

Alepam

contains the active ingredient oxazepam

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Alepam.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Alepam against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Alepam is used for

Alepam is used for:

- anxiety, such as the anxiety associated with depression

- tremor, anxiety and confusion associated with alcohol withdrawal.

Alepam contains the active ingredient oxazepam, which belongs to a group of medicines called benzodiazepines. These medicines are thought to work by their action on brain chemicals.

Ask your doctor if you have any questions about why Alepam has been prescribed for you.

Your doctor may have prescribed Alepam for another reason.

In general, benzodiazepines such as Alepam should be taken for short periods only (for example 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Alepam is not recommended for use in children under 16 years of age, as its safety and effectiveness have not been established in this age group.

Alepam is available only with a doctor's prescription.

Before you take Alepam

When you must not take it

Do not take Alepam if you are allergic to:

- oxazepam or any other benzodiazepine medicine

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Alepam if you have:

- severe and chronic respiratory (lung or airways) disease
- sleep apnoea.

Do not take Alepam if the expiry date (EXP) printed on the bottle has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Alepam if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Like other benzodiazepine medicines, Alepam may cause unwanted effects in the newborn baby if used during

pregnancy. Your doctor will discuss the risks and benefits of taking Alepam during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Alepam passes into breast milk and may cause drowsiness and/or feeding difficulties in the baby. Your doctor will discuss the risks and benefits of taking Alepam when breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- low blood pressure
- myasthenia gravis, a condition where there is severe muscle weakness
- glaucoma (increased pressure in the eye)
- liver or kidney problems
- depression, psychosis or schizophrenia
- respiratory or breathing problems
- epilepsy, fits or convulsions
- drug or alcohol dependence or a past history of these problems.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of Alepam.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking Alepam.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Alepam, or may affect how well it works. These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression, schizophrenia and other mental illnesses
- medicines to treat epilepsy and fits
- antihistamines, medicines for allergies, colds or travel sickness
- medicines used to treat stomach cramps
- some medicines used to treat Parkinson's disease
- muscle relaxants

- strong pain relievers.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Alepam.

How to take Alepam

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist.

How much to take

The dose varies from person to person, depending on age and the condition being treated.

Your doctor will tell you how many tablets you need to take each day and when to take them.

Elderly people may need smaller doses.

Alepam is not approved for use in children under 16 years of age.

How to take Alepam

Swallow the tablets with a glass of water.

Alepam can be taken with or without food.

If you forget to take Alepam

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take Alepam for

Take Alepam only for as long as your doctor recommends.

Usually, Alepam should be taken for short periods only (for example 2 to 4 weeks). Continuous long-term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

If you take too much Alepam (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Alepam.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Alepam, you may feel drowsy, tired, confused, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are taking Alepam

Things you must do

Take Alepam exactly as your doctor has prescribed.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Alepam.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Alepam.

If you become pregnant while taking Alepam, tell your doctor immediately.

If you plan to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are taking Alepam.

If you have to have any blood tests, tell your doctor that you are taking Alepam.

Alepam may affect the results of some tests.

Tell your doctor if you feel Alepam is not helping your condition or if you have any problems.

This is especially important if your anxiety attacks become worse or more frequent. Talking to your doctor will determine the best treatment for you.

Visit your doctor regularly so they can check on your progress.

You may need to have tests to check your blood and liver function. Also, your doctor can advise you on whether you need to keep taking Alepam.

Things you must not do

Do not drive or operate machinery until you know how Alepam affects you.

Alepam may cause drowsiness or dizziness in some people. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

Do not stop taking Alepam, or change the dose, without checking with your doctor.

Stopping Alepam suddenly may cause some unwanted effects. Your doctor may want you to gradually reduce the amount of Alepam you are taking before stopping completely.

Do not suddenly stop taking Alepam if you suffer from epilepsy.

Stopping Alepam suddenly may make your epilepsy worse.

Do not take Alepam for a longer time than your doctor has prescribed.

Alepam should be taken for short periods only (for example 2 to 4 weeks) unless advised otherwise by your doctor.

Do not use Alepam to treat any other conditions unless your doctor tells you to.

Do not give Alepam to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when drinking alcohol while taking Alepam.

Combining Alepam and alcohol can make you more drowsy or dizzy. Your doctor may suggest that you avoid alcohol while you are taking Alepam.

Be careful if you are elderly, unwell or taking other medicines.

You may have an increased chance of getting side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Alepam.

Alepam helps most people with anxiety, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dizziness, drowsiness, feeling tired
- unsteadiness, tremor
- headache
- nausea, stomach pain

- unpleasant dreams
- slurred speech
- blurred vision
- tingling or numbness of the hands or feet.

The above list includes the milder side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- confusion
- behavioural or mood changes such as sudden rage, increased excitement, aggression
- hallucinations
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes and skin
- dark coloured urine.

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- fainting
- any type of skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath.

The side effects listed above are serious and require urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Alepam

Storage

Keep Alepam where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Alepam or any other medicine in the bathroom or near a sink.

Do not leave Alepam in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Alepam, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Alepam tablets are available in 2 strengths:

- Alepam 15 - round pale yellow tablet marked OM/15 and G. Each bottle contains 25 tablets and each blister pack carton (hospital only) contains 90 tablets
- Alepam 30 - round pale orange tablet marked OM/30 and G. Each bottle contains 25 tablets.

Ingredients

The active ingredient in Alepam is oxazepam.

- Each Alepam 15 tablet contains
15 mg of oxazepam.
- Each Alepam 30 tablet contains
30 mg of oxazepam.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- quinoline yellow CI47005 (E104)
- erythrosine CI45430 (E127)
- magnesium stearate.

The tablets are gluten free.

The tablets contain trace amounts of sulfites and galactose.

Manufacturer

Alepam is made in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Alepam 15

AUST R 17572 (bottle)

Alepam 30

AUST R 17573 (bottle).

This leaflet was prepared on

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