

Package leaflet: Information for the patient

Sodium Oxybate 500 mg/ml oral solution

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

1. What Sodium oxybate is and what it is used for

Sodium oxybate contains the active substance sodium oxybate. Sodium oxybate works by consolidating night-time sleep, though its exact mechanism of action is unknown.

Sodium oxybate is used to treat narcolepsy with cataplexy in adults, adolescents and children from 7 years of age.

Narcolepsy is a sleep disorder that may include attacks of sleep during normal waking hours, as well as cataplexy, sleep paralysis, hallucinations and poor sleep. Cataplexy is the onset of sudden muscle weakness or paralysis without losing consciousness, in response to a sudden emotional reaction such as anger, fear, joy, laughter or surprise.

2. What you need to know before you take Sodium oxybate

Do not take Sodium oxybate

- if you are allergic to sodium oxybate or any of the other ingredients of this medicine (listed in section 6);
- if you have succinic semialdehyde dehydrogenase deficiency (a rare metabolic disorder);
- if you suffer from major depression;
- if you are being treated with opioid or barbiturate medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium oxybate

- if you have breathing or lung problems (and especially if you are obese),

- because Sodium oxybate has the potential to cause difficulty in breathing;
- if you have or have previously had depressive illness, suicidal thoughts, anxiety, psychosis (a mental disorder that may involve hallucinations, incoherent speech, or disorganised and agitated behaviour) or bipolar disorder;
 - if you have heart failure, hypertension (high blood pressure), liver or kidney problems as your dose may need to be adjusted;
 - if you have previously abused drugs;
 - if you suffer from epilepsy as the use of Sodium oxybate is not recommended in this condition;
 - if you have porphyria (an uncommon metabolic disorder).
- If any of these apply to you, tell your doctor before you take Sodium oxybate.

While you are taking Sodium oxybate, if you experience bed-wetting and incontinence (both urine and faeces), confusion, hallucinations, episodes of sleepwalking or abnormal thinking, you should tell your doctor straight away. Whilst these effects are uncommon, if they do occur they are usually mild to moderate in nature.

If you are elderly, your doctor will monitor your condition carefully to check whether Sodium oxybate is having the desired effects.

Sodium oxybate has a well-known abuse potential. Cases of dependency have occurred after the illicit use of sodium oxybate.

Your doctor will ask if you have ever abused any drugs before you start taking Sodium oxybate and whilst you are using the medicine.

Children and adolescents

Sodium oxybate can be taken by adolescents and children from 7 years of age when they are over 15 kg in weight.

Sodium oxybate cannot be taken by children below 7 years of age or below 15 kg in weight.

If you are a child or adolescent, your doctor will monitor your body weight regularly.

Whilst the doctor is adjusting the dose, which may take a number of weeks, parent/caregivers should carefully monitor the child's breath during the first 2 hours after sodium oxybate intake to assess if there is any abnormality in breathing, for example stoppage of breathing for short periods while sleeping, noisy breathing and bluish colour of the lips and face. If abnormality in breathing is observed, medical support should be sought and the doctor should be informed as soon as possible. If any abnormality is noted after the first dose, the second dose should not be administered. If no abnormality is noted, the second dose can be administered. The second dose should not be given earlier than 2.5 hours or later than 4 hours after the first dose.

If you have had or are having upsetting feelings, particularly if you are feeling very sad or have lost interest in life, it is important that you tell the doctor or caregiver.

Other medicines and Sodium oxybate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, Sodium oxybate should not be taken together with sleep inducing medicines and medicines that reduce central nervous system activity (the central

nervous system is the part of the body related to the brain and spinal cord).

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

- medicines that increase central nervous system activity
- 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 treatment of epilepsy)
- If you are taking valproate, your daily dose of Sodium oxybate will need to be adjusted (see section 3) as it may lead to interactions with valproate.

Sodium oxybate with food, drink and alcohol

You must not drink alcohol while taking Sodium oxybate, as its effects can be increased.

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 for advice before taking this medicine.

