

Valpro

contains the active ingredient sodium valproate

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.

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 Valpro is used for

Valpro is used to control:

- * different types of epilepsy, a condition where you have repeated seizures (fits).
- * mania, a mental condition with episodes of excitement, overactivity, uninhibited behaviour or irritability.

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.

In mania, Valpro has shown to help reduce the symptoms and occurrence of manic episodes.

Valpro may be prescribed alone, or if control of symptoms is poor, in combination with other medicines, to treat your condition.

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

Valpro is available only with a doctor's prescription.

There is no evidence that Valpro is addictive.

Before you take Valpro

When you must not take it

Do not take Valpro if you are allergic to medicines containing sodium valproate or any of the ingredients listed at the end of this leaflet.

Do not take Valpro if you have:

- * liver problems
- * urea cycle disorders
- * a family history of hepatitis, especially when caused by medicines
- * porphyria, which is a rare blood disease of blood pigments
- * known ornithine transcarbamylase deficiency or a family history of ornithine transcarbamylase deficiency.

Do not take Valpro if you are pregnant or intend to become pregnant, without talking to your doctor first.

Like most medicines for epilepsy, Valpro is not recommended for use during pregnancy, as it may affect your developing baby. However, it is very important to control your condition while you are pregnant. Your doctor will help you decide whether or not to take Valpro during pregnancy.

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

It is recommended that you do not breastfeed while taking Valpro, as it passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Valpro when breastfeeding.

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 it has expired or is damaged, return it to your pharmacist for disposal.

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 have or have had any of the following medical conditions:

- * systemic lupus erythematosus (SLE)
- * kidney problems
- * liver problems
- * bleeding tendency or disorder
- * urea cycle disorders
- * ornithine transcarbamylase deficiency.

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

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

Valpro may affect your developing baby if taken in the first trimester of pregnancy. However, do not stop taking Valpro unless your doctor says so, as there are risks to the mother and child from uncontrolled epilepsy.

Your doctor may adapt your treatment and/or prescribe a folate supplement, e.g. 5mg folate daily, before becoming pregnant and during the first 12 weeks of your pregnancy.

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

Valpro passes into breast milk.

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

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:

- * other medicines used to treat fits and convulsions, e.g., carbamazepine, phenytoin, phenobarbitone, clonazepam, ethosuximide, lamotrigine and primidone
- * anticoagulants, medicines used to prevent blood clots, e.g., warfarin
- * aspirin and other salicylates
- * sleeping tablets, sedatives and tranquillisers

- * medicines for depression, including tricyclic antidepressants, selective serotonin reuptake inhibitors, monoamine oxidase inhibitors
- * medicines used to treat mental conditions such as anxiety, psychosis and schizophrenia
- * oral contraceptives (birth control pill). Valpro should have little effect on the oral contraceptive pill; however, you should let your doctor know that you are taking it.
- * erythromycin and carbapenem antibiotics such as Invanz and Merram
- * medicines used to treat ulcers such as cimetidine
- * mefloquine, a medicine used to treat malaria
- * zidovudine, a medicine used to treat viral infections.

These medicines may be affected by Valpro or may affect how well it works. You may need different amounts of your medicines, or you may need to take different 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 Valpro.

How to take Valpro

How much to take

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

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

How to take it

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

Valpro tablets have a special coating. If you crush or chew the tablets, they will not work as well.

When to take it

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 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

Most anticonvulsant medicines take time to work. It may take up to 2 to 6 weeks to feel the full benefit of Valpro.

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 regularly.

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 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 very drowsy and have shallow breathing. You may also lose consciousness.

While you are taking Valpro

Things you must do

Before starting 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, including dental surgery, tell your doctor or dentist that you are taking Valpro.

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

- * increase in seizures (fits)
- * yellowing of the eyes or skin
- * swelling of the face
- * severe upper stomach pain, often with nausea and vomiting and/or loss of appetite
- * feeling generally unwell with tiredness, weakness and vomiting.

These symptoms may mean that you have a serious condition affecting your liver or pancreas. You may need urgent medical attention.

Children under 3 years of age are more at risk of liver reactions, especially those taking more than one epilepsy medicine, who are mentally retarded, brain damaged or have congenital abnormalities.

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

Your doctor may ask you to have tests to check your liver, kidney and blood from time to time. This helps to prevent unwanted side effects.

Tell your doctor if you feel Valpro is not helping your condition.

If you continue to have seizures or manic symptoms, or if they become more frequent, your doctor may need to adjust your treatment.

Tell your doctor if, for any reason, you have not taken Valpro exactly as prescribed.

Otherwise, your doctor may adjust your treatment unnecessarily.

If you have to have any medical tests, including urine and thyroid function tests, tell your doctor that you are taking Valpro.

Valpro may affect the results of some tests.

Keep Valpro tablets in their foil pack until it is time to take them.

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

Things you must not do

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

Do not stop taking Valpro, or change the dose, without checking with your doctor. Do not let yourself run out of Valpro over the weekend or on holidays.

Stopping Valpro suddenly may cause unwanted effects or make your condition worse. Your doctor may want you to gradually reduce the amount of Valpro you are taking before stopping completely.

Things to be careful of

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

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

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

Valpro may cause drowsiness or dizziness in some people.

Be careful drinking alcohol while taking Valpro.

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

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

Unplanned pregnancy may not be desirable in patients taking anticonvulsants. You should use an effective method of contraception.

If you are planning pregnancy, your doctor may want you to start taking folate tablets to help prevent neural tube defects in the baby.

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, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you get any side effects, do not stop taking Valpro without talking to your doctor or pharmacist.

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, confusion
- * unsteadiness when walking
- * mood changes such as restlessness, aggression or excitement
- * diarrhoea, stomach pain or cramps
- * nausea (feeling sick) or vomiting
- * changes in appetite or weight
- * double vision, uncontrollable jerky eye movements
- * skin rash, itching, hives

- * hair loss
- * enlarged breasts or unusual secretion of breast milk
- * irregular or no menstrual periods.

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)
- * swelling of the face
- * yellowing of the eyes or skin (jaundice)
- * severe stomach pains, often with nausea and vomiting
- * feeling generally unwell with tiredness, weakness and vomiting
- * depression
- * seeing or hearing things that are not there
- * signs of frequent infections such as fever, chills, swollen glands, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * tiredness, headache, shortness of breath, dizziness or looking pale
- * severe skin rash which may include redness, blistering, bleeding and peeling of the skin
- * loss of consciousness.

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

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

After using Valpro

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 degrees 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.

Product description

What it looks like

Valpro comes in 2 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
- * cellacephate

- * 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)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Valpro 200 - AUST R 46379

Valpro 500 - AUST R 46380

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