

VALCONTIN 200/ 500 (CONTROLLED RELEASE TABLETS OF SODIUM VALPROATE AND VALPROIC ACID)

PACKAGE LEAFLET: INFORMATION FOR THE USER

WARNING

Valcontin 200/500, sodium valproate, can seriously harm an unborn baby when taken during pregnancy. If you are a female able to have a baby, you must use an effective method of birth control (contraception) at all times during your entire treatment with Valcontin 200/500. Your doctor will discuss this with you, but you must also follow the advice in section 2 of this leaflet.

Schedule an urgent appointment with your doctor if you want to become pregnant or if you think you are pregnant.

Do not stop taking Valcontin 200/500 unless your specialist tells you to as your condition may become worse.

If you are a parent or caregiver of a female child treated with Valcontin 200/500, you must also read section 2 of this leaflet carefully and contact your child's doctor once they experience their first period.

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider or pharmacist.

What is in this leaflet?

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1. What Valcontin 200/ 500 is and what it is used for?

What Valcontin 200/500 tablets is

The name of your medicine is Valcontin 200/ 500 Continus Controlled Release Tablets. "Controlled release" means that the active ingredient sodium valproate is slowly released from the tablets over a period of time.

What Valcontin 200/500 tablets contains

Valcontin 200/500 contains Sodium Valproate. It belongs to a group of medicines called anti-convulsant or anti-epileptic agents. It works by helping to calm the brain down.

What Valcontin 200/500 tablets is used for

Valcontin 200/ 500 is used to treat epilepsy (fits) in adults and children.

2. What you need to know before you take Valcontin 200/ 500?

Do not take Valcontin 200/500 if:

- You are allergic (hypersensitive) to sodium valproate or any of the other ingredients of Valcontin 200/500. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have liver problems, or you or your family have a history of liver problems, especially if caused by taking a medicine.
- You have a rare illness called porphyria which affects your metabolism.
- You have a known metabolic disorder, i.e. a urea cycle disorder.
- You have a genetic problem caused by a mitochondrial disorder (e.g. Alpers-Huttenlocher syndrome).
- You are pregnant, unless nothing else works for you.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Valcontin 200/ 500.

Warnings and Precautions

A small number of people being treated with antiepileptics such as sodium valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your doctor immediately

Talk to your doctor or pharmacist before taking Valcontin 200/500 if:

You have a brain disease or a metabolic condition affecting your brain.

You have problems with your pancreas.

You have diabetes or are being tested for diabetes. This medicine may affect the results of urine tests.

You have a carnitine palmitoyl transferase type II deficiency.

You have kidney problems. Your doctor may monitor your valproate level or adjust your dose.

You have a 'urea cycle disorder' where too much ammonia builds up in the body.

You have an illness called 'systemic lupus erythematosus (SLE)' – a rare disease of the immune system which affects skin, bones, joints and internal organs.

You know that there is a genetic problem caused by a mitochondrial disorder in your family.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Valcontin 200/500.

Taking Other medicines with Valcontin 200/ 500 tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Valcontin 200/500 can affect the way some other medicines work. Also, some medicines can affect the way Valcontin 200/500 works.

In particular, check with your doctor if you are taking any of the following:

- Some medicines used for pain and inflammation (salicylates) such as aspirin.

- Some other medicines used to treat fits (epilepsy), ‘Patients taking other medicines for fits’. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide, lamotrigine and felbamate.
- Medicines used to calm emotional and mental health disorders (including schizophrenia, bipolar disorder and depression) such as quetiapine, diazepam and olanzapine.
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (used to treat depression and anxiety), selegiline (used to treat Parkinson’s disease), linezolid (used to treat infections).
- Anticoagulants such as warfarin – used to thin the blood and prevent clots. Your doctor may change your dose of the blood thinning medicine and monitor your treatment closely.
- Zidovudine and protease inhibitors such as lopinavir and ritonavir – used to treat HIV infection and AIDs.
- Carbapenem agents (antibiotics used to treat bacterial infections) such as panipenem, imipenem, meropenem, rifampicin and erythromycin. The combination of Valcontin 200/500 and carbapenems should be avoided because it may decrease the effect of your medicine.
- Some medicines used to treat or prevent malaria such as mefloquine and chloroquine.
- Temozolomide – used to treat cancer.
- Cimetidine – used to treat stomach ulcers.
- Cholestyramine – used to lower blood fat (cholesterol) levels.
- Nimodipine – used to treat bleeding in the brain (subarachnoid haemorrhage).
- Propofol – used for anaesthesia.
- Oestrogen-containing products (including some birth control pills).
- Metamizole – used to treat pain and fever.