There have been very few women who have taken Sodium oxybate sometime during their pregnancy and a few of them had spontaneous abortions. The risk of taking Sodium oxybate during pregnancy is unknown and, therefore, the use of Sodium oxybate in pregnant women or women trying to become pregnant is not recommended.

Patients taking Sodium oxybate should not breast feed since it is known that Sodium oxybate passes into breast milk. Changes in sleep patterns have been observed in breastfed infants from exposed mothers.

Driving and using machines

Sodium oxybate will affect you if you drive or operate tools or machines. Do not drive a car, operate heavy machinery or perform any activity that is dangerous or that requires mental alertness for at least 6 hours after taking Sodium oxybate.

When you first start taking Sodium oxybate, 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.

For paediatric patients, physicians, parents or caregivers are advised that the waiting time for performing activities that require mental alertness, motor co-ordination or any activities that may have a physical risk may have to be longer than 6 hours, depending on individual sensitivity.

Sodium oxybate contains sodium

You need to monitor the amount of salt you take as Sodium oxybate contains sodium (which is found in table salt), which may affect you if you have had high blood pressure, heart or kidney problems in the past.

If you take two 2.25 g doses of sodium oxybate each night you will take 0.82 g of sodium, or if you take two 4.5 g doses of sodium oxybate each night you will take in 1.6 g sodium. Ask your doctor for advice since you may need to moderate your intake of salt.

3. **How to take Sodium oxybate**

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

It is important that you only use the syringe provided in the box when preparing doses of Sodium oxybate. The 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. There are other oral solutions with sodium oxybate, but each one can have a different method of administration. Read carefully how to use this medicine and check with your doctor or pharmacist if you are not sure.

Adults – taking Sodium oxybate on its own

- For adults, the recommended starting dose is 4.5 g each day, given as two separate doses of 2.25 g.
- Your doctor may gradually increase your dose up to a maximum of 9 g each day given as two separate doses of 4.5 g.
- Take Sodium oxybate orally two times each night:
 - Take the first dose upon getting into bed and the second dose 2½ to 4 hours later. You may need to set an alarm clock to make sure you wake up to take the second dose.
 - Food decreases the amount of Sodium oxybate that is absorbed by your body. Therefore, it is best to take Sodium oxybate at set times 2 to 3 hours after a meal.
 - Prepare both doses before bedtime.
 - Take doses within 24 hours after preparation.

Adolescents and children aged 7 years and over who weigh 15 kg or more - taking Sodium oxybate on its own

For those aged 7 years and over who weigh 15 kg or more, a doctor will work out the right dose based on your body weight.

Your doctor will work out the right dose for you. Do not exceed the dose prescribed for you.

Adults - taking Sodium oxybate with Valproate

If you are taking valproate together with Sodium oxybate, the dose of Sodium oxybate will be adapted by your doctor.

- Take the first dose when getting into bed and the second dose 2½ to 4 hours later.

Adolescents and children aged 7 years and older who weigh 15 kg or more - taking Sodium oxybate with Valproate

If you are taking Valproate together with Sodium oxybate, the dose of Sodium oxybate will be adapted by your doctor.

Kidney or liver problems

If you have kidney problems, you should consider a dietary recommendation to reduce sodium (salt) intake. If you have liver problems, the starting dose should be halved. Your doctor may gradually increase your dose.

Instructions on how to dilute Sodium oxybate

The following instructions explain how to prepare Sodium oxybate. Please read the instructions carefully and follow them step by step. Do not allow children to prepare Sodium oxybate.

To help you, the Sodium oxybate carton contains 1 bottle of medicine, a measuring syringe (with two different measurement scales), an adaptor and two dosing cups with child-resistant caps.

1. Remove the bottle cap by pushing down while turning the cap anticlockwise (to the left). After removing the cap, set the bottle upright on a table-top. While holding the bottle in its upright position, insert the press-in-bottle-adaptor into the neck of the bottle. This needs only to be done the first time that the bottle is opened. The adaptor can then be left in the bottle for all subsequent uses.
2. Push the syringe plunger to the bottom of the syringe barrel (towards the tip) to remove excess air. Next, insert the tip of the measuring syringe into the centre opening of the bottle and press down firmly (See Figure 1).

