

Valproate-AFT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Valproate-AFT?

Valproate-AFT is a medicine used for the treatment of epilepsy in adults and children. Valproate-AFT may also be used to control mania, a mental condition with episodes of overactivity, elation or irritability. For more information, see Section [1. Why am I given Valproate-AFT?](#) in the full CMI.

2. What should I know before I am given Valproate-AFT?

Do not use if you have ever had an allergic reaction to Valproate-AFT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Valproate-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Valproate-AFT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Valproate-AFT given?

Valproate-AFT will be given to you as an infusion or injection into the veins. More instructions can be found in Section [4. How is Valproate-AFT given?](#) in the full CMI.

5. What should I know while I am given Valproate-AFT?

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|----------------------------------|---|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Valproate-AFT.If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.Call your doctor or nurse straight away if you do not feel well while Valproate-AFT being given to you. |
| Things you should not do | <ul style="list-style-type: none">Do not stop using this medicine suddenly, or lower the dosage, without checking with your doctor.Do not give this medicine to anyone else, even if they have the same condition as you. |
| Driving or using machines | <ul style="list-style-type: none">Valproate-AFT may cause drowsiness in some people. Make sure you know how you react to Valproate-AFT before you drive a car, operate machinery or do anything else that could be dangerous if you are drowsy or lightheaded. |
| Drinking alcohol | <ul style="list-style-type: none">Tell your doctor if you drink alcohol.The effects of alcohol could be made worse while you are receiving Valproate-AFT. |

For more information, see Section [5. What should I know while using Valproate-AFT?](#) in the full CMI.

6. Are there any side effects?

Gastrointestinal-related side effects may include nausea or vomiting, abdominal cramps or pain, changes in appetite, and diarrhoea. Brain and nerve symptoms may include headache, unusual movement including shaking or tremors, rapid uncontrollable movements of the eye, unsteadiness when walking, dizziness or light-headedness, feeling very tired or drowsy, memory impairment, and confusion. Mood and mental health changes include feeling low or depressed, hallucinations, difficulty concentrating and changes in behaviour, including being aggressive or very agitated. Other effects include hair loss, changes to nail or nail bed disorders, irregular menstrual periods, changes in weight, and sore, bleeding, or swollen gums.

Serious side effects include more frequent or more severe seizures, bizarre behaviour, suicidal thoughts, or attempts. Blood clotting problems and spontaneous bruising or bleeding may occur. Skin rashes can also occur. Watch for signs of liver or digestive 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, and severe upper stomach pain, often with nausea, vomiting and/or loss of appetite especially when prolonged. Other serious effects include swelling of the feet and legs, weight increase due to fluid build up, and fainting. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Valproate-AFT

Active ingredient(s): *Sodium Valproate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Valproate-AFT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Valproate-AFT.**

Where to find information in this leaflet:

- [1. Why am I given Valproate-AFT?](#)
- [2. What should I know before I am given Valproate-AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Valproate-AFT given?](#)
- [5. What should I know while I am given Valproate-AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given Valproate-AFT?

Valproate-AFT contains the active ingredient sodium valproate. Valproate-AFT belongs to a group of medicines called anticonvulsants.

Valproate-AFT 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.

These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

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

Valproate-AFT may be used alone or in combination with other medicines to treat your condition.

Valproate-AFT may be used short-term in place of oral sodium valproate tablets or liquid when the medicine cannot be given by mouth.

Your doctor, however, may have prescribed Valproate-AFT for another reason.

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

There is no evidence that Valproate-AFT is addictive.

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

2. What should I know before I am given Valproate-AFT?

Warnings

You should not receive Valproate-AFT if:

- you have or have had any of the following medical conditions:
 - liver disease (hepatic dysfunction) or severe hepatitis
 - family history of hepatitis, especially when caused by medicines. Medicines used in the treatment of epilepsy, including Valproate-AFT 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
- you are allergic to sodium valproate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can receive this medicine. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Tell your doctor if you:

- take any medicines for any other condition
- are allergic to any medicine listed at the end of this leaflet
- plan to have surgery
- have or have had any other medical conditions, especially the following:
 - liver problems (hepatic insufficiency, hepatic damage)
 - kidney problems
 - urea cycle disorders
 - ornithine transcarbamylase (OTC) deficiency
 - carnitine palmitoyltransferase (CPT) type II deficiency
 - systemic lupus erythematosus (a disease affecting the skin, joints and kidneys)
 - family history of a genetic problem causing mitochondrial disorder

If you have not told your doctor about any of the above, tell them before you are given Valproate-AFT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Valproate-AFT 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 Valproate-AFT throughout their pregnancy may be at risk of impaired cognitive development or withdrawal syndrome.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Medicines used in the treatment of epilepsy, including Valproate-AFT, pass into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Valproate-AFT 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. Valproate-AFT should have little effect on the oral contraceptive pill, however, you should let your doctor know that you are taking it
- zidovudine or any other antiviral medications
- antipsychotic medicines including clozapine (a medicine used to treat schizophrenia)
- quetiapine or olanzapine (a 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 (Questran Lite)
- acetazolamide (Diamox)

These medicines and others may be affected by Valproate-AFT 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 they are given Valproate-AFT, 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 Valproate-AFT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Valproate-AFT. Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Valproate-AFT.

