

How to Access Xyrem (Sodium Oxybate) in Australia

What is Xyrem?

The active substance in Xyrem is Sodium Oxybate, which is a sodium salt of **gamma-hydroxybutyrate** - sometimes referred to as GHB. GHB is a naturally occurring neurotransmitter and a central nervous system (CNS) depressant drug. This drug has a history of abuse when acquired illicitly and used illegally. Abuse of illicit GHB has been associated with adverse CNS events, including seizures, respiratory depression, and profound decreased consciousness, with instances of coma and even death.

Sodium oxybate comes as a solution (liquid) to be mixed with water and taken by mouth. It is usually taken twice each night because sodium oxybate wears off after a brief time, and the effects of one dose will not last for the entire night. The first dose is taken at bedtime, and the second dose is taken 2 1/2 to 4 hours after the first dose.



Is Xyrem accessible in Australia?

Xyrem is accessible in Australia; however, there are several barriers to accessing Xyrem due to it being a highly restricted Schedule 8 poison (controlled drug.) [The TGA determines the Factors for controlled drugs \(schedule 8\).](#) *

Who can access Xyrem in Australia?

People diagnosed with narcolepsy who are currently a patient of a sleep specialist.

How much does Xyrem cost?

Xyrem comes in a bottle that contains 90gm (180mL) of liquid which holds the medication, and depending on the pharmacy, a 180mL bottle will cost between \$550 to \$600. Bottles must be purchased in pairs, so the minimum cost at any one time is around \$1100.

Is Xyrem on the PBS?

Xyrem is not on the Pharmaceutical Benefits Scheme (PBS) or registered with the Therapeutic Goods Administration (TGA). Normally when a medication is approved and listed on the PBS, the Australian government pays for a portion of the medication, and the individual pays for a smaller portion of the medication. As Xyrem is not funded by the government like other medications are under the PBS it means that you must pay for it in full. *

* You can read more about Xyrem and the TGA & PBS in our other factsheet, [Why is Xyrem \(Sodium Oxybate\) not PBS listed or TGA registered \(approved\)?](#)

How long will a bottle last?

This depends on the dosage. Your doctor will start you with a low dose of sodium oxybate and gradually increase the amount. The maximum dose of Xyrem per night is 18 mL, 9g of liquid taken in 2 doses. One bottle of Xyrem is 180mL, so taking the maximum dose will last for 10 days. Some people never go as high as the maximum dose because they find benefit at a lower dose or cannot afford the full dose. Some may choose to skip nights or reduce their dose to save money. Xyrem's cost is the main reason most people with Narcolepsy do not access the medication.

I have heard that some people get it cheaper through their hospital. How do I do that?

To qualify, you must be a patient of a sleep specialist in a public hospital, have tried all other medications, and be unable to afford to pay the full price for Xyrem. Technically, provided your doctor is willing to complete more paperwork and is prepared to be persistent, every public hospital that has a sleep service should be able to provide Xyrem at a subsidised price through the hospital's **Medicine Access Program** (also referred to as Compassionate Use Programs, Expanded Access Programs, Product Familiarisation Programs, Cost-Share Programs, and Early Access Programs). Once approved, the state government then pays for the drug via the public hospital. Your doctor will need to complete an individual patient authorisation through the hospital. Once approved, the state government then pays for the drug via the public hospital.

The process is the same in each state and territory - except Western Australia.

Unlike in other states and territories, Xyrem is included in the WA Statewide Medicines Formulary (SMF). The WA SMF is a list of approved medicines that may be initiated in public hospitals in WA. This means if you are a patient in a public hospital in WA and you meet the necessary criteria** your doctor does not need to apply for individual approval via the process described above. Your doctor can prescribe Xyrem directly via the Formulary. The drug is then subsidised by the WA State Government.

***refractory narcolepsy where licenced medications were ineffective, had significant side effects or were contraindicated.*

Note: There may be some resistance initially from the hospital administration because of the huge cost of the drug and because many hospital pharmacies are unfamiliar with it. Your doctor may not be successful, to begin with. According to the doctors that have been successful, persistence usually pays off, so hopefully, your doctor is willing to keep pushing!