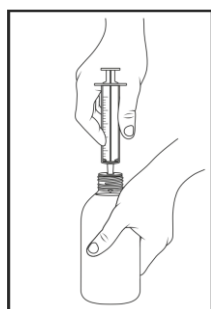


Figure 1

3. While holding the bottle and syringe with one hand, turn the bottle upside down and draw up the prescribed dose (following the 0.20 g or 0.25 g graduations on the barrel of the syringe) with the other hand by pulling on the plunger. **NOTE:** Medicine will not flow into the syringe unless you keep the bottle in its upside down position (See Figure 2).

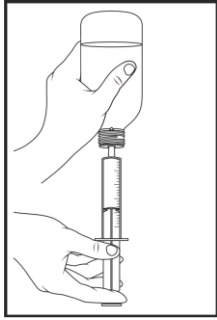


Figure 2

4. Put the bottle in an upright position. Remove the syringe from the centre opening of the bottle. Empty the medicine from the syringe into one of the dosing cups provided by pushing on the plunger (See Figure 3). Repeat these steps for the second dosing cup. Then add about 60 ml of water to each dosing cup (60 ml is about 4 tablespoons).

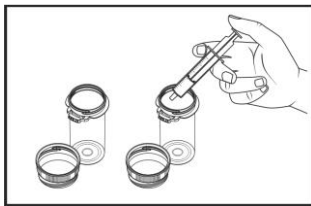


Figure 3

5. Place the caps provided on the dosing cups and turn each cap clockwise (to the right) until it clicks and locks into its child-resistant position (See Figure 4). Rinse out the syringe with water.



Figure 4

6. Just before going to sleep:
 - Adult patients should place the second dose near the bed.
 - The parent or caregiver of adolescents and children aged 7 years and over should not leave the second dose near the child's bed or within easy reach of the child
 - You may need to set an alarm so you wake up to take your second dose no earlier than 2.5 hours and no later than 4 hours after your first dose.

Then:

- Remove the cap from the first dosing cup by pressing down on the child-resistant locking tab and turning the cap anticlockwise (to the left).

- Drink all of the first dose while sitting in bed, recap the cup, and then lie down right away.
 - For children who sleep longer than 8 hours but less than 12 hours, the first dose may be given after the child has been sleeping for 1 to 2 hours
7. When you wake up or wake up the child 2.5 to 4 hours later, remove the cap from the second dosing cup. While sitting in bed, drink all of the second dose right before lying down to continue sleeping. Recap the second cup.

If you have the impression that the effect of Sodium oxybate is too strong or too weak, talk to your doctor or pharmacist.

If you take more Sodium oxybate than you should

Symptoms of Sodium oxybate overdose may include agitation, confusion, impaired movement, impaired breathing, blurred vision, profuse sweating, headache, vomiting, decreased consciousness leading to coma and seizures, excessive thirst, muscle cramps and weakness.

If you take more Sodium oxybate than you were told to take, or take it by accident, get emergency medical help right away. You should take the labelled medicine bottle with you, even if it is empty.

If you forget to take Sodium oxybate

If you forget to take the first dose, take it as soon as you remember and then continue as before. If you miss the second dose, skip that dose and do not take Sodium oxybate again until the next night. Do not take a double dose to make up for a forgotten dose.

If you are unsure if you took Sodium oxybate

If in doubt about administration of a dose, do not re-administer the dose to reduce the risk of overdose.

If you stop taking Sodium oxybate

You should continue to take Sodium oxybate for as long as instructed by your doctor. You may find that your cataplexy attacks return if your medicine is stopped and you may experience insomnia, headache, anxiety, dizziness, sleeping problems, sleepiness, hallucination and abnormal thinking.

If you stop taking Sodium oxybate for more than 14 consecutive days you should consult your doctor as you should restart taking Sodium oxybate at a reduced dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are usually mild to moderate.

