PACKAGE LEAFLET

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Convulex 500 mg Prolonged-release Tablets

Sodium valproate

1. WHAT IS IN CONVULEX PROLONGED-RELEASE TABLETS?

Each Convulex prolonged-release tablet contains 300 mg sodium valproate as the active substance.

The other ingredients are: Tablet core: citric acid monohydrate, ethylcellulose, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) copolymer (contains sorbic acid), purified talc, colloidal hydrated silica, magnesium stearate; film-coating material: ammonio methacrylate copolymer (type A & B) (contains sorbic acid), purified talc, carmellose sodium, titanium dioxide (E 171), triethyl citrate, vanillin.

The active substance in Convulex prolonged-release tablets is released slowly into your body over a long period of time.

Convulex prolonged-release tablets are white, oval-shaped, with a score line and an engraving "CC5" on one side. The tablets are supplied in containers of 50 or 100.

The Marketing Authorisation holder and manufacturer for Convulex Prolonged-release tablets is G.L. Pharma GmbH, Schlossplatz 1, A-8502 Lannach

2. WHAT ARE CONVULEX PROLONGED-RELEASE TABLETS USED FOR?

Convulex prolonged-release tablets are used to treat epilepsy (fits).

3. BEFORE YOU TAKE CONVULEX PROLONGED-RELEASE TABLETS

Do not take Convulex prolonged-release tablets
- if you are hypersensitive (allergic) to sodium valproate or any of the other ingredients of Convulex prolonged-release tablets
- if you have liver problems
- if members of your family have or used to have serious liver problems
- if you suffer from hepatic porphyria (a rare metabolic disease).

Take special care with Convulex prolonged-release tablets
- Before you start treatment and during therapy, your doctor may wish to do certain tests (e.g. blood count, liver function).
- If you need to go in for surgery: Inform the physician that you are taking valproate.
- Tell your doctor immediately or go to the casualty department at your nearest hospital, if sudden illness occurs, especially during the first six months of treatment and particularly if it includes repeated vomiting, nausea (feeling sick), extreme tiredness, abdominal pain, loss of appetite, jaundice (yellow discoloration of the skin and the whites of the eyes), swelling of the legs or worsening of your epilepsy. These may be symptoms of a rare condition affecting the liver in a very small number of patients. Particular caution is needed in the case of children under 3 or those with other nervous system disease.
- If you experience abdominal pain, nausea and/or vomiting: Contact your doctor immediately, as these may be symptoms of pancreatitis (an inflammation of the pancreas). The risk of this potentially life-threatening condition is especially high in young children, in patients receiving combination treatment and in those with severe liver function disturbance.
- Valproate therapy may cause marked and progressive weight gain. This is a very common side effect, and you should consult your doctor about appropriate strategies to minimise this risk.
- If you have lupus (an inflammatory skin disorder), please tell your doctor before taking Convulex prolonged-release tablets.
- If you suffer from urea cycle enzymatic deficiency (a rare metabolic disorder). In these cases, please consult your treating physician.
- Women of childbearing age should discuss the potential risks and benefits of continuing anti-epileptic treatment during pregnancy with their doctor.
- If you are diabetic: Inform your doctor before taking Convulex prolonged-release tablets, as it may make urine tests give false results.

Please check with your doctor if you are taking (or have recently taken) any of the following:
- antidepressant therapy - including monoamine oxidase inhibitors
- benzodiazepines - used to treat anxiety and sleeplessness
- neuroleptics - drugs with antipsychotic and/or sedating effects
- other antiepileptic therapy, e.g. phenobarbital, primidone, phenytoin, carbamazepine, lamotrigine, felbamate
- zidovudine - used to treat HIV
- anticoagulant therapy - used to thin the blood (e.g. warfarin)
- temozolomide - used to treat cancer
- mefloquine and chloroquine - used to prevent malaria
- acetylsalicylic acid (aspirin)
- cimetidine - used to treat stomach ulcers
- erythromycin - an antibiotic
- carbapenem antibiotics (e.g. imipenem, meropenem)
- cholestyramine - used to treat high blood lipid (fat) levels

Valproate does not appear to influence the effect of oral contraceptives.

Valproate may potentiate the effects of alcohol.

Pregnancy:

It is known that women who have epilepsy have a slightly higher risk of having a child with an abnormality than other women. Women who have to take valproate during the first 3 months of pregnancy to control their epilepsy have about a 1–2% chance of having a baby with spina bifida. This however can usually be detected in the first part of pregnancy by normally used screening tests. Taking dietary supplements of folate may lower the risk of having a baby with spina bifida. It is therefore essential that you discuss your treatment with your doctor if you are thinking of becoming pregnant or tell your doctor as soon as you know you are pregnant.

Breast feeding:

Very little valproate gets into the breast milk, but you should discuss with your doctor whether you should breast feed your baby.

Driving and using machines:
You will need to discuss with your doctor whether you should drive or operate machinery, which will depend on how well your disease is controlled and whether Convulex Prolonged-release tablets make you drowsy.