4. How is Valproate-AFT given?

How it is given

Valproate-AFT will be given to you as an infusion or injection into the veins.

Adults:

If you are currently taking an oral formulation of Valproate-AFT (tablets, liquid or syrup) and are now changing over to Valproate-AFT, the total daily dose of Valproate-AFT should remain the same. In these circumstances, Valproate-AFT may be given as several separate injections, drips or infusions throughout the day, or as one long continuous drip or infusion lasting 24 hours a day.

If you are not currently taking Valproate-AFT or any other form of sodium valproate by mouth, your doctor will decide what dose you will receive, depending on your condition and other factors such as your weight.

Children:

The dose for children is usually 20 to 30 mg for each kg of body weight every day. If epilepsy is not controlled the dose may be increased up to 40 mg for each kg of body weight every day, as long as blood tests are done to check the amount of Valproate-AFT in the blood. If higher doses are needed, further blood tests must be done to check that Valproate-AFT is not causing side effects.

If you use too much Valproate-AFT

Your doctor will decide what dose of Valproate-AFT you need, and this will be given under close supervision, usually in a hospital setting.

The risk of overdose in these circumstances is low. In the event of an overdose occurring, your doctor will decide on the necessary treatment.

5. What should I know while I am given Valproate-AFT?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using valproate-AFT.
- Remind any doctor, dentist or pharmacist you visit that you are using Valproate-AFT.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- Call your doctor or nurse straight away if you do not feel well while Valproate-AFT being given to you.

Things you should not do

- Do not stop using this medicine suddenly, or lower the dosage, without checking with your doctor.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Valproate-AFT affects you.

Valproate-AFT may cause drowsiness in some people. Make sure you know how you react to Valproate-AFT before you drive a car, operate machinery or do anything else that could be dangerous if you are drowsy or lightheaded.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol could be made worse while you are receiving Valproate-AFT.

Combining Valproate-AFT and alcohol can make you more sleepy, dizzy or lightheaded.

If you have more than 2 drinks per day, you may be putting yourself at risk of a seizure or fit.

Your doctor may suggest you avoid alcohol while you are treated with Valproate-AFT.

Looking after your medicine

Valproate-AFT will be stored in the pharmacy or on the ward. It is kept in a cool, dry place, protected from light, where the temperature stays below 30°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Gastrointestinal related</p> <ul style="list-style-type: none"> • Nausea or vomiting • Abdominal cramps or pain • Changes in appetite • Diarrhoea <p>Brain and nerve symptoms</p> <ul style="list-style-type: none"> • Headache • Unusual movement including shaking or tremors • Rapid uncontrollable movements of the eye • unsteadiness when walking, dizziness or light-headedness • Feeling very tired or drowsy • Memory impairment • Confusion <p>Mood and mental health changes</p> <ul style="list-style-type: none"> • Feeling low or depressed • Seeing or hearing things that aren't there (hallucinations) • Difficulty concentrating or paying attention • Changes in behavior, including being aggressive or very agitated <p>Hair, skin, and nails related</p> <ul style="list-style-type: none"> • hair loss • Changes to nail or nail bed disorders <p>Hormone and period changes</p> <ul style="list-style-type: none"> • Irregular menstrual periods <p>Body as a whole:</p> <ul style="list-style-type: none"> • Changes in weight • Sore, bleeding, or swollen gums | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Seizure and mental health concerns</p> <ul style="list-style-type: none"> • More frequent or more severe seizures (fits) • Bizarre behaviour • Suicidal thoughts • Suicide attempts <p>Bleeding and clotting issues</p> <ul style="list-style-type: none"> • Blood clotting problems • Spontaneous bruising or bleeding <p>Skin and allergic reactions</p> <ul style="list-style-type: none"> • Skin rashes | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

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| <p>Liver and digestive problems</p> <ul style="list-style-type: none"> • 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 • Severe upper stomach pain, often with nausea, vomiting and/or loss of appetite especially when prolonged <p>Swelling and fluid retention</p> <ul style="list-style-type: none"> • Swelling of the feet and legs, weight increase due to fluid build up <p>Fainting or Blackouts</p> <ul style="list-style-type: none"> • Fainting | |
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- Valproate-AFT sodium valproate 300 mg/3 mL solution for injection vials (Aust R 297324)
- Valproate-AFT sodium valproate 400 mg/4 mL solution for injection ampoules (Aust R 297323)
- Valproate-AFT sodium valproate 400 mg/4 mL solution for injection vials (Aust R 297321)
- Valproate-AFT sodium valproate 1000 mg/10 mL solution for injection ampoules (Aust R 297322)
- Valproate-AFT sodium valproate 1000 mg/10 mL solution for injection vials (Aust R 297319)

Who distributes Valproate-AFT

AFT Pharmaceuticals Pty Ltd
 113 Wicks Road
 North Ryde NSW 2113

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Valproate-AFT contains

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|---|---|
| Active ingredient (main ingredient) | Sodium valproate |
| Other ingredients (inactive ingredients) | Potassium dihydrogen phosphate, Disodium phosphate dodecahydrate and Water for injections |

Do not take this medicine if you are allergic to any of these ingredients.

What Valproate-AFT looks like

Valproate-AFT comes as a clear colourless solution in glass ampoules or vials:

- Valproate-AFT sodium valproate 300 mg/3 mL solution for injection ampoules (Aust R 297320)