**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** **S3**

**Convulex® Syrup**

**Convulex® 150 Capsules**

**Convulex® 300 Capsules**

**Convulex® 500 Capsules**

**Sodium valproate / Valproic acid**

**Sugar free**

**WARNING**

**Convulex® (sodium valproate) can seriously harm an unborn child when taken during pregnancy. It can cause serious birth defects to body organs and/or body structures as well as harm the developing brain of the foetus and can also affect the way in which the child develops as it grows. Children whose mothers took Convulex® during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, be intellectually less able than other children and have difficulties with language and memory.**

**Children whose mothers took Convulex® during pregnancy have an increased risk of developing autistic spectrum disorders, childhood autism and attention deficit hyperactivity disorder (ADHD).**

**Convulex® treatment should be started and supervised by a medical practitioner experienced in the treatment of epilepsy or bipolar disorder.**

**You should not take Convulex® if the Risk Minimisation Measures (Pregnancy Prevention Program), have not been explained to you and if you cannot commit to follow the pregnancy risk minimisation measures.**

**Read all of this leaflet carefully before start taking Convulex®**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your health care provider.
- Convulex® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is 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® belongs to a group of medicines called anticonvulsants, which are used to treat epilepsy (fits) or used to treat bipolar disorder. Convulex® is also used to prevent migraine headaches in adults**.**

## 2. What you need to know before you take Convulex®

**Do not take Convulex®:**

- If you are hypersensitive (allergic) to valproic acid or sodium valproate or any of the ingredients of Convulex® (listed in section 6).
- If you have liver problems.
- If you have a family history of liver problems.
- If you suffer from liver porphyria (a rare metabolic condition).
- If you have pancreatic problems.
- 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, breastfeeding and fertility – Important advice for women”).
- If you suffer from urea cycle disorders (a metabolic disorder).
- If you have a deficiency in carnitine (a very rare metabolic disease) that is untreated.

*Migraine*

- You must not use CONVULEX for preventing migraines when you are pregnant. Pregnancy should be excluded before you start treatment for migraine, and you should use effective contraception.

**Warnings and precautions**

*Take special care with Convulex®:*

- if you have bone marrow abnormalities
- if you have a tendency to bruise or bleed easily
- if your child is younger than 3 years because they are at risk of liver damage or mentally retarded
- if you have kidney problems
- if you have any mental disorders
- if you have severe epileptic fits
- if you have brain damage
- 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.
- if your child is below 3 years of age, Convulex® should not be taken together with acetylsalicylic acid (aspirin)
- Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis

(TEN), 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.

- 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 minimise this risk.

*Tell your doctor before starting Convulex®*

- if you have systemic lupus erythematosus (SLE) (an immune system condition affecting skin, bones and joints, lungs, kidneys)
- if you have a problem with your pancreas
- if you are diabetic. Convulex® 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 metabolic disorders, particularly hereditary enzyme disorders such as urea cycle enzymatic disorder because of a risk of increased ammonia 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 know that there is a genetic problem causing mitochondrial disorder in your family
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking valproate

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 Convulex® have had thoughts of harming or killing themselves. If you have these thoughts at any time, contact your

doctor.

**Other medicines and Convulex®**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some other medicines may influence the effect of Convulex® or vice versa:

- Neuroleptic medicines (used to treat psychological disorders)
- Medicines used to treat depression, including MAO inhibitors
- Benzodiazepine, used as sleeping tablets or to treat anxiety
- Other medicines used to treat epilepsy including phenobarbitone, phenytoin, primidone, lamotrigine, carbamazepine and felbamate
- Cannabidiol (used to treat epilepsy and other conditions)
- Certain anticoagulants (used to thin the blood, e.g. warfarin)
- Acetylsalicylic acid (e.g. aspirin) especially in children below 3 years of age (see Warnings and precautions.
- Zidovudine (used to treat HIV-infections and AIDS)
- Mefloquine and chloroquine (used to treat or prevent malaria) may increase the likelihood of a fit. Before travelling to a malaria area, you should get advice from your or your child's doctor or pharmacist on the most appropriate tablets for prevention.
- Anticoagulants (used to prevent blood clots)
- Cimetidine (used to treat ulcers)
- Cholestyramine (used to treat high blood lipid (fat) levels)
- Erythromycin, c arbepenem such as imipenem, panipenem and meropenem (antibiotics) rifampicin (used to treat infections)
- Rufinamide (used to treat convulsions)
- Protease inhibitors (used to treat HIV), such as lopinavir and ritonavir
- Acetazolamide (used to treat glaucoma, seizures or brain swelling) and Topiramate (also used to treat seizures/fits). The combination with Convulex® may cause a build-up of ammonia in the body.
- When used in combination with olanzapine (used to treat psychiatric disorders)