4. HOW TO USE CONVULEX PROLONGED-RELEASE TABLETS

Adults: The usual dose of Convulex prolonged-release tablets is between 1000 mg and 2000 mg (i.e. 20–30 mg per kg body weight) per day, but may be increased by your doctor to up to 2500 mg per day. This quantity may be taken in one dose or can be divided and given in 2 separate doses, e.g. half in the morning and half in the evening.

Children over 20 kg: The dose of Convulex prolonged-release tablets is based on the child's weight. The usual dose per day is between 20 and 30 mg for each kg of body weight, but may be increased by your doctor to 35 mg for each kg of body weight per day or a higher daily dose. This quantity may be taken in one dose or can be divided and given in 2 separate doses, e.g. half in the morning and half in the evening.

Convulex prolonged-release tablets are not suitable for children under 20 kg.

When treatment is first started you may be prescribed a lower dose. This is because some patients need less Convulex prolonged-release tablets than others to control their fits. Your doctor will increase the dosage until your condition is controlled. Because of this it is very important that you follow the instructions your doctor has given you about how much to take. Blood tests may be needed.

If you are taking other medicines to control your epilepsy at the same time as Convulex prolonged-release tablets, your doctor may gradually reduce the dose of these antiepileptics while increasing the dose of Convulex prolonged-release tablets in small units based on your body weight. If you have severe liver or kidney disease, your doctor may prescribe a lower dose.

Swallow the tablets whole (do not crush them), with a drink of water.

If at the start of treatment gastro-intestinal irritation (upset stomach, indigestion) occurs, it may help to take Convulex prolonged-release tablets with or after food.

If you forget to take a dose at the right time, take it as soon as you remember, then go on as before.

An overdose of this medicine may be dangerous. If you have taken an overdose, tell your doctor or go to the nearest hospital casualty department immediately.

Keep taking your medicine until your doctor tells you to stop. Do not stop taking the tablets just because you feel better. If you stop them, your condition may get worse.

5. POSSIBLE SIDE EFFECTS

Like all medicines, Convulex prolonged-release tablets can have side effects.

Valproate may cause reversible changes in the blood, which are usually associated with doses higher than those recommended (you may either notice a sore throat and an increased susceptibility to infections, or abnormal bleeding or a tendency to bruise more easily).

Occasionally, vasculitis (inflammation of blood vessels usually characterised by pain, redness or itching) has been reported. Allergic reactions (ranging from rash to hypersensitivity reactions), as well as rarely a systemic lupus erythematosus (a rare immune system disorder) have also been reported.

Anorexia, vomiting, diarrhoea and constipation may also occur.

Very rarely women may experience irregular periods. Very rarely increased breast growth in men has occurred.

Symptoms such as vomiting, disturbed co-ordination and increasing clouding of consciousness may indicate an elevation of the amount of ammonia in the blood. In these cases you should discontinue treatment and immediately consult your doctor.

In very rare cases, the symptoms mentioned above may also indicate an inflammation of the pancreas which may sometimes be life-threatening. Oedema (swelling of the limbs) has rarely been reported.

Very rarely, depressive states were reported.

Disturbed co-ordination, dizziness and trembling have occasionally been reported at high doses.

Drowsiness has occasionally been reported, but especially when Convulex prolonged-release tablets were taken in combination with other anticonvulsants. Rare cases of lethargy, confusion, and occasionally disturbed consciousness, sometimes associated with hallucinations or convulsions, have been reported. Very rare cases of severe disturbances of body movement including parkinsonism as well as dementia (general mental deterioration) have been reported. These effects usually reverse on stopping Convulex prolonged-release tablets. If you experience any of these effects or if you notice any unusual symptoms, you should tell your doctor as soon as possible as you may have to stop taking the tablets.

An increase in alertness may occur. This is generally beneficial, but occasionally aggression, hyperactivity and behavioural deterioration have been reported.

Rarely hearing loss, either reversible or irreversible, has been reported.

Rarely headache and jerky eye movements have been reported.

Very rare cases of pancreatitis, sometimes fatal, have been reported. Appetite may increase and valproate very commonly causes weight gain, which may be marked and progressive. Frequently at the start of treatment minor gastrointestinal irritation (upset stomach), and less frequently, nausea (feeling sick) may occur, which can usually be overcome by taking Convulex prolonged-release tablets with or after food or by using enteric-coated Convulex capsules.

Rarely severe hepatic damage has been reported after intake of sodium valproate, occasionally with a fatal outcome (see Section "Take special care with Convulex prolonged-release tablets"). Rarely, porphyria has been reported.

Transient hair loss has been noted in some patients. Regrowth normally begins within six months, although the hair may become more curly than previously. Acne and excessive growth of facial and/or body hair have been reported in very rare cases. Rarely, skin reactions such as rash have been reported. In exceptional cases more severe skin reactions have been reported.

There have been isolated reports of a reversible Fanconi's syndrome (a rare kidney disorder).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING CONVULEX PROLONGED-RELEASE TABLETS

Keep Convulex prolonged-release tablets out of the reach and sight of children.

Make sure the container is tightly closed after each use.

Do not use Convulex prolonged-release tablets after the "use before" date on the label.

This leaflet was approved on (date).

GEROT LANNACH