What APO-SODIUM VALPROATE is used for

APO-SODIUM VALPROATE is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

APO-SODIUM VALPROATE 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.

APO-SODIUM VALPROATE may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability.

APO-SODIUM VALPROATE may be used alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that it is addictive.

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

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

Do not take APO-SODIUM VALPROATE if you have, 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 APO-SODIUM VALPROATE 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.

• known ornithine transcarbamylase deficiency or a family history of ornithine transcarbamylase deficiency.

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 take it

When you must not take it

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 the use of APO-SODIUM VALPROATE during pregnancy.
Tell your doctor if you are pregnant or intend to become pregnant.

APO-SODIUM VALPROATE 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, do not stop taking APO-SODIUM VALPROATE 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 APO-SODIUM VALPROATE 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 APO-SODIUM VALPROATE when breast-feeding.

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 medical conditions, especially the following:

• liver problems (any hepatic insufficiency or disease)
• 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 APO-SODIUM VALPROATE.

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 APO-SODIUM VALPROATE, 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 phenobarbital, methylphenobarbitone, primidone, phenytoin, carbamazepine, clonazepam, felbamate, lamotrigine, diazepam, lorazepam, oxcarbazepine, ethosuximide
• medicines used to treat depression such as monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants
• oral contraceptives. APO-SODIUM VALPROATE 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
• mefloquine, a medicine used to treat malaria
• cimetidine, a medicine used to treat stomach ulcers
• erythromycin and carbapenem antibiotics.

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.

If APO-SODIUM VALPROATE 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 APO-SODIUM VALPROATE.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APO-SODIUM VALPROATE.

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.

Ask your doctor if you are unsure of the correct dose for you. They will tell you exactly how much to take.

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

If you take the wrong dose, APO-SODIUM VALPROATE may not work well.

How to take it

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

Do not crush or chew the tablets. APO-SODIUM VALPROATE 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 APO-SODIUM VALPROATE 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.

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.
Ask your pharmacist for hints if you have trouble remembering when to take your medicine.

How long to take it
Keep taking APO-SODIUM VALPROATE 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), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much APO-SODIUM VALPROATE. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

If you take too much APO-SODIUM VALPROATE you may feel dizzy, drowsy or have cramps in the abdomen.

While you are taking it

Things you must do
Before starting any new medicine, tell your doctor or pharmacist that you are taking APO-SODIUM VALPROATE.
Tell all the doctors, dentists and pharmacists who are treating you that you are taking APO-SODIUM VALPROATE.
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 APO-SODIUM VALPROATE.
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 APO-SODIUM VALPROATE, 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 APO-SODIUM VALPROATE 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.
Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or dizzy.
It may cause drowsiness or dizziness in some people.

Be careful drinking alcohol.
Combining APO-SODIUM VALPROATE 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.
APO-SODIUM VALPROATE 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 APO-SODIUM VALPROATE.
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 APO-SODIUM VALPROATE 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.

Tell your doctor if you notice any of the following and they worry you:
- nausea or vomiting
- abdominal cramps
- changes in appetite
- changes in your weight
- irregular menstrual periods
- diarrhoea
- headache
- tremor
- rapid uncontrollable movements of the eye
- unsteadiness when walking, dizziness or light-headedness
- depression
- hair loss
- feeling tired or drowsy
- memory impairment
- confusion
- disturbance in attention
- changes in behaviour including aggression and agitation

These are the more common side effects of APO-SODIUM VALPROATE. 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 side effects. You may need urgent medical attention.
All of these serious side effects are rare.

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.

Do not store APO-SODIUM VALPROATE 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 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 APO-SODIUM VALPROATE comes in 2 strengths:
- APO-SODIUM VALPROATE 200 mg: a purple, round, coated, biconvex tablet, approximately 9.7 mm in diameter.
- APO-SODIUM VALPROATE 500 mg: a purple, round, coated, biconvex tablet, approximately 13 mm in diameter.

Each pack of APO-SODIUM VALPROATE contains 100 tablets.

Ingredients

The active ingredient in APO-SODIUM VALPROATE is sodium valproate:
- each APO-SODIUM VALPROATE 200 mg tablet contains 200 mg of sodium valproate
- each APO-SODIUM VALPROATE 500 mg tablet contains 500 mg of sodium valproate.

APO-SODIUM VALPROATE tablets also contain:
- povidone
- magnesium stearate
- microcrystalline cellulose
- colloidal anhydrous silica
- sodium starch glycollate

After using it

Storage

Keep APO-SODIUM VALPROATE 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 may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.
• purified talc
• citric acid anhydrous
• Opadry White AMB OY-B-28920
• Eudragit L 30 D-55
• triethyl citrate
• Opadry 85F60017 Purple.

Australian Registration Numbers

• APO-Sodium valproate 200 mg tablet
  AUST R 208635
• APO-Sodium valproate 500 mg tablet
  AUST R 208634

Sponsor

Aspen Pharma Pty Ltd
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Distributor

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