- Concomitant treatment of valproate and clozapine may increase the risk of neutropenia and clozapine-induced myocarditis
- Concomitant treatment of valproate and quetiapine may increase the risk of neutropenia/leucopoenia.
- Propofol (used for anaesthesia)
- Nimodipine (used in brain bleeds)
- Oestrogen-containing medicines (including some birth control tablets) (see Warnings and precautions). Your doctor will monitor seizures (fits) and mood control when you or your child starts or stops taking estrogen-containing medicines
- Metamizole (used to treat pain and fever) may reduce blood levels of valproate (in Convulex®). Blood test or close monitoring of seizure (fit) control and mood control may need to be initiated by your doctor.
- Methotrexate (used to treat cancer and inflammatory diseases)
- Some anti-infectives that contain pivalate (e.g. pivampicillin, adefovir dipivoxil
- Fluoxetine (an antidepressant) and
- Temozolomide (for cancer treatment)

These medicines and others may be affected by Convulex® or affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Convulex® does not appear to influence the effect of oral contraceptives.

**Taking Convulex® with food and drink**

During treatment with Convulex® you should not drink alcoholic beverages, as it may potentiate the effects of alcohol.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take Convulex® if you are pregnant or breastfeeding your baby.

**Important advice for women**

If you or your female (girl) child is pregnant, you must not use Convulex®, unless your doctor has determined there is no suitable alternative treatment.

If you or your female (girl) child is able to have a baby, you must not use Convulex® unless the conditions of the pregnancy prevention program are met.

Convulex® can be harmful to unborn children when taken by a woman during pregnancy. Convulex® can cause serious birth defects and can affect the way in which the child develops as it grows.

The conditions of the pregnancy prevention program require that before Convulex® is prescribed for you:

- your doctor must explain what might happen to your baby if you become pregnant while taking Convulex®. You need to ensure you understand these risks.
- you will be asked to perform a pregnancy test before starting Convulex®, or thereafter if needed. This is to make sure you are not pregnant.
- effective birth control (contraception) will be recommended for you to avoid becoming pregnant while taking Convulex®.
- your doctor will assess your understanding of contraception and the need for contraception without interruption during the entire duration of treatment with Convulex®.
- your doctor will review your treatment regularly (at least once a year)
- your doctor will explain what to do if you decide later that you want to have a baby. If you are planning a baby, you must first discuss this with your doctor. You must not stop taking Convulex® or interrupt your method of contraception until you have discussed this with your doctor.
- parents or caregivers of a female (girl) child treated with Convulex®, must contact the doctor once the female child using Convulex® experiences her first menstrual period.

**Please choose the situations which apply to you and read the descriptions that follow**

- I AM STARTING TREATMENT WITH CONVULEX® (First Prescription)
- I AM TAKING CONVULEX® AND I AM NOT PLANNING TO HAVE A BABY
- I AM TAKING CONVULEX® AND I AM PLANNING TO HAVE A BABY
- I AM PREGNANT AND I AM TAKING CONVULEX®

**I AM STARTING TREATMENT WITH CONVULEX® (First Prescription)**

- 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.

- If you are able to have a baby or once you are able to have a baby, you will need to make sure that you use an effective method of birth control (contraception) throughout your treatment. Talk to your doctor or family planning clinic if you need advice on contraception.
- Pregnancy must be excluded before start of treatment with Convulex® through the result of a pregnancy (blood) test, to be confirmed by your doctor.
- You must discuss appropriate methods of birth control (contraception) with your doctor.
- You must make sure you are using an effective method of birth control (contraception) during your entire treatment.
- You must get regular (at least annual) appointments with a medical practitioner experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor at once if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- It is important you contact your doctor if your female (girl) child, treated with Convulex®, experiences her first menstrual period.

**I AM TAKING CONVULEX® AND I AM NOT PLANNING TO HAVE A BABY**

If you are continuing treatment with Convulex® and you do not plan to have a baby, make sure you are using an effective method of birth control (contraception) without interruption during your entire treatment with Convulex®. Talk to your doctor or family planning clinic if you need advice on contraception.

