
Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VALPAM. 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 VALPAM against the benefits they expect it will have 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 VALPAM is used for

VALPAM is used to:

- treat anxiety (anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.)
- relieve symptoms associated with alcohol withdrawal such as acute agitation and tremor
- relax muscles.

VALPAM belongs to a group of medicines called benzodiazepines. These medicines are thought to work by acting on brain chemicals.

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

Your doctor may have prescribed it for another reason.

In general, benzodiazepines such as VALPAM should be taken for short periods only (around 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.

VALPAM is not recommended for use in children less than six months old.

VALPAM is available only with a doctor's prescription.

Before you take it

When you must not take it

Do not take VALPAM if you are allergic to:

- diazepam or any other benzodiazepine
- any of the ingredients listed at the end of this leaflet.

Do not take VALPAM if you have:

- severe and chronic lung disease
- severe liver disease
- sleep apnoea
- myasthenia gravis
- drug or alcohol dependence
- depression, anxiety associated with depression, or any mental illness which is not being treated with another medicine.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

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

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, VALPAM may cause unwanted effects in the newborn baby if used during pregnancy. Your doctor will discuss the risks and benefits of taking VALPAM during pregnancy.

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

VALPAM is not recommended for use in breastfeeding as it passes into breast milk and may cause drowsiness and feeding difficulties in the baby. Your doctor will discuss the risks and benefits of taking VALPAM when breastfeeding.

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

- liver or kidney disease
- lung or breathing problems
- depression, psychosis or schizophrenia
- epilepsy, fits or convulsions
- low blood pressure
- a history of drug or alcohol dependence
- glaucoma (high pressure in the eye).

Tell your doctor if you drink alcohol.

Alcohol may increase the side effects of VALPAM.

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

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 VALPAM or may affect how well it works. These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines used to treat depression
- medicines used to treat mental illness
- other medicines for anxiety
- medicines used to treat epilepsy, fits or convulsions
- antihistamines, medicines used to treat allergies and colds
- medicines used to treat stomach cramps
- some medicines used to treat Parkinson's disease
- medicines for travel sickness
- muscle relaxants
- strong pain relievers
- medicines used to treat ulcers and reflux such as cimetidine, cisapride and omeprazole
- disulfiram, a medicine used in alcohol abuse
- ketoconazole, a medicine used to treat fungal infections.

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 VALPAM.

How to take it

How much to take

The dose varies from patient to patient. This depends on your age, the condition being treated and whether or not you are taking any other medicines.

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

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

How to take it

Swallow the tablets with a glass of water.

If you forget to take it

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.

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

How long to take it for

Take VALPAM only for as long as your doctor recommends.

Usually, it 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 such as VALPAM, may lead to dependence on the medicine.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much VALPAM. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much VALPAM you may feel drowsy, tired, weak, confused or dizzy or become unconscious.

While you are taking it

Things you must do

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

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

If you become pregnant while taking VALPAM, tell your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking VALPAM.

If you need a thyroid function test, tell your doctor that you are taking VALPAM.

VALPAM may affect the results of this test.

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

You may need to have tests to check your blood and liver. Your doctor will also advise whether you need to continue taking VALPAM.

Things you must not do

Do not take VALPAM for longer than your doctor has prescribed.

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

Do not stop taking it or lower the dose, without checking with your doctor.

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

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

Suddenly stopping this medicine may make your epilepsy worse.

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

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

Things to be careful of

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

This medicine may cause drowsiness, dizziness or poor concentration in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while taking VALPAM.

Combining VALPAM and alcohol can make you more drowsy or dizzy. Your doctor may suggest you avoid alcohol while being treated with this medicine.

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

Some people may experience side effects such as drowsiness, dizziness, confusion or 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 VALPAM.

Like all other medicines, VALPAM may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

You may have an increased chance of getting side effects if you are elderly, unwell or taking other medicines.

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:

- drowsiness, tiredness
- tremor, weakness, unsteadiness

- dizziness
- loss of memory, poor concentration
- confusion
- depression
- nausea
- headache
- blurred vision
- constipation
- loss of bladder control, passing little or no urine
- changes in sex drive
- unpleasant dreams
- slurred speech.

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

- anxiety, restlessness, agitation, irritability, aggressiveness
- hallucinations or delusions
- sudden rage or increased excitement
- severe sleep disturbances
- yellowing of the skin and/or eyes
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- fainting
- chest pain
- severe skin rash
- swelling of the face, lips or tongue which may cause difficulty swallowing or breathing
- wheezing or shortness of breath.

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

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

After taking it

Storage

Keep your medicine 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 VALPAM or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking VALPAM 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

VALPAM comes in 2 strengths of tablets:

VALPAM 2: round, flat, bevel edged, white to off-white tablet marked DZ/2 on one side and plain on the other. Available in blister packs.

VALPAM 5: round, flat, bevel edged, light yellow tablet marked DZ/5 on one side and plain on the other. Available in bottle or blister packs.

Each pack contains 50 tablets.

Ingredients

The active ingredient in VALPAM is diazepam.

VALPAM 2: Each tablet contains 2 mg of diazepam.

VALPAM 5: Each tablet contains 5 mg of diazepam.

The tablets also contain:

- lactose
- maize starch
- magnesium stearate.

VALPAM 5 tablets also contain:

- quinoline yellow CI47005 (104).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian registration numbers:

VALPAM 2 mg blister pack: AUST R 80809

VALPAM 5 mg blister pack: AUST R 80811

VALPAM 5 mg bottle: AUST R 80812.

This leaflet was revised in April 2016.