PACKAGE LEAFLET: INFORMATION FOR THE USER

Convulex® 150 mg capsules
Convulex® 300 mg capsules
Convulex® 500 mg capsules
Active substance: Valproic acid

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

WARNING

Convulex (valproic acid) can seriously harm an unborn child when taken during pregnancy. If you are a female able to have a baby you must use effective method of birth control (contraception) without interruptions during your entire treatment with Convulex. Your specialist will discuss this with you but you must also follow the advice in section 2 of this leaflet.
Schedule an urgent appointment with your general practitioner (GP) for a referral to a specialist if you want to become pregnant or if you think you are pregnant.
Do not stop taking Convulex 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 Convulex, you must also read section 2 of this leaflet carefully and contact your child's GP once they experience their first period, the GP will refer your child to their specialist.

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 GP, specialist 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 you get any side effects, talk to your GP, specialist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Convulex is and what it is used for
2. What you need to know before you take Convulex
3. How to take Convulex
4. Possible side effects
5. How to store Convulex
6. Contents of the pack and other information

1. What Convulex is and what it is used for

Convulex is an antiepileptic, i.e. a medicine which is used to treat epilepsy (fits). Its active ingredient is valproic acid.

For male patients aged under 55 years not having used valproate before and for female patients aged under 55 years: this medicine is only used when two specialists have agreed that your condition does not respond to other treatments.

2. What you need to know before you take Convulex

Do not take Convulex

- if you are **allergic** (hypersensitive) to valproic acid or any of the other ingredients of Convulex (see section 6).
  Signs of an allergic reaction include: a rash, swallowing or breathing problems,swelling of your lips, face, throat or tongue.
- if you have **liver problems** (e.g. hepatitis).
- if you have a **family history of liver problems,** especially if caused by taking a medicine.
- if you suffer from **porphyria** (a rare metabolic condition).
- If you have a **genetic problem** causing a mitochondrial disorder **(e.g. Alpers-Huttenlocher syndrome)**
- if you suffer from **urea cycle disorders** (a metabolic condition).
- if you have a **deficiency in carnitine** (a very rare metabolic disease) that is untreated.
- if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.
- if you are a woman aged under 55 years who is able to have a baby, you must not take Convulex unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks and you use effective method of birth control (contraception) during your entire treatment with Convulex. Do not stop taking Convulex or your contraception, until you have discussed this with your specialist. Your specialist will advise you further (see below under “Pregnancy, breast-feeding and fertility – Important advice for female patients aged under 55 years”).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your GP, specialist or pharmacist before taking Covulex.

Warnings and precautions

- The risk of liver damage is increased if Convulex is taken by children under 3 years of age, in people taking other antiepileptic medicine at the same time or having other neurological or metabolic disease and severe forms of epilepsy.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme and angioedema have been reported in association with valproate treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- A small number of people being treated with anti-epileptics such as valproate have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your GP or specialist.
- As with other anti-epileptic drugs, convulsions may become worse or happen more frequently whilst taking this medicine. If this happens contact your GP or specialist immediately.
- If you or your child taking Convulex develops problems with balance and co-ordination, feeling lethargic or less alert, vomiting, tell your doctor immediately. This may be due to increased amount of ammonia in the blood.

Talk to your GP, specialist or pharmacist before starting Convulex

- if you have a **brain disease** or a metabolic condition affecting your brain.
- if you have **problems with your pancreas**.
- if you are **diabetic** or are being tested for diabetes. This medicine may affect the results of urine tests.

- If you know or your doctor suspects that there is a **genetic problem** caused by a mitochondrial disorder in your family, because of a risk of damage to your liver.
- If you are suspected to suffer from any metabolic disorders, particularly hereditary enzyme deficiency disorders such as a "urea cycle disorder" because of a risk of **increased ammonia level in the blood**.
- if you have a rare disorder named "**carnitine-palmitoyl transferase (CPT-)II deficiency"** because you are at an increased risk of muscle disorders.
- if you have **impaired dietary intake in carnitine**, found in meat and dairy products, especially in children less than 10 years old.
- If you have a **deficiency in carnitine** and are taking carnitine.
- if you have **kidney problems**. Your specialist may monitor your valproate level or adjust your dose.
- if you have an illness called '**systemic lupus erythematosus (SLE)**' – a rare disease of the immune system which affects skin, bones, joints and internal organs.
- If you have a history of **bone marrow damage**.
- if you have ever developed a **severe skin rash or skin peeling, blistering and/or mouth sores** after taking valproate.