- Make sure you are using an effective method of contraception during your entire treatment.
- You must get regular (at least annual) appointments with a medical practitioner experienced in the management of epilepsy or bipolar disorder.
- Tell your doctor immediately if you are pregnant or think you might be pregnant.
- Tell your doctor if you plan to become pregnant.
- Parents or caregivers of a female child (girl) treated with Convulex®, must contact the doctor once the female child using Convulex® experiences her first menstrual period.

**I AM TAKING CONVULEX® AND I AM PLANNING TO HAVE A BABY**

If you are on treatment with Convulex® and planning to have a baby, first schedule an appointment with your doctor. You should talk to your doctor long enough before you become pregnant so that you and your doctor can put several actions in place to ensure that your

pregnancy goes as smoothly as possible, and any risks to you and your unborn child are reduced as much as possible. Your doctor may prescribe another medicine for your epilepsy which may have less risk for your baby.

Do not stop taking Convulex® or your birth control (contraception) until you have discussed this with your doctor. Your doctor will advise you on when you can stop your contraception.

Babies born to mothers who have been on Convulex® are at serious risk of birth defects and problems with development, which can be seriously debilitating.

Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folic acid.

Folic acid may lower the risk of spina bifida (a birth defect) and early miscarriage. However, it is unlikely that folic acid will reduce the risk of birth defects associated with Convulex® use.

You must not stop taking Convulex® unless your doctor agrees, as there are severe risks to yourself and your developing baby if your epilepsy is not controlled.

If you are pregnant, or think you might be pregnant, see your doctor immediately.

**I AM PREGNANT AND I AM TAKING CONVULEX®**

Women should not become pregnant while receiving Convulex®. You should use an effective method of birth control (contraception) and consult your doctor before planning pregnancy.

Convulex® has no effect on the efficacy of your oral contraceptive pill.

Schedule an urgent appointment with your doctor if you are pregnant or think you might be pregnant.

Your doctor will advise you further.

Do not stop taking Convulex® unless your doctor tells you to as your condition may become worse.

During pregnancy, should a mother suffer from a serious type of seizure, where the oxygen supply to her and her unborn baby may be cut off, the risk of death to the mother and unborn child is increased. Your doctor will advise you further.

Make sure you are referred to a medical practitioner experienced in the treatment of epilepsy or bipolar disorder to re-assess your treatment options.

You must get thorough counselling on the risks of Convulex® during pregnancy, including malformations and developmental effects in children.

Make sure you are referred to a medical practitioner 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.

**The risks of Convulex® when taken during pregnancy**

- Babies born to mothers who are taking Convulex®, are at serious risk of birth defects and problems with development which can be seriously debilitating.
- It is known that in women who take Convulex®, around 10 babies in every 100 will have birth defects, as compared to 2 – 3 babies in every 100 born to women who do not have epilepsy.
- These birth defects to your developing baby include spina bifida (condition where bones of the spine are not properly developed), craniofacial defects (face and skull malformations), malformation of the limbs, heart, kidney and sexual organ malformations, hypospadias (malformation of the urethra) and multiple anomalies involving various body systems.
- Children born to mothers who take Convulex® during pregnancy, may have impaired physical and mental development or autistic disorders.
- It is estimated that up to 30 to 40 % of pre-school children whose mothers took Convulex® during pregnancy may have problems with early childhood development. Children affected can be slow to walk and talk, less intellectually able than other children, and have difficulty with language and memory.
- 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.
- Your doctor may want to adjust your treatment and/or prescribe dietary supplements of folate.
- You must not stop taking Convulex® unless your doctor agrees, as there are severe risks to yourself and your developing baby if you have uncontrolled epilepsy.

**Newborn babies of mothers who took Convulex® during pregnancy may have**

- blood clotting problems (blood not clotting very well). This may appear as bruising or bleeding which takes a long time to stop.
- hypoglycaemia (low blood sugar levels).
- hypothyroidism (underactive thyroid gland, which can cause tiredness or weight gain).
- withdrawal syndrome (agitation, irritability, hyper-excitability, jitteriness, hyperkinesia (muscle spasm), muscle problems, tremor, convulsions and feeding problems); when taken during the last trimester of pregnancy.

**Breastfeeding**

Convulex® passes into the breast milk. You should not breastfeed your baby if you are taking Convulex®.

**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). The risk for children born to fathers who stopped valproate treatment 3 months (the time needed to form new sperm) or longer before conception is not known. The study has limitations and therefore it is not clear if the increased risk for movement and mental developmental disorders suggested by this study is caused by valproate. The study was not large enough to show which particular type of movement and mental developmental

disorder children may be at risk of developing.

