml oral solution. Talk to your doctor for medical advice about side effects.

4. Can Sodium Oxybate 500 mg/ml oral solution be abused? Is it addictive?

Sodium Oxybate 500 mg/ml oral solution contains Sodium Oxybate, a form of gamma-hydroxybutyrate (GHB). Abuse of Sodium Oxybate 500 mg/ml oral solution 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).

Sodium Oxybate 500 mg/ml oral solution, an approved pharmaceutical product, should not be equated with illicit substance purchased from any other source. The potency and purity of Sodium Oxybate 500 mg/ml oral solution is highly controlled and regulated to ensure you receive a correct and consistent dose that will be defined by your doctor for correct use.

5. 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 Sodium Oxybate 500 mg/ml oral solution dose without consulting your doctor!





6. Why do I have to be in bed, ready to sleep, before taking Sodium Oxybate 500 mg/ml oral solution?

Sodium Oxybate 500 mg/ml oral solution rapidly induces sleep; therefore, as a safety precaution, it is best to be in bed as its effects begin to take place.

7. Can I reuse Sodium Oxybate syringes or dosing cups from other packages of Sodium Oxybate?

No. It is very important that you only use the syringe and dosing cup that are included in the package of Sodium Oxybate 500 mg/ml oral solution that you have been prescribed.

For Sodium Oxybate there are several products in the market. There are differences regarding the scales included in the syringes of these products. If you reuse the syringe of other product, it may lead you to make mistakes when preparing the doses that you should take.

If you reuse the syringe or dosing cups of other products, you may experience lack of efficacy (due to taking a lower dose than the one prescribed by your physician) or an overdose (due to taking a higher dose than the one prescribed by your physician). Both situations may be dangerous for your health.

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

The active ingredient in Sodium Oxybate 500 mg/ml oral solution is short acting and the beneficial effects of a single dose of Sodium Oxybate 500 mg/ml oral solution will not last for the entire night. Therefore, it is required that you take a second dose of Sodium Oxybate 500 mg/ml oral solution 2.5 to 4 hours after the first dose, for the desired therapeutic effect.

9. How will I wake up to take the second dose of Sodium Oxybate 500 mg/ml oral solution?

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.

10. Would I wake up in an urgent situation or emergency after having taken Sodium Oxybate 500 mg/ml oral solution?

In this regard, Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution the urgent situation occurs, the size of the Sodium Oxybate 500 mg/ml oral solution dose being taken, the nature of the urgent situation, and your individual response to Sodium Oxybate 500 mg/ml oral solution.

11. What do I do if I forget to take Sodium Oxybate 500 mg/ml oral solution?

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 Sodium Oxybate 500 mg/ml oral solution again until the next night. Do not take a doubledose to make up for any individual doses you have forgotten.

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

Taking too much Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution 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.

13. Is Sodium Oxybate 500 mg/ml oral solution 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 500 mg/ml oral solution 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 valproate, topiramate, phenytoin or ethosuximide.

Ask your healthcare professional for the Sodium Oxybate 500 mg/ml oral solution Patient Alert Card to keep with you to remind you about the use of Sodium Oxybate 500 mg/ml oral solution. Show this card to all your doctors so they know you are taking Sodium Oxybate 500 mg/ml oral solution, especially if they prescribe other medications for you.

14. What does Sodium Oxybate 500 mg/ml oral solution taste like? Can I mix it with liquids other than water?

Because Sodium Oxybate 500 mg/ml oral solution contains sodium, it has a salty taste. Sodium Oxybate 500 mg/ml oral solution should be mixed with water as instructed in the package leaflet. Using cold tap water rather than warm water can minimize the salty taste. Sodium Oxybate 500 mg/ml oral solution should not be mixed with any other liquids, such as soft drinks or fruit juice because mixing Sodium Oxybate 500 mg/ml oral solution with any other beverage can change the chemical properties of the drug which may affect how it works.

15. Can I use Sodium Oxybate 500 mg/ml oral solution if I am pregnant or breastfeeding?

There are no adequate data on the use of Sodium Oxybate 500 mg/ml oral solution during pregnancy. Sodium Oxybate 500 mg/ml oral solution is therefore not recommended during pregnancy. Sodium Oxybate 500 mg/ml oral solution is excreted into breast milk, so you should not breastfeed when on Sodium Oxybate 500 mg/ml oral solution. Tell your doctor if you are pregnant or plan to become pregnant before starting Sodium Oxybate 500 mg/ml oral solution, or at any point during your treatment.





16. How soon might I see a change in my symptoms?

Most patients can expect to see some improvements within the first weeks of Sodium Oxybate 500 mg/ml oral solution therapy. However, it may take up to several weeks after you begin using Sodium Oxybate 500 mg/ml oral solution 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.

17. May I take Sodium Oxybate 500 mg/ml oral solution with food?

Food will decrease the amount of Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution dose to ensure consistent effects from the medication.

18. For how long will I need to take Sodium Oxybate 500 mg/ml oral solution?

Although Sodium Oxybate 500 mg/ml oral solution is taken to treat your disease symptoms, it is not a cure and you should continue taking Sodium Oxybate 500 mg/ml oral solution for as long as your doctor determines it is necessary. If you believe you don't require it anymore, or want to stop taking Sodium Oxybate 500 mg/ml oral solution for any other reason, be sure to discuss this with your doctor first.

19. Are there any precautions I should take while on Sodium Oxybate 500 mg/ml oral solution?

- 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 Sodium Oxybate 500 mg/ml oral solution.
- When you first start taking Sodium Oxybate 500 mg/ml oral solution, 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.

20. How often should I see my doctor?

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

21. Will Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution did not demonstrate a decrease in effectiveness.

22. What if I stop taking Sodium Oxybate 500 mg/ml oral solution 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 Sodium Oxybate 500 mg/ml oral solution, 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 Sodium Oxybate 500 mg/ml oral solution

- Do not share your Sodium Oxybate 500 mg/ml oral solution with anyone.
- Use only the dose your doctor prescribed. If you believe the dose needs to be changed, contact your doctor.
- Don't take Sodium Oxybate 500 mg/ml oral solution if you are less than 7 years old.
- Always respect a 2-hour interval between the last meal and the intake of Sodium

Oxybate 500 mg/ml oral solution.

- Always keep Sodium Oxybate 500 mg/ml oral solution and its syringe, in its original package, in a safe location.
- Keep Sodium Oxybate 500 mg/ml oral solution 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 500 mg/ml oral solution, please contact 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. Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store, and also some clinical IT systems for healthcare professionals. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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



Notes