If you are not sure if any of the above apply to you, talk to your GP, specialist or pharmacist before taking Convulex.

Talk to your GP, specialist or pharmacist even if you no longer have these conditions, but have had them in the past.

Taking Convulex may make you **put on weight**. Talk to your GP, specialist or pharmacist about how this will affect you.

Your GP and/or specialist may request **blood tests** and liver function tests before and during your treatment with this medicine. Convulex can change the levels of liver enzymes shown in blood tests. This can mean that your or your child's liver is not working properly.

Other medicines and Convulex
Tell your GP, specialist 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 Convulex can affect the way some other medicines work. Also, some medicines can affect the way Convulex works.

Please tell your GP, specialist or pharmacist if you are taking any of the following:
- Some medicines used for pain and inflammation (salicylates), e.g. aspirin.
- Some other medicines used to treat fits (epilepsy) – see section 3. This includes medicines such as phenobarbital, primidone, phenytoin, carbamazepine, rufinamide, topiramate, acetazolamide, lamotrigine and felbamate.
- Cannabidiol (used to treat epilepsy and other conditions).
- 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, used to thin the blood and prevent clots (e.g. warfarin). Your GP, specialist or pharmacist 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 (antibiotic used to treat bacterial infections) such as panipenem, imipenem, meropenem, rifampicin and erythromycin. The combination of valproic acid and carbapenems should be avoided because it may decrease the effect of your medicine.
- Some anti-infectives that contain pivalate (e.g., pivampicillin, adefovir dipivoxil).
- 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.
- Methotrexate – used to treat cancer and inflammatory diseases.
- Clozapine – used to treat mental health conditions.

If you require a blood test to have your thyroid function checked, please inform your doctor about this, because treatment with Convulex may lead to a **false diagnosis of hypothyroidism** (insufficient production of thyroid hormone).

If you have to undergo any type of **surgery, including dental procedures** where anaesthesia is required**,** tell the doctor that you are taking Convulex.
Convulex does not appear to influence the effect of oral contraceptives.

Convulex with food, drink and alcohol
Convulex may be taken with food and drink.
The capsules are usually taken after meals.
Convulex may enhance the effects of alcohol. Therefore the consumption of alcohol should be avoided during Convulex therapy.

Pregnancy, breast-feeding and fertility

Pregnancy

Important advice for female patients aged under 55 years
- You must not use Convulex if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.
- If you are a female patient aged under 55 years, you must not take Convulex unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If you are able to have a baby, you must use an effective method of birth control (contraception) during your entire treatment with Convulex.
- Do not stop taking Convulex or your contraception, until you have discussed this with your specialist. Your specialist will advise you further.

The risks of valproate when taken during pregnancy
- Contact your GP immediately if you are planning to have a baby or are pregnant. Your GP will urgently refer you to your specialist.
- 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 the physical and mental development of the child as it grows after birth and may lead to permanent disability. 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 to 3 babies in every 100 born to women who don't have epilepsy.
  - 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 and/or permanent.
  - 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 preschool 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.
  - Autistic spectrum disorders are more often diagnosed in children exposed to valproate and there is some evidence children may be more likely to develop symptoms of Attention Deficit Hyperactivity Disorder (ADHD).
- Before prescribing this medicine to you, two specialists will have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks, and your specialists will have explained what might happen to your baby if you become pregnant whilst taking valproate.
- If you decide later you want to have a baby you must not stop taking your medicine or your method of 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 GP once your child using valproate experiences their first period (menarche). Their GP will refer your child to their specialist who will decide with another specialist whether valproate is the only possible treatment or whether another medicine should be prescribed.
- 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 specialist about taking folic acid when trying for 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.

Please choose and read the situations which apply to you from the situations described below:

O I AM STARTING TREATMENT WITH CONVULEX
O I AM TAKING CONVULEX AND NOT PLANNING TO HAVE A BABY
O I AM TAKING CONVULEX AND PLANNING TO HAVE A BABY
O I AM PREGNANT AND I AM TAKING CONVULEX

I AM STARTING TREATMENT WITH CONVULEX

If you are a female patient aged under 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. If this is the first time you have been prescribed Convulex, your specialist will have explained the risks to an unborn child if you become pregnant. If you are able to have a baby, you must use an effective method of birth control (contraception) without interruption throughout your treatment with Convulex. Talk to your GP, specialist or sexual health and contraception clinic if you need advice on birth control (contraception).