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.**

**Fertility**

Convulex® can cause infertility in both men and women that may not always be reversible.

**Driving and using machines**

In many cases the seizure control resulting from treatment with Convulex® may enable patients to actively drive.

However, patients driving a vehicle or using machines should be warned of the risk of transient drowsiness especially in cases of combined therapy with several antiepileptics or concomitant

treatment with benzodiazepines.

## 3. How to take CONVULEX®

Do not share medicines prescribed for you with any other person.

Always take CONVULEX® exactly as described in this leaflet. You should check with your doctor, pharmacist or other healthcare professional if you are not sure. The total daily dose should be taken in divided dosages. Convulex® capsules should be taken whole, with some liquid, during or after meals.

**Epilepsy**

**Adults**

The initial dose is 600 mg per day in divided doses, increasing by 150 mg per day to a maintenance dosage of 1 000 - 1 600 mg per day (approx. 3 - 5 capsules of 300 mg each or 2 - 3 capsules of 500 mg each).

**Children**

Children weighing less than 20 kg may be given 15 - 20 mg per kg per day. Children weighing more than 20 kg may be given 450 mg daily in divided doses (e.g. 3 x 1 capsule Convulex® 150 mg). – syrup.

**Acute mania in Bipolar I affective disorders**

The recommended initial dose is 600 – 900 mg daily, divided into several doses, up to a maximum of 1500 mg per day in highly agitated patients.

**Migraine (Adults only)**

Starting at 300 mg per day in divided doses, the daily dose is slowly increased until the desired therapeutic effect is achieved, or side effects occur. Most patients can be effectively treated with 600 – 900 mg per day.

If you have the impression that the effect of Convulex® is too strong or too weak, talk to your doctor, pharmacist or other healthcare professional.

**If you take more Convulex® than you should**

An overdose of Convulex® may be dangerous. Symptoms of acute overdose may include nausea, vomiting, dizziness, sometimes also serious, or even fatal, side- effects on the part of the central nervous system and breathing difficulty. In serious cases immediate medical

assistance is required.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take Convulex®**

If you forgot to take a dose at the right time, take it as soon as you remember. However, if you are already nearing the time for your next scheduled dose, you should skip the forgotten dose and then continue treatment as prescribed. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Convulex®**

Do not interrupt or stop the treatment with Convulex® without consulting your doctor. This could endanger the positive effects of treatment and might induce more seizures. Please discuss any signs of intolerance or changes in the course of your illness with your treating doctor. If you have any further questions on the use of Convulex®, ask your doctor or pharmacist.

**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 or pharmacist.

## 4. Possible side effects

CONVULEX® can have side effects.

Not all side effects reported for CONVULEX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CONVULEX®, please consult your health care provider for advice.

If any of the following happen, stop taking Convulex® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat (angioedema) which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic

reaction to Convulex®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- bizarre behaviour associated with or not with more frequent or more severe fits, loss of drive particularly if phenobarbitone is taken at the same time or if Convulex® dose has been suddenly increased,
- repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, nausea, jaundice (yellowing of the skin or whites of the eyes), swelling of the legs or worsening of your epilepsy or a general feeling of being unwell,
- blood clotting problems,
- spontaneous bruising or bleeding,
- blisters and skin detachment.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent:*

- nausea, vomiting, diarrhoea and minor gastric irritation,
- tremor (uncontrolled trembling or shaking movements in one or more parts of your body)
- temporary elevation of liver test values (which can be seen in blood tests) may occur at the beginning of treatment,
- nail and nail bed disorders,
- anaemia, hyponatraemia (decreased sodium levels in the blood), thrombocytopenia (low platelet count)
- increased weight
- upper abdominal pain
- increased bleeding
- movement disorders due to impaired regulation of muscle coordination in the brain (so-called extrapyramidal symptoms; stupor)
- disturbance in attention
- aggression

- agitation
- headache
- twitching of the eyes
- memory impairment
- dizziness
- gingival hyperplasia (gum overgrowth)
- hypersensitivity reactions
- alopecia (loss of hair)
- urinary incontinence (unintentional passing of the urine)
- dysmenorrhea (painful menstrual periods)

*Less frequent:*

- weight gain,
- 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),
- decreased production of blood cells by the bone marrow (including pure red cell aplasia, agranulocytosis, macrocytic anaemia, macrocytosis)
- abnormal blood clotting
- low levels of carnitine in the blood
- 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), excessive growth of facial or body hair, temporary hair loss
- hair disorder (e.g. altered hair texture, change of hair colour, abnormal hair growth), transient hair loss
- confusion (occasionally followed by disturbed consciousness or associated with hallucinations or convulsions),
- oedema (swelling of the fingers, legs and toes),