Adults - most common side effects observed in clinical studies (occurring in 10% to 20% of patients):

- dizziness
- nausea
- headache.

If you experience any of these side effects, **tell your doctor straight away.**

Children and adolescents - most common side effects observed in a clinical study:

- bed wetting (18.3%)
- nausea (12.5%)
- vomiting (8.7%)
- weight decrease (8.7%)
- decreased appetite (6.7%)
- headache (5.8%)
- dizziness (5.8%)
- suicidal thoughts (1%)
- feeling mentally unwell (loss of contact with reality) (1%)

If you experience any of these side effects, **tell your doctor straight away.**

The side effects in adults and children are the same. If you experience any of the side effects listed below, tell your doctor straight away:

Very common (may affect more than 1 in 10 people):

- nausea, dizziness, headache.

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

- sleeping problems including insomnia, abnormal dreams, sleep paralysis, sleepiness, nightmares, sleep walking, bed wetting, excessive daytime sleepiness, difficulty in falling asleep in the middle of the night
- feeling drunk, trembling, confusion/ disorientation, blurred vision, balance disorder, fall, feeling of “spinning” (vertigo)
- feeling the heartbeat, increased blood pressure, shortness of breath
- vomiting, stomach pains, diarrhoea
- anorexia, decreased appetite, weight loss
- weakness, tiredness, sedation
- sweating
- depression
- muscle cramps, swelling
- joint pain, back pain
- disturbance in attention, disturbed sensitivity particularly to touch, abnormal touch sensation, abnormal taste
- anxiety, nervousness
- urinary incontinence
- snoring, congestion of the nose
- rash
- inflammation of the sinuses, inflammation of nose and throat

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

- psychosis (a mental disorder that may involve hallucinations, incoherent speech, or disorganised and agitated behaviour)
- paranoia, abnormal thinking, hallucination, agitation, suicide attempt
- difficulty in falling asleep
- restless legs
- forgetfulness
- myoclonus (involuntary contractions of muscles)
- involuntary passage of faeces
- hypersensitivity.

Not known (cannot be estimated from the available data):

- convulsion
- decreased breathing depth or rate, short cessation of breathing during sleep
- hives
- suicidal thoughts, delusion, thoughts of committing violent acts (including harming others)
- irritability, aggression
- euphoric mood
- panic attack
- mania / bipolar disorder
- dry mouth, dehydration
- swelling face (angioedema)
- bruxism (teeth grinding and jaw clenching)
- pollakiuria / micturition urgency (increased need to urinate)
- tinnitus (noise in the ears such as ringing or buzzing)
- sleep-related eating disorder
- increased appetite
- loss of consciousness
- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs)
- dandruff
- increased sexual desire
- nocturia (excessive urination at night)
- choking sensation.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Sodium oxybate

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the bottle after (EXP). The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After dilution in the dosing cups, the preparation should be used within 24 hours.

Once you open a bottle of Sodium oxybate, any contents that you have not used within 90 days of opening should be disposed of.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Sodium oxybate contains

- The active substance is sodium oxybate. Each ml contains 500 mg of sodium oxybate.
- The other ingredients are purified water, malic acid and sodium hydroxide for pH adjustment.

What Sodium oxybate looks like and contents of the pack

Sodium oxybate is supplied in a 200 ml amber PET bottle containing 180 ml of oral solution and closed with a white external and inner transparent child-resistant HDPE/polypropylene screw cap with a white sealing disk made of expanded polyethylene.

Each pack contains one bottle, a transparent plastic measuring syringe with white PE piston and graduations of 0.20 g and 0.25g, a transparent LDPE adaptor for the syringe, two orange polypropylene dosing cups of 90 ml capacity and two white HDPE screw closures. Note: a comma is used as a decimal separator on the syringe graduation.

Sodium oxybate is a clear solution.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH
Wallenroder Straße 8 - 10
13435 Berlin
Germany.

You should have received an Information Pack from your doctor, which includes a booklet on how to take the medicine, a Frequently Asked Questions patient information sheet and a Patient Alert Card.

This leaflet was last revised in 01/2025
