

## 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 (sodium valproate) 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 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 Convulex unless your doctor tells you to as your condition may become worse.

**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 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 doctor 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.

## **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 6 "Further information").
- if you have **liver problems**.
- if you have a **family history of liver problems**.

- if you suffer from **porphyria** (a rare metabolic condition).
- If you have a **genetic problem** causing a mitochondrial disorder (e.g. **Alpers-Huttenlocher syndrome**)

#### *Epilepsy*

- For epilepsy, you must not use Convulex if you are pregnant, unless nothing else works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Convulex unless 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 doctor. Your doctor will advise you further (see below under “Pregnancy, breast-feeding and fertility – Important advice for women”).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Convulex.

Take special care with Convulex

- if you experience **abdominal pain, nausea and/or vomiting: Contact your doctor immediately**, as these may be symptoms of pancreatitis (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 disorder.
- Convulex may cause marked and progressive **weight gain**. This is a very common side effect. Consult your doctor about appropriate strategies to minimize this risk.

#### ***Tell your doctor before starting Convulex***

- if you have **lupus** (an immune system condition affecting skin, bones and joints, lungs, kidneys).
- if you are **diabetic**. Valproic acid may give an indication that ketones are present in the urine when this is not the case.
- if you have **kidney problems**. You may need a lower dose.
- if you suffer from **urea cycle enzymatic deficiency** (a rare metabolic disorder).
- If you know that there is a **genetic problem** causing a mitochondrial disorder **in your family**.

Talk to your doctor even if you no longer have these conditions, but have had them in the past.

Your doctor may advise **blood tests** before you start taking Convulex and during the first six months of treatment.

A small number of people being treated with anti-epileptics such as valproic acid have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

### **Other medicines and Convulex**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

If taken with some other medicines, the effects of Convulex or the effects of the other medicines may be changed.

#### **Please tell your doctor if you are taking any of the following:**

- salicylates, e.g. aspirin.
- antidepressants including monoamine oxidase inhibitors.
- anticoagulants, used to thin the blood (e.g. warfarin).
- benzodiazepines, used as sleeping tablets and to treat anxiety.
- other antiepileptics, e.g. phenytoin, carbamazepine, phenobarbital, lamotrigine, primidone, felbamate.
- cholestyramine, used to treat high blood lipid (fat) levels.
- cimetidine, used to treat stomach ulcers.
- antibiotics, e.g. erythromycin, carbapenem, imipenem, panipenem and meropenem.

- medicines to prevent and treat malaria, e.g. mefloquine and chloroquine. They may increase the likelihood of a fit. Before travelling to a high-risk malaria area, seek advice from your doctor or pharmacist on the most appropriate prevention medicines.
- zidovudine, used to treat HIV and AIDS.
- temozolomide, used to treat cancer.

In particular, tell your doctor or nurse if you are taking any of the following medicines:

Carbapenem agents (antibiotic used to treat bacterial infections). The combination of valproic acid and carbapenems should be avoided because it may decrease the effect of sodium valproate.

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 and drink**

Convulex may be taken with food and drink.

The capsules are usually taken after meals.

### **Pregnancy, breast-feeding and fertility**

#### ***Pregnancy***

#### **Important advice for women**

#### **Epilepsy**

- For epilepsy, you must not use Convulex if you are pregnant, unless nothing else works for you.
- For epilepsy, if you are a woman able to have a baby, you must not take Convulex unless 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 doctor. Your doctor will advise you further.

The risks of valproate when taken during pregnancy (irrespective of the disease for which valproate is used)

- 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.
- It can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported 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.
- 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 10 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.
- 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, your doctor 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 doctor.
- If you are a parent or a caregiver of a female child treated with valproate, you should contact the doctor once your child using valproate experiences menarche.
- Ask your doctor 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:

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

#### I AM STARTING TREATMENT WITH CONVULEX

If this is the first time you have been prescribed Convulex your doctor will have explained the risks to an unborn child if you become pregnant. Once you are able to have a baby, you will need to make sure you use an effective method of contraception without interruption throughout your treatment with Convulex. Talk to your doctor or family planning clinic if you need advice on contraception.

Key messages:

- Pregnancy must be excluded before start of treatment with Convulex with the result of a pregnancy test, confirmed by your doctor.
- 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 doctor. Your doctor 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 doctor will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor 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 continuing treatment with Convulex but 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 doctor or family planning 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 doctor. Your doctor 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 doctor will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Tell your doctor if you want to have a baby.
- Tell your doctor 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 doctor.

Do not stop taking Convulex or your contraception, until you have discussed this with your doctor. Your doctor 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. Your doctor will refer you to a specialist experienced in the management of epilepsy, so that alternative 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.