- vasculitis (inflammation of the blood vessels),
- lethargy, temporary disturbance of brain functions, twitching of the eyes,
- impairment of hearing,
- skin changes, e.g. rash,
- obesity,
- double vision
- temporary loss of consciousness, Parkinson-like symptoms such as reduced capacity of movement, trembling (shakiness), increased muscular tension, involuntary movements, reversible dementia (impaired memory),
- abnormal tingling and numbness and aggravated convulsions (fits)
- increased breast growth in men.
- male infertility
- changes in women's periods
- changes on the ovaries in women (polycystic ovarian syndrome) and infertility
- an increase in alertness, hyperactivity, inappropriate behaviour, abnormal behaviour, learning disorder
- bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures
- myelodysplastic syndrome (a type of blood cancer)
- water in the lungs
- swelling of the pancreas
- potential life-threatening condition skin condition where the top layer of the skin dies and peels away (Stevens-Johnson syndrome)
- life-threatening condition skin condition where the top layer of the skin dies and peels away (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)

- breakdown of damaged skeletal muscle (rhabdomyolysis)
- Fanconi syndrome (reversible failure of the tubules in the kidney to reabsorb small molecules, passing a lot of urine and feeling thirsty,
- enuresis (involuntary discharge of urine)
- tubule-interstitial nephritis (inflammation of the spaces between the kidney tubes),
- kidney failure
- cerebral atrophy (loss of brain neurons and connections between them)
- abnormally low level of thyroid gland hormone

If any of these side effects continue, are severe or bother you, tell your doctor, pharmacist or other healthcare professional.

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

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. You can also report side effects at the company email address: drugsafety_ZA@arceralifesciences.com.

By reporting side effects, you can help provide more information on the safety of Convulex®.

## 5. How to store CONVULEX®

Store all medicines out of reach of children.

- Store at or below 25 ºC, protected from light and moisture.
- Tightly close the container after each use.
- Do not use Convulex® after the expiry date which is stated on the container.
  The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What Convulex® contains**

The active substance is as follows in the formulations:

Convulex® Syrup: One ml contains 50 mg sodium valproate. Sugar free. Preservatives: methylhydroxybenzoate 0,1 % *m/v &* propylhydroxybenzoate 0,04 % *m/v.*

Convulex® 150 Capsules: valproic acid (per capsule) 150 mg

Convulex® 300 Capsules: valproic acid (per capsule) 300 mg

Convulex® 500 Capsules: valproic acid (per capsule) 500 mg

The other ingredients are:

*Capsule:* gelatine, glycerol monostearate, hydrochloric acid, hydrogenated hydrolysed starch, macrogol 6000, methacrylic acid-ethylacrylate copolymer, red iron oxide, titanium dioxide, triethyl citrate.

*Syrup:* lycasin, saccharin sodium, sodium cyclamate, sodium chloride, sodium hydroxide.

**What Convulex® looks like and contents of the pack**

Convulex® Syrup is sugar-free, clear, slightly yellow syrup, with a peach/raspberry odour and taste.

Convulex® 150 is a pinkish, enteric-coated, oval, soft gelatine capsule without imprinting. The capsule contains a clear, slightly yellow liquid.

Convulex® 300 is a pinkish, enteric-coated, oval, soft gelatine capsule with a grey ‘300’ imprint. The capsule contains a clear, slightly yellow liquid.

Convulex® 500 is a pinkish, enteric-coated, oval, soft gelatine capsule without imprint. The capsule contains a clear, slightly yellow liquid.

**Contents of the pack**

Convulex® Syrup: 100 ml amber glass bottles

Convulex® 150: Blister packs containing 100 capsules

Convulex® 300: Blister packs containing 100 capsules

Convulex® 500: Blister packs containing 100 capsules.

**Holder of Certificate of Registration**

Acino Pharma (Pty) Ltd 106

16th Road Midrand

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Tel: 011 516 1700

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24 July 2026

**Registration numbers**

Convulex® Syrup: W/2.5/390

Convulex® 150 Capsules: R/2.5/218

Convulex® 300 Capsules: R/2.5/219

Convulex® 500 Capsules: W/2.5/20

**Access to the corresponding Professional Information**

By scanning the QR code