Key messages:

- Pregnancy must be excluded before start of treatment with Convulex with the result of a pregnancy test, confirmed by your specialist.

- You must use an effective method of birth control (contraception) during your entire treatment with Convulex.
- You must discuss the appropriate methods of birth control (contraception) with your GP or specialist. Your GP or specialist will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. The specialist will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your specialist if you want to have a baby.
- Tell your specialist immediately if you are pregnant or think you might be pregnant.

I AM TAKING CONVULEX AND NOT PLANNING TO HAVE A BABY

If you are a female patient aged under 55 years who is able to have a baby, this medicine can only be prescribed for you if two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks . If you are continuing treatment with Convulex and you are not planning to have a baby make sure you are using an effective method of contraception without interruption during your entire treatment with Convulex. Talk to your GP, specialist or sexual health and contraception clinic if you need advice on contraception.

Key messages:

- You must use an effective method of birth control (contraception) during your entire treatment with Convulex.
- You must discuss contraception (birth control) with your GP or specialist. They will give you information on preventing pregnancy, and may refer you to a specialist for advice on birth control.
- You must get regular (at least annual) appointments with a specialist experienced in the management of epilepsy. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Tell your GP or specialist if you want to have a baby.
- Tell your specialist, or GP to be urgently referred to your specialist, immediately if you are pregnant or think you might be pregnant.

I AM TAKING CONVULEX AND PLANNING TO HAVE A BABY

If you are planning to have a baby, first schedule an appointment with your GP. Your GP will urgently refer you to your specialist.

Do not stop taking Convulex or your contraception, until you have discussed this with your specialist. Your specialist will advise you further.

Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating and/or permanent. Your GP will refer you to a specialist experienced in the management of epilepsy, so that other treatment options can be evaluated early on. Your specialist can put several actions in place so that your pregnancy goes as smoothly as possible and any risks to you and your unborn child are reduced as much as possible.

You must not use Convulex if you are pregnant, unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks. Your specialist may decide to change the dose of Convulex or switch you to another medicine and stop treatment with Convulex, a long time before you become pregnant – this is to make sure your illness is stable.

Ask your specialist 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.

Key messages:
- Do not stop taking Convulex unless your specialist tells you to.
- Do not stop using your methods of birth control (contraception) before you have talked to your specialist and worked together on a plan to ensure your condition is controlled and the risks to your baby are reduced.
- First schedule an appointment with your specialist. During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware and have understood all the risks and advice related to the use of valproate during pregnancy.
- Your specialist will try to switch you to another medicine, or stop treatment with Convulex a long time before you become pregnant.
- Schedule an urgent appointment with your GP to be urgently referred to your specialist, immediately if you are pregnant or think you might be pregnant.

I AM PREGNANT AND I AM USING CONVULEX
Do not stop taking Convulex, unless your specialist tells you to as your condition may become worse. Schedule an urgent appointment with your GP. Your GP will refer you immediately to your specialist if you are pregnant or think you might be pregnant. Your specialist will then advise you further.
Babies born to mothers who have been on valproate are at serious risk of birth defects and problems with development which can be seriously debilitating and/or permanent.
Your GP will refer you to your specialist experienced in the management of epilepsy, so that other treatment options can be evaluated.
In the exceptional circumstances when two specialists have agreed that Convulex is the only available treatment option during pregnancy, you will be monitored very closely both for the management of your underlying condition and to check how your unborn child is developing. You and your partner could receive counselling and support regarding the valproate exposed pregnancy.

Ask your specialist about taking folic acid. 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.

Key messages:
- Schedule an urgent appointment with your GP. Your GP will refer you immediately to your specialist if you are pregnant or think you might be pregnant. Your specialist will then advise you further.
- Do not stop taking Convulex unless your specialist tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for other treatment options.
- You must get thorough counselling on the risks of Convulex during pregnancy, including teratogenicity and developmental effects in children.
- Make sure you are referred to a specialist for prenatal monitoring in order to detect possible occurrences of malformations.

Make sure you read the patient guide that you will receive from your specialist, GP or pharmacist. If you are a female of childbearing potential, your specialist will discuss and complete the Annual Risk Acknowledgement Form with you and will ask you to sign it and keep it. You will also receive a Patient Card from your pharmacist to remind you of valproate risks in pregnancy.

