

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Valprease. 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 Valprease against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

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

What Valprease is used for

Valprease tablets contain sodium valproate as the active ingredient, which belongs to a group of medicines called anticonvulsants.

Valprease is used to control epilepsy. Epilepsy is a condition where you have repeated seizures or fits. There are many different types of seizures, ranging from mild to severe. It is thought to work by controlling brain chemicals, which send signals to nerves so that seizures do not happen.

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

Valprease may be used alone or in combination with other medicines to treat your condition.

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

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

This medicine is available only with a doctor's prescription.

Before you take it

When you must not take it

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

Do not take Valprease 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 caused by medicines. Medicines used in the treatment of epilepsy, including Valprease 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, a rare disease of blood pigments.

Talk to your doctor or pharmacist if you are not sure whether you should be taking this 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 intend to become pregnant.

This medicine should not be used during pregnancy and in women of child-bearing potential unless clearly necessary. Your doctor will be able to advise you about the risks and benefits associated with the use of Valprease.

Valprease 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.

However, if taking this medicine whilst pregnant, do not stop taking it suddenly 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 prescribe dietary supplements of folate.

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

Tell your doctor if you are breast-feeding or wish to breast-feed.

Medicines used in the treatment of epilepsy pass into breast milk. Your doctor will discuss the risks and benefits of taking Valprease when breast-feeding.

Tell your doctor if you drink alcohol.

It is not recommended to drink alcohol during treatment with this medicine.

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

- liver problems (any hepatic insufficiency or disease)
- pancreas problems
- kidney problems
- urea cycle disorders
- ornithine transcarbamylase (OTC) deficiency.

Tell your doctor if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take Valprease.

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

- aspirin and other salicylates
- anticoagulants, medicines used to prevent clots such as warfarin
- other medicines used to treat epilepsy such as phenobarbitone, methylphenobarbitone, primidone, phenytoin, carbamazepine, clonazepam, felbamate, lamotrigine, diazepam, lorazepam, oxcarbamazepine, ethosuximide

- medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs) and tricyclic antidepressants
- oral contraceptives
- zidovudine, a medicine used to treat viral infections
- neuroleptic agents including clozapine, a medicine used to treat schizophrenia
- mefloquine, a medicine used to treat malaria
- cimetidine, a medicine used to treat stomach ulcers
- erythromycin and carbapenem antibiotics
- rifampicin
- topiramate.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines.

Your doctor will tell you what to do if you are.

Use in children

If Valprease has been prescribed for your child, ensure that your child's doctor is aware of any other medications that your child is taking, e.g. other medicines to treat epilepsy or aspirin.

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

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

How to take it

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.

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

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

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

How to take it

Swallow the tablets whole, with or after food, with a little water if necessary. Do not crush or chew the tablets.

VALPREASE tablets have a special coating to stop them dissolving until they have gone through the intestines. If you crush or chew the tablets, the coating is destroyed and they will not work as well.

When to take it

Take VALPREASE 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

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.

Ask your doctor or pharmacist if you are not sure what to do.

How long to take it

Keep taking Valprease for as long as your doctor recommends.

This medicine helps control your condition but does not cure it. To properly control your condition, it 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 Valprease. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose are variable and include coma, below normal or absent reflexes, trouble breathing and feeling dizzy or drowsy.

While you are taking it

Things you must do

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

Tell your doctor immediately if you become pregnant while taking this medicine.

If you have to have surgery or emergency treatment that requires a general anaesthetic, tell your doctor or dentist that you are taking Valprease.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

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 stop taking Valprease or lower the dose without checking with your doctor.

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

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

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

This medicine may cause dizziness or drowsiness in some people, especially at the beginning of treatment. If either of these occurs, do not drive, operate machinery or do anything else that could be dangerous.

Be careful drinking alcohol.

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

Things 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 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.

Valprease should have little effect on the oral contraceptive pill, however tell your doctor if 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 Valprease.

This medicine 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 VALPREASE without talking to your doctor or pharmacist.

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

- nausea or vomiting
- abdominal cramps
- changes in appetite
- changes in weight
- diarrhoea
- headache
- tremor
- unsteadiness when walking, dizziness or light-headedness
- depression
- hair loss
- feeling tired or drowsy
- changes in hearing.

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

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 serious, rare side effects. You may need urgent medical attention.

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.

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

You may not experience any of them.

After taking it

Storage

Keep the tablets in the protective blister foil until it is time to take them.

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

Store the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it 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.

Keep this 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.

Disposal

If your doctor tells you to stop taking your medicine or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Valprease tablets come in 2 strengths.

200 mg: a purple, round, coated, biconvex tablet, approximately 9.7 mm in diameter.

500 mg: a purple, round, coated, biconvex tablet, approximately 13 mm in diameter.

Blister packs of 100 tablets.

Ingredients

Active ingredient:

Valprease tablets contain either 200 mg or 500 mg of sodium valproate.

Inactive ingredients:

- povidone
- magnesium stearate
- microcrystalline cellulose
- colloidal anhydrous silica
- sodium starch glycollate
- purified talc
- citric acid
- Opadry white AMB OY-B-28920
- Eudragit L30 D-55
- triethyl citrate
- Opadry II 85F60017 purple.

Sponsor

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

Australian registration numbers:

Valprease 200 - AUST R 153053

Valprease 500 - AUST R 153054

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