

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Valpro.

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 Valpro against the benefits they expect it will have for you.

Please read this leaflet very carefully before you start to take your Valpro, even if you have taken Valpro before.

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

Keep this leaflet with the medicine. You may need to read it again.

What Valpro is used for

Valpro is a medicine used for the treatment of epilepsy in adults and children.

Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Valpro belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Valpro may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability.

Valpro may be used alone or in combination with other medicines to treat your condition. Your doctor, however, may have prescribed Valpro for another reason.

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

There is no evidence that Valpro is addictive. Valpro is available only with a doctor's prescription.

Before you take Valpro

When you must not take it

Do not take Valpro if you have an allergy to:

- any medicines containing sodium valproate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Valpro if you have or have had any of the following medical conditions:

- liver disease (hepatic dysfunction) or severe hepatitis
- a family history of hepatitis, especially when caused by medicines. Medicines used in the treatment of epilepsy,

including Valpro may have adverse effects on the liver and the kidneys

- a urea cycle disorder or a family history of urea cycle disorders
- a family history of unexplained infant deaths
- porphyria, which is a rare blood disease of blood pigments
- known ornithine transcarbamylase deficiency or a family history of ornithine transcarbamylase deficiency.
- known or suspected of having a genetic problem causing a mitochondrial disorder.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

Before you start to take it

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

If you are a female patient of child-bearing age, make sure that you talk to your doctor about the risks associated with taking Valpro during pregnancy.

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

Like most medicines of this kind, Valpro may affect your developing baby if taken in the first trimester of pregnancy, as it is suspected of causing an increased risk of malformations in the exposed foetus. Also, children born to mothers who take Valpro throughout their pregnancy may be at risk of impaired cognitive development or withdrawal syndrome. However, do not stop taking Valpro unless your doctor says so as there are risks to the mother and child from uncontrolled epilepsy or uncontrolled mania episodes.

Your doctor may want to adapt your treatment and/or prescribe dietary supplements of folate.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

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

Medicines used in the treatment of epilepsy, including Valpro, pass into breast milk.

Your doctor will discuss the risks and benefits of taking Valpro if you are breastfeeding or planning to breastfeed.

Tell your doctor if you drink alcohol. If you have more than 2 drinks per day, you may be putting yourself at risk of a seizure or fit.

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

- kidney problems
- liver problems (hepatic insufficiency, hepatic damage)
- urea cycle disorders
- ornithine transcarbamylase (OTC) deficiency
- carnitine palmitoyltransferase (CPT) type II deficiency.

- systemic lupus erythematosus (SLE) (a disease affecting the skin, joints and kidneys)
- family history of a genetic problem causing mitochondrial disorder.

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

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 Valpro.

Taking other medicines

Tell your doctor or pharmacist 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 and Valpro may interfere with each other. These include:

- aspirin (and other salicylates)
- medicines used to prevent clots (anticoagulants) e.g. warfarin
- other medicines used to treat epilepsy e.g. phenobarbitone, methylphenobarbitone, primidone, phenytoin, carbamazepine, clonazepam, felbamate, lamotrigine, topiramate, diazepam, lorazepam, oxcarbamazepine, rifunamide and ethosuximide
- medicines used to treat depression e.g. monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants
- benzodiazepines (medicines used as sedatives or to treat anxiety)
- oral contraceptives. Valpro should have little effect on the oral contraceptive pill, however, you should let your doctor know that you are taking it
- zidovudine (a medicine used to treat viral infections)
- neuroleptic agents including clozapine (a medicine used to treat schizophrenia)
- quetiapine or olanzapine (medicine used to treat bipolar disorder and schizophrenia)
- mefloquine (a medicine used to treat malaria)
- propofol (a medicine used before and during general anaesthesia)
- nimodipine (a medicine used to help blood flow to the brain)
- cimetidine (used to treat stomach ulcers)
- erythromycin, rifampicin and carbapenem antibiotics such as Invanz and Merrem
- cholestyramine
- acetazolamide

These medicines and others may be affected by Valpro or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Tell your doctor or pharmacist if your child is taking any other medicines before you start giving them Valpro, for example, aspirin or any other drugs used to treat epilepsy.

Children, especially young children, can be more sensitive to some of the side effects of Valpro.

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 Valpro.

How to take Valpro

How much to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of Valpro and slowly increase the dose to the lowest amount needed to control your condition.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Valpro may not work as well.

How to take it

Swallow the tablets whole with a glass of water or other liquid.

Do not crush or chew the tablets.