How do I try Xyrem?

Discuss with your sleep physician and care team your options and eligibility for accessing Xyrem. If you decide to go ahead, you follow the same pathway outlined below.

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How do I access Xyrem?

Once you and your doctor decide that a trial of Xyrem is appropriate for you, there are several lengthy steps that must be taken. Some steps are required by the federal government, others by the state government and by UCB Pharma, the company that sells and distributes Xyrem.

Permit to write Prescription



Since Xyrem is a Schedule 8 drug, the doctor must first apply for and then be granted a permit to write a prescription. They must do this for each patient. Although each state has its own specific procedure for doing this, the general idea is the same.

Note: Once a doctor has a permit to prescribe a Schedule 8 medication to you, only that doctor can prescribe the medication. You cannot ask another doctor to apply for a permit, as only one doctor can have a permit for each patient at any given time.

Permit for Import & Supply



As Xyrem is not registered for use in Australia, each patient treated with Xyrem needs to be granted specific permission for Xyrem to be imported and supplied to them. This approval is given by the TGA under the Special Access Scheme (SAS), category B. Forms requesting this permission are completed online by the prescribing doctor via the SAS online system. When applying to access an unapproved product on behalf of a patient under the SAS Category B pathway, prescribers must provide a clinical justification which should include the seriousness of the condition, consideration for the use of medicines that are included in the ARTG, and the potential risks and benefits of using the proposed unapproved medicine. Once approved, your doctor should receive an email, including the letter of approval, usually within a week of submitting the request.

Sign the Consent Form



Once your doctor has a Schedule 8 permit and SAS approval from the TGA, the TGA and UCB Australia will ask you to sign a consent form agreeing to the use of Xyrem. This needs to be done during a face-to-face appointment with your sleep specialist. By signing this consent form, you are acknowledging that Xyrem has not been formally registered with the TGA and is, therefore, not officially approved for use.

Note: Your doctor should discuss Xyrem's side effects and what to watch out for. Ensure your doctor reviews any other medications you are taking to ensure there are no interactions, or formulate a plan for managing possible interactions.

Write Prescription



Your doctor can now write your Xyrem prescription and will provide the pharmacist that has been chosen to dispense your prescription with copies of the SAS Category B approval, Schedule 8 permit and prescription.

Filling Prescription



The pharmacy can then order in Xyrem. As Xyrem is not subsidised via the PBS, pharmacies may ask you to pay for Xyrem before they order it for you. It is helpful if the senior pharmacist and your doctor have a good working relationship.

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How is the medication dispensed once I am approved?

The medication will be dispensed via the hospital pharmacy pharmacist that has been chosen to dispense your prescription. As Xyrem use is complex and it is an unregistered product, few doctors have experience using it, and pharmacists are not familiar with it. That means there are likely to be challenges along the way, with forms not being completed correctly or people being unsure of the process.

Is Xyrem the right drug for me?

This is a decision for you to make and one that needs to be discussed with your sleep specialist and your other medical practitioners to see if it will be suitable and appropriate for you. It takes time to work out the correct dose of Xyrem and to work through the side effects, so it is important to work closely with your treating team to troubleshoot any problems and adjust the dose accordingly.

Fact Sheet produced by:



ADVOCACY EDUCATION AWARENESS

Links to sources used to write this fact sheet:

[Xyrem \(sodium oxybate\) Information - FDA](#)
[Xyrem \(sodium oxybate\) in Australia - SleepHub](#)
[Authorised Prescriber Scheme](#)
[Sodium Oxybate MedlinePlus Drug Information](#)
[TGA 4.1 Sodium oxybate Scheduling medicines and poisons](#)
[Unapproved products for individual patients \(Special Access Scheme\)](#)
[Medicines Access Programs \(MAP\)](#)
[Statewide Medicines Formulary Policy](#)
Conversations with Dr Chris Kosky and Dr Sutapa Mukherjee

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