Newborn babies of mothers who took valproate during pregnancy may have:
- Blood clotting problems (such as blood not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- Hypoglycaemia (low blood sugar).

- Hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).
- Withdrawal syndrome (including agitation, irritability, hyperexcitability, jitteriness, hyperkinesia, muscle problems, tremor, convulsions and feeding problems). In particular, this may occur in newborns whose mothers have taken valproate during the last trimester of their pregnancy.

Breast-feeding
Very little valproate gets into the breast milk. However, talk to your GP or specialist about whether you should breast-feed your baby. Ask your GP, specialist or pharmacist for advice before taking any medicine.

Important advice for male patients
- If you are a male aged under 55 years, before prescribing this medicine to you for the first time, two specialists will have agreed that your condition does not respond to other treatments or the risk to fertility does not apply to you.
- Your specialist will have explained to you the known risk of male infertility (see section 4) and the potential risk in children born to fathers treated with valproate.
- If you are a parent or a caregiver of a male child treated with valproate, a specialist will explain to you that there are studies showing toxic effects of valproate on the testes of animals receiving the medicine and it is unclear what this means for humans.

Potential risks related to taking valproate in the 3 months before conception of a child

A study suggests a possible risk of mental and movement related developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3 months before conception. In this study, around 5 children in 100 had such disorders when born to fathers treated with valproate as compared to around 3 children in 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your disease).

Other studies did not suggest an increased risk of mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3-4 months before conception. In these studies the risk was similar compared to children of fathers treated with lamotrigine or levetiracetam before conception.

Differences in how these studies were designed may explain the different results. Overall, it is not known whether any possible risk of childhood developmental disorders is caused by valproate itself or by other factors, such as the father's underlying medical condition.

As a precautionary measure, your GP or specialist will discuss with you:
- The potential risk in children born to fathers treated with valproate
- The need to use effective contraception (birth control) for you and your female partner during treatment and for 3 months after stopping treatment
- The need to consult your specialist when you are planning to conceive a child and before stopping contraception (birth control)
- The possibility of other treatments that can be used to treat your disease, depending on your individual situation

Do not donate sperm when taking valproate or for 3 months after stopping valproate.

Talk to your GP or specialist if you are thinking about having a baby.

If your female partner becomes pregnant while you used valproate in the 3 months period before conception and you have questions, contact your GP or specialist. Do not stop your treatment without talking to your GP or specialist. If you stop your treatment, your symptoms may become worse.

You should get regular appointments with your GP. During this visit your GP will discuss with you the precautions associated with valproate use. They will refer you to a specialist to discuss the possibility of other treatments that can be used to treat your disease, depending on your individual situation.

Make sure you read the Patient Guide that you will receive from your specialist, GP or pharmacist. If you are a male aged under 55 years starting treatment with valproate, your specialist will discuss and complete a risk acknowledgement form with you and will ask you to sign it and keep it.

Driving and using machines
You may feel sleepy when taking Convulex. 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 Convulex

Always take Convulex exactly as your specialist has told you. Check with your specialist, GP or pharmacist if you are not sure.

Convulex treatment must be started and supervised by a specialist experienced in the treatment of epilepsy.

Your specialist will decide how much Convulex 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 GP or specialist.

Swallow the capsules whole, after meals, with a drink of water, unless your doctor advises differently. Do not crush or chew the capsules.

Adults
The usual dose of Convulex is between 1000 and 2000 mg per day but may be increased to 2500 mg per day. Usually, this quantity is evenly divided and taken in 2 separate doses, e.g. half in the morning and half in the evening.

Use in children and adolescents

Children over 20 kg
The usual dose of Convulex is based on the child's weight. The usual dose is between 20 and 30 mg for each kg of body weight but may be increased to 35 mg for each kg of body weight per day. Usually, this quantity is evenly divided and taken in 2 separate doses, e.g. half in the morning and half in the evening.

Children under 20 kg
The usual dose of Convulex is based on the child's weight. The usual dose is 20 mg for each kg of body weight. Usually, this quantity is evenly divided and taken in 2 separate doses, e.g. half in the morning and half in the evening.

When Convulex is first commenced, you may be prescribed a lower dose. This is because some patients need less Convulex than others to control their fits. Your specialist will increase the dosage until your condition is controlled. As a result of this it is very important that you follow the instructions your specialist has given you about how much to take. Blood tests may be needed.