Valpro tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines. If you chew them, the coating is destroyed.

When to take it

Your doctor will advise you when to take Valpro.

Always follow your doctor's instructions.

Take Valpro with or immediately after food.

This will lessen the chance of a stomach upset.

Take Valpro at about the same time each day.

This will have the best effect and also help you remember when to take it.

If you are not sure when to take it, ask your doctor.

How long to take it for

Keep taking Valpro for as long as your doctor recommends.

Valpro helps control your condition but does not cure it. To properly control your condition Valpro must be taken every day.

If you forget to take it

Always remember to take your prescribed dose otherwise you may find that either your seizures or manic symptoms may return.

If you forget a dose, take your next dose as usual.

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

This may increase the chance of you getting unwanted side effects.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

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 that you or anyone else may have taken too much Valpro.

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

You may need urgent medical attention.

If you take too much Valpro, you may feel dizzy, drowsy or have cramps in the abdomen.

While you are taking Valpro

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Valpro.

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

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

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Valpro may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while taking Valpro, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability, or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

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

Be sure to keep all your doctors' appointments so that they can check on your progress.

Your doctor will check your progress and may want to take some tests from time to time. This helps prevent unwanted side effects.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not use Valpro to treat any other complaints unless your doctor tells you to.

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

Do not stop taking Valpro, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Valpro affects you.

Valpro may cause drowsiness or lightheadedness in some people, especially at the beginning of treatment. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or lightheaded.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Valpro may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

The effects of alcohol could be made worse while taking Valpro.

Combining Valpro and alcohol can make you more drowsy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with Valpro.

What do I need to consider about contraception?

Use an effective method of contraception and consult your doctor before planning pregnancy.

Unplanned pregnancy may not be desirable in patients receiving medicines for epilepsy or mania. You should use an effective method of contraception and consult your doctor before planning pregnancy; for example, your doctor may want you to start taking folate tablets.

Valpro should have little effect on the oral contraceptive pill, however, you should let your doctor know that you are taking it.

Side effects

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

Valpro helps most people with epilepsy and mania, but it may have unwanted side effects in some people.

All medicines can have side effects.

Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

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:

- nausea or vomiting
- bleeding, tender or enlarged gums
- abdominal cramps or pain
- changes in appetite
- changes in your weight
- irregular menstrual periods
- diarrhoea
- loss of bladder control
- headache
- unusual movements, including tremor and shaking
- rapid uncontrollable movements of the eye

- unsteadiness when walking, dizziness or light-headedness
- depression
- hair loss
- feeling tired or drowsy
- memory impairment
- confusion
- hallucinations
- disturbance in attention
- changes in behaviour including aggression and agitation
- nail and nail bed disorders

These are the more common side effects of Valpro. Mostly these are mild and short-lived.

Tell your doctor immediately or go to the Accident and Emergency Department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

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

- more frequent or more severe seizures (fits)
- blood clotting problems
- spontaneous bruising or bleeding
- rashes
- signs of liver problems such as vomiting, loss of appetite, generally feeling unwell, tiredness, yellowing of the skin and/or eyes, dark urine or blood in urine, pain in the abdomen
- swelling of the feet and legs, weight increase due to fluid build up
- fainting
- bizarre behaviour
- suicidal thoughts
- suicide attempts
- severe upper stomach pain, often with nausea and vomiting

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Ask your doctor to answer any questions you may have.

After using Valpro

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Valpro 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 the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

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

Do not store Valpro or any other medicine in the bathroom or near a sink. Do not leave Valpro in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Return any unused medicine to your pharmacist.

Product description

What it looks like

Valpro comes in two strengths of tablets:

- Valpro 200
- Valpro 500

They are both round, enteric-coated, purple tablets.

Each blister pack contains 100 tablets.

Ingredients

The active ingredient in Valpro is sodium valproate. Each Valpro tablet contains 200 mg or 500 mg of sodium valproate.

The tablets also contain:

- maize starch
- magnesium stearate
- sodium starch glycollate
- microcrystalline cellulose
- colloidal anhydrous silica
- purified talc
- hypromellose
- diethyl phthalate
- cellulose
- macrogol 400
- Opadry Violet OY-6721 (includes colours titanium dioxide CI 77891, indigo carmine CI 73015, erythrosine CI 45430, sunset yellow FCF CI 15985).

The tablets are gluten free.

Manufacturer

Valpro is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

Valpro 200 - AUST R 46379

Valpro 500 - AUST R 46380

This leaflet was prepared on 5 October 2018.

Valpro_cmi\Oct18\00