Your specialist may decide to change the dose of Convulex or switch you to another medicine, or stop treatment with Convulex, a long time before you become pregnant – this is to make sure your illness is stable.

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.

Key messages:

- Do not stop taking Convulex unless your doctor tells you to.
- Do not stop using your methods of birth control (contraception) before you have talked to your doctor 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 doctor. During this visit your doctor will make sure you are well aware and have understood all the risks and advices related to the use of valproate during pregnancy.
- Your doctor 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 doctor 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 doctor tells you to as your condition may become worse. Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant. Your doctor 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.

You will be referred to a specialist experienced in the management of epilepsy, so that alternative treatment options can be evaluated.

In the exceptional circumstances when 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 doctor 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 doctor if you are pregnant or think you might be pregnant.
- Do not stop taking Convulex unless your doctor tells you to.
- Make sure you are referred to a specialist experienced in the treatment of epilepsy to evaluate the need for alternative 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 doctor. Your doctor will discuss the Annual Risk Acknowledgement Form 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.**

### **Driving and using machines**

When you first start taking Convulex, or if you are taking it with other medicines, you may notice some drowsiness.

Do not drive or use any tools or machines until you know if you are affected by the intake of Convulex.

## **3. How to take Convulex**

Always take Convulex exactly as your doctor has told you. Check with your doctor if you are not sure.

Convulex treatment must be started and supervised by a doctor specialised in the treatment of epilepsy.

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 doctor will increase the dosage until your condition is controlled. As a result 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 have a **kidney disease**, your doctor may prescribe a lower dose.

If you are taking **other medicines to control your epilepsy** at the same time as Convulex, your doctor 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 doctor. They are very important as your dosage may need to be changed.

**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, talk to a doctor or pharmacist, or go to the nearest hospital casualty department immediately.

#### **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 doctor 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.

If you have any further questions on the use of this product, ask your doctor 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 contact your doctor if 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 doctor or pharmacist, if you develop any of the following side effects:**

**Very common side effects** (affecting more than 1 person in 10):

- During treatment, increased appetite leading to weight gain, which may be marked in some cases.

**Common side effects** (affecting less than 1 person in 10):

- Drowsiness. This side effect is mostly seen when other antiepileptics are used at the same time; more rarely it also occurs if Convulex only is taken.
- Trembling, particularly at higher dosages, abnormal sensations (e.g. tickling or tingling sensation).
- Nail and nail bed disorders

**Uncommon side effects** (affecting less than 1 person in 100):

- Disturbed coordination of movements and dizziness, particularly at higher dosages
- Confusion (occasionally followed by disturbed consciousness or associated with hallucinations or convulsions)
- Headache
- Weight loss

- minor gastrointestinal irritation (e.g. nausea) at the beginning of treatment; this can usually be overcome by taking the capsules with or after food (see under 3. “How to take Convulex”).
- Excessive formation of saliva.
- Oedema (swelling of the fingers, legs and toes).
- Vasculitis (inflammation of the blood vessels), which may present as pain, reddening or itching of the skin.

**Rare side effects** (affecting less than 1 person in 1,000):

- Lethargy, temporary disturbance of brain functions, twitching of the eyes.
- Impairment of hearing, usually temporary. However, it is not known if this occurs due to the treatment with valproic acid.
- Reversible Fanconi’s syndrome (a rare kidney disorder).
- Skin changes, e.g. rash.
- Changes in women’s periods and cysts on the ovaries; elevated testosterone levels in both sexes (leading to e.g. increased growth of face or body hair).
- Systemic lupus erythematosus (an allergic condition, which causes joint pain, skin rashes and fever).
- Porphyria (a rare metabolic disease which may be associated with red coloration of the urine, abdominal spasms and pain as well as vomiting).
- Obesity
- Double vision

**Very rare side effects** (affecting less than 1 person in 10,000):

- Temporary loss of consciousness, Parkinson-like symptoms such as reduced capacity of movement, trembling, increased muscular tension, involuntary movements, reversible dementia (impaired memory).
- Acne and excessive growth of facial or body hair.
- Increased breast growth in men.

**The following side effects have also been reported with no frequency given:**

- Noises in one or both ears.
- Vomiting, diarrhoea, lack of appetite, constipation.
- Involuntary discharge of urine in children.
- Temporary hair loss has been noted in some patients. Regrowth normally begins within six months, although the hair may become curlier than before.
- Temporary elevation of liver test values (which can be seen in blood tests) may occur at the beginning of treatment.
- Depression.
- An increase in alertness may occur. This is generally considered a positive effect, but occasionally symptoms such as hyperactivity, aggression and inappropriate behaviour have been reported.
- 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 antiepileptic medication, have a history of osteoporosis, or take steroids.

**Reporting of side effects**

If you get any side effects, talk to your doctor 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](http://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

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