If you have a **kidney disease,** your specialist may decide to adjust your dose.

If you are taking **other medicines to control your fits (epilepsy)** at the same time as Convulex**,** your specialist may gradually reduce the dose of these antiepileptics while increasing the dose of Convulex in small units per day, based on your body weight.

Make sure you keep your regular **check up appointments** with your specialist. They are very important as your dosage may need to be changed. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Convulex.

If you take more Convulex than you should
An overdose of this medicine may be dangerous. If you think you have taken more Convulex than you should, contact your GP or specialist urgently or go to the nearest hospital casualty department immediately. 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 take Convulex
If you forget to take a dose at the right time, take it as soon as you remember, unless it is nearly time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Convulex
If you wish to stop taking Convulex, talk to your specialist first.
Do not stop taking Convulex just because you feel better, as this may lead to an immediate relapse and your condition may get worse.

Tests
Make sure you or your child keep your regular appointments for a check-up. They are very important as your or your child's dose may need to be changed. If you or your child go into hospital or visit another doctor or a dentist, tell them you are taking Convulex.

If you have any further questions on the use of this product, ask your GP, specialist or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Please note that the following list includes all reported side effects – even those that occur very rarely.

It is very important that you immediately tell your GP, specialist or go to a hospital straight awayif you develop any of the following symptoms, because urgent medical measures may be necessary:
- Certain changes in the blood, which may lead to an increased risk of weakness, bleeding or bruising, and can make infections more likely.
- Severe or persisting abdominal pain, nausea and/or vomiting (these may be symptoms of severe liver damage or of an inflammation of the pancreas, which may take a life-threatening course).
- Vomiting, disturbed coordination of movements and progressive clouding of consciousness (these may be signs of increased ammonia levels in the blood).

- Serious (sometimes life-threatening) skin reactions with blistering of the skin, mouth, eyes or genitals.

Tell your GP, specialist or pharmacist, if you develop any of the following side effects:

Very common (may affect more than 1 in 10 people):
- uncontrolled trembling or shaking movements in one or more parts of your body (tremor)
- nausea

Common (may affect up to 1 in 10 people):
- Isolated, moderate hyperammonaemia (increased levels of ammonia in the blood without abnormal liver test values)
- especially in case of excessively high doses, treatment with valproate may cause transitory anomalies of the blood count or blood clotting disturbances
- lack of enough red blood cells (anaemia)
- increased appetite
- weight gain
- decreased sodium levels in the blood (hyponatraemia)
- loss of appetite (anorexia)
- irritability
- seeing or sensing things that aren't there while a person is awake and conscious (such as hearing voices)
- confusional state
- aggression
- agitation
- disturbance in attention
- tickling/tingling sensation or numbness, trembling
- movement disorders due to impaired regulation of muscle coordination in the brain (so-called extrapyramidal symptoms; stupor)
- dizziness
- sleepiness, the state of feeling drowsy, ready to fall asleep
- trouble with memory
- convulsions (fits)
- headache
- twitching of the eyes (nystagmus)
- partly reversible tinnitus and partly reversible impairment of hearing
- increased bleeding
- vomiting, diarrhoea, lack of appetite or constipation may occur at the beginning of treatment
- gingival disorder, especially gingival hyperplasia
- upper abdominal pain
- hypersensitivity reactions
- nail and nail bed disorders
- transient hair loss
- severe abdominal cramps during a women's period
- urinary incontinence (unintentional passing of urine)

Uncommon (may affect up to 1 in 100 people):
- Reduced number of blood platelets (especially in children), transitorily severely reduced number of white blood cells (leucopenia)
- severe reduction in all blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- increased formation of “antidiuretic” hormone (leading to increased build-up of fluid in tissue) (Syndrome of inappropriate antidiuretic hormone secretion (SIADH))
- excessive levels of androgens in the female body (hyperandrogenaemia)
- acne and excessive growth of facial or body hair