Pregnancy and breast-feeding

Important advice for women

- You must not use Valcontin 200/500 if you are pregnant, unless your specialist has determined that no alternative treatment works for you.
- If you are a woman able to have a baby, you must not take Valcontin 200/500 unless you use an effective method of birth control (contraception) at all times during your entire treatment with Valcontin 200/500.
- Do not stop taking Valcontin 200/500 or your birth control (contraception), until you have discussed this with your specialist. Your specialist will advise you further.

The risks of valproate when taken during pregnancy

- Talk to your doctor immediately if you are planning to have a baby or are pregnant.
- Valproate carries a risk if taken during pregnancy. The higher the dose, the higher the risks but all doses carry a risk, including when valproate is used in combination with other medicines to treat epilepsy.
- It can cause serious birth defects and can affect physical and mental development of the child as it grows after birth. If you take valproate during pregnancy, you have a higher risk than other women of having a child with birth defects that require medical treatment. Because valproate has been used for many years, we know that in women who take valproate around 11 babies in every 100 will have birth defects. This compares to 2-3 babies in every 100 born to women from the general population. – The most frequently reported birth defects include spina bifida (where the bones of the spine are not properly developed); facial and skull malformations; heart, kidney, urinary tract and sexual organ malformations; limb defects and multiple associated malformations affecting several organs and parts of the body. Birth defects may result in disabilities which may be severe. – Hearing problems or deafness have been reported in children exposed to valproate during pregnancy. – Eye malformations have been reported in children exposed to valproate during pregnancy in association with other congenital malformations. These eye malformations may affect vision.

- It is estimated that up to 30-40% of children whose mothers took valproate during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, intellectually less able than other children, and have difficulty with language and memory. – Autism and related disorders are more often diagnosed in children exposed to valproate during pregnancy and there is some evidence that children exposed to valproate during pregnancy are at increased risk of developing attention deficit hyperactivity disorder (ADHD).
- Before prescribing this medicine to you, your specialist will have explained what might happen to your baby if you become pregnant whilst taking valproate. If you decide later that you want to have a baby, you must not stop taking your medicine or your method of birth control (contraception) until you have discussed this with your specialist.
- If you are a parent or a caregiver of a female child treated with valproate, you must contact their doctor once your child using valproate experiences their first period (menarche).
- Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you talk to your doctor about the method of birth control (contraception) that is the most appropriate for you.
- Ask your doctor about taking folic acid when planning to have a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

Breast-feeding

Very little Valcontin 200/500 gets into the breast milk. However, talk to your doctor about whether you should breast-feed your baby. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy when taking Valcontin 200/500. If this happens to you, do not drive or use any tools or machines. Taking other medicines used to treat fits or calm emotional and mental health problems may increase sleepiness.

3. How to take Valcontin 200/500 Tablets?

Always take Valcontin 200/500 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Valcontin 200/500 treatment must be started and supervised by a doctor specialised in the treatment of epilepsy. Your doctor will decide how much Valcontin 200/500 to give you or your child depending on your or your child's body weight. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself but ask your doctor.

How to take this medicine

- Take this medicine by mouth. Do not crush or chew the tablets.
- Take Valcontin 200/500 with or after food. This will help to stop the feelings of sickness that may happen after taking Valcontin 200/500.
- This medicine can be taken twice daily.
- You may see what appears to be part of the tablet in your stool. This is normal as the matrix of Valcontin 200/500 is not digested by the body. It does not mean that the medicine is not working.

How much to take.

Doses as decided & Prescribed by Treating Doctor should be adhered.

If you take more Valcontin 200/500 tablets than recommended.

If you or your child take more Valcontin 200/500 than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling sick or being sick, headache, blurred vision due to pupil of the eye becoming smaller, dizziness, poor reflexes, confusion, memory loss and tiredness. You may also have weak or 'floppy' muscles, fits (seizures), loss of consciousness, behavioural changes and breathing difficulties such as fast breathing, shortness of breath or chest pain.

If you forget to use Valcontin 200/500 tablets.

If you or your child forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Valcontin 200/500 tablets.

Do not stop taking Valcontin 200/500 or alter your or your child's dose without checking with your specialist. If you or your child stop taking Valcontin 200/500 without your specialist's advice, your condition may get worse.

4. Possible side effects?

Tell your doctor or go to a hospital straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

You have an allergic reaction which may manifest as: –

Blisters with skin detachment (blistering, peeling or bleeding on any part of your skin (including your lips, eyes, mouth, nose, genitals, hands or feet) with or without rash), sometimes with flu-like symptoms such as fever, chills, or aching muscles. These may be signs of conditions named 'Toxic epidermal necrolysis' or 'Stevens-Johnson Syndrome'.

– Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These may be signs of a condition named 'erythema multiforme'.

– Allergy-triggered swelling with painful itchy welts (most often around the eyes, lips, throat and sometimes hands and feet) and swallowing or breathing problems. These may be signs of 'angioedema' or an anaphylactic reaction.

– Syndrome with skin rash, fever, lymph node enlargement and possible impairment of other organs. These may be signs of a condition named 'Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)'.

• Drowsiness, change in consciousness level (including coma), confusion, loss of memory, abnormal behaviour including changes in attention, concentration and mood. This could also be associated with hallucinations or more frequent or severe fits. This is more likely if other medicine to treat fits such as phenobarbital and topiramate are taken at the same time or if the Valcontin 200/500 starting dose is high or has been suddenly increased.

• Underactive thyroid gland, which may cause tiredness or weight gain (hypothyroidism)

• Breathing difficulty and pain due to inflammation of the envelope of the lungs (pleural effusion)

• An increase in the number and severity of convulsions

• Muscle pain and weakness (rhabdomyolysis)

- Joint pain, fever, fatigue or rash. These may be signs of systemic lupus erythematosus (SLE).
- Problems with balance and co-ordination, feeling lethargic or less alert, associated with being sick (vomiting). This may be due to an increased amount of ammonia in your blood.
- Shakiness (tremor), jerky muscle movements, unsteadiness when walking (parkinsonism, extrapyramidal disorder, ataxia)
- Rapid, uncontrollable movement of the eyes
- Kidney disease or kidney problems (renal failure, tubulointerstitial nephritis and Fanconi syndrome) which may manifest as reduced urinary output or blood in the urine
- Confusion, that could be due to decreased levels of sodium in your blood, identified by a blood test, or to a condition named ‘Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion’

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

Feeling sick (nausea), being sick (vomiting), stomach-ache or diarrhoea, especially when starting treatment. This may be helped by taking the tablets with food.

- Overgrowth of gums (gingival hypertrophy), swelling of gums or mouth, sore mouth, mouth ulcers and burning feeling of mouth (stomatitis)
- Headache
- Hearing loss, hearing problems or deafness
- Double vision • Nail and nail bed disorders
- Skin problems such as rashes. These happen rarely, but more often in people also taking lamotrigine.
- Transient hair loss, abnormal hair growth, abnormal hair texture, changes in hair colour
- Increased levels of some hormones (androgens), which may lead to increased hair growth on the face, breasts or chest (particularly in women), acne or thinning hair
- Skin rash caused by inflammation of small blood vessels (vasculitis)
- Irregularity or absence of women’s period, pain during women’s period, cysts in the ovaries (polycystic ovaries)
- Breast enlargement in men, male infertility (usually reversible after treatment discontinuation and may be reversible after dose reduction. Do not stop your treatment without speaking to your doctor first)
- Swelling of the feet and legs (oedema)
- Obesity, weight gain – as your appetite may be increased
- Bedwetting or increased need to pass urine, urinary incontinence (unintentional passing of urine)
- Seeing, feeling or hearing things that are not there (hallucinations)
- Aggression, agitation, disturbance in attention, abnormal behaviour, restlessness/hyperactivity, memory impairment, or cognitive or learning disorder
- Tingling or numbness in the hands and feet
- Lowering of normal body temperature

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids.

5. How to store Valcontin 200/500 Tablets?

Keep this medicine out of the sight and reach of children.

Store at or below 30° C in dry place, protected from light.

Do not use this medicine after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

6. Other information

What Valcontin 200/500 tablets contains?

- Valcontin 200: Each 200mg continus controlled release tablet contains a mixture of 133.5mg sodium valproate and 58mg valproic acid, equivalent to 200mg of the active substance, sodium valproate.
- Valcontin 500: Each 500mg continus controlled release tablet contains a mixture of 333mg sodium valproate and 145mg valproic acid, equivalent to 500mg of the active substance, sodium valproate.
- The other ingredients are Microcrystalline Cellulose, Cetostearyl Alcohol, Magnesium Stearate, Hydroxyethylcellulose, Purified Talc, Colloidal Silicon Dioxide, Diethyl Phthalate, Insta moistshield IC – MS – 2673 White, Isopropyl Alcohol, Methylene Chloride, Purified water.

What Valcontin 200/500 tablets looks like and contents of the pack?

Valcontin 200: White to off-white, round, biconvex, film coated tablets engraved with ‘VLC’ on one of the facets and scored on the other side.

Valcontin 500: White to off-white, caplet, biconvex, film-coated tablets engraved with ‘VLC’ on one side and scored on the other side.

Valcontin 200/ 500: Box of 100 Tablets (10x10’s Aluminium strip)

Manufactured by:

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110

U.P., India

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