- hair disorder (e.g. altered hair texture, change of hair colour, abnormal hair growth), transient hair loss
- unconscious state
- continual tightening and contraction of certain muscles resulting in problems walking and talking
- loss of muscle coordination; awkward, uncoordinated walking unsteadiness when walking
- abnormal brain function
- lethargy (occasionally followed by disturbed consciousness and sometimes associated with hallucinations or convulsions)
- reversible parkinsonism (tremor, stiffness and shuffling)
- aggravated convulsions
- pain, reddening or itching of the skin, which may be signs of an inflammation of the blood vessels (vasculitis)
- difficulty breathing, pain or pressure in the chest (especially when breathing in), shortness of breath and dry cough due to buildup of fluid around the lungs (pleural effusion)
- increased formation of saliva (hypersalivation)
- inflammation of the pancreas, which may take a life-threatening course (see section 2. under "Other things you should know before taking Convulex").
- severe liver damage, sometimes taking a fatal course (see section 2. "Other things you should know before taking Convulex")
- rash
- bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures Check with your GP, specialist or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis, or take steroids.
- kidney disorder (renal insufficiency)
- absence of menstrual period in women
- low body temperature
- peripheral oedema (accumulation of fluid in tissue)

Rare (may affect up to 1 in 1,000 people):
- tissue damage when valproate was inadvertently injected into an artery or in the area around a vein; inflammation at the injection site, pain.
- decreased production of blood cells by the bone marrow (including pure red cell aplasia, agranulocytosis, macrocytic anaemia, macrocytosis)
- allergic reactions (ranging from rash to hypersensitivity reactions)
- abnormally low level of thyroid gland hormone
- elevation of testosterone levels
- vomiting, disturbed coordination of movements and progressive clouding of consciousness may be signs of increased ammonia levels in the blood. If such symptoms occur, consult a doctor immediately.
- obesity
- hyperactivity
- abnormal behavior
- learning disorder
- chronic abnormal brain function
- reversible dementia
- loss of neurons and the connections between them
- cognitive impairment
- double vision
- potentially life-threatening condition affecting less than 10% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer; Stevens-Johnson syndrome)
- life-threatening condition affecting greater than 30% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer; Toxic Epidermal Necrolysis)
- severe reaction of the skin and gut lining that may include rash and shedding or death of tissue (erythema multiforme)

- Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome)
- systemic lupus erythematosus (a rare immune disorder)
- allergic painful swelling of skin and mucous membranes, particularly in the face
- breakdown of damaged skeletal muscle (rhabdomyolysis)
- enuresis (involuntary discharge of urine)
- inflammation of the spaces between renal tubules (tubulo-interstitial nephritis)
- reversible failure of the tubules in the kidney to reabsorb small molecules, passing a lot of urine and feeling thirsty (Fanconi syndrome)
- male infertility
- changes on the ovaries and menstrual irregularities in women (polycystic ovarian syndrome)
- abnormal blood clotting
- abnormal coagulation tests
- biotin deficiency / biotinidase deficiency (a rare nutritional disorder)
- porphyria (a rare metabolic disease)

Very rare (may affect up to 1 in 10,000 people):
- increased breast growth in men
- transient brain affection or loss of consciousness; if you notice any of these or similar symptoms, contact a specialist as quickly as possible.

Not known (frequency cannot be estimated from the available data):
- depressed states
- increase in alertness
- decrease in carnitine levels (shown in blood or muscular tests)
- darker areas of skin and mucosae (hyperpigmentation)

Additional side effects in children
Some side effects of valproate occur more frequently in children or are more severe compared to adults. These include liver damage, inflammation of the pancreas (pancreatitis), bedwetting (enuresis), renal disfunction (Fanconi Syndrome), overgrowth of gum tissue, aggression, agitation, disturbance in attention, abnormal behaviour, hyperactivity and learning disorder.

Reporting of side effects
If you get any side effects, talk to your GP, specialist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Convulex

Keep out of the sight and reach of children.

Do not store above 25 °C.
Store in the original container in order to protect from light.

Do not use Convulex after the expiry date which is stated on the blister and on the carton after “use before”. The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Convulex contains

- The active substance is valproic acid.
  One Convulex capsule 150 contains 150 mg valproic acid.
  One Convulex capsule 300 contains 300 mg valproic acid.
  One Convulex capsule 500 contains 500 mg valproic acid.
- The other ingredients are gelatine, glycerol 85%, dry substance of Karion 83, titanium dioxide (E 171), red ferric oxide (E 172), hydrochloric acid, methacrylic acid-ethylacrylate copolymer (1:1)-dispersion 30%, triethyl citrate, macrogol 6000 and glycerol monostearate 44-55 Type II

What Convulex looks like and contents of the pack

Convulex capsules are oval, old-rose coloured gastro-resistant soft-gelatine capsules in blister packs and are supplied in cartons of 30 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH
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