

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

Convulex[®] Syrup

Convulex[®] 150 Capsules

Convulex[®] 300 Capsules

Convulex[®] 500 Capsules

Read all of this leaflet carefully before you receive 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 CONVULEX[®] MEDICINE CONTAINS

The active substance is as follows in the formulations:

Convulex[®] Syrup One ml contains 50mg sodium valproate

Sugar-free

Preservatives: methylhydroxybenzoate 0,1% m/v

propylhydroxybenzoate 0,04% m/v

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

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

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

The other ingredients are:

Capsule: Glycerol, gelatin, hydrochloric acid, titanium dioxide, red iron oxide, sorbitol

Syrup; Lycasin, saccharin sodium, sodium cyclamate, sodium chloride, sodium hydroxide,

WHAT CONVULEX® IS USED FOR

Convulex® belongs to a group of medicines called anticonvulsants, which are used to treat epilepsy (fits) or used to treat or prevent bipolar disorders.

BEFORE YOU TAKE CONVULEX®

Do not take **Convulex®**:

If you are hypersensitive (allergy) to valproic acid or sodium valproate or any of the other ingredients of **Convulex®**

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are pregnant or breastfeeding your baby while taking this medicine please consult your doctor, pharmacist or healthcare professional.

Special care should be taken with Convulex®:

If you have bone marrow abnormalities, kidney problems, severe epilepsy, mentally retarded children, head lesions, and children younger than 3 years.

If you need advice about the above conditions, contact a doctor/or healthcare professional.

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

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 your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

It is very important to discuss pregnancy or your intention to become pregnant with your doctor as **Convulex**[®] can cause damage to your unborn baby. Women who have been exposed to **Convulex**[®] in the first three months of pregnancy should be told of the risk, and be offered counseling before the baby is born.

Convulex[®] should not be used in female children, in female adolescents, in women of childbearing potential and in pregnant women unless other treatments are ineffective or not tolerated. Women of childbearing potential have to use effective contraception during treatment. In women planning to become pregnant all efforts should be made to switch to appropriate alternative treatment prior to conception, if possible.

Driving and using machinery

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.

TAKING OTHER MEDICINES WITH CONVULEX[®]:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **Convulex**[®] with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Convulex[®] may potentiate the effect of:

- Neuroleptic agents (used to treat psychological disorders)
- Medicines used to treat depression
- Benzodiazepine, used as sleeping tablets or to treat anxiety

- Other medicines used to treat epilepsy including phenobarbital, phenytoin, primidone, lamotrigine, carbamazepine and felbamate
- Certain anticoagulants (used to thin the blood, e.g. warfarin)
- Acetylsalicylic acid (e.g. aspirin)
- Zidovudine (used to treat HIV-infections and AIDS)
- Mefloquine (used to treat or prevent malaria)
- Cimetidine (used to treat ulcers)
- Erythromycin, carbepenem such as imipenem, panipenem and meropenem (antibiotics)
- Fluoxetine (an antidepressant) and
- Temozolomide (for tumour 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.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **Convulex**[®] with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE CONVULEX[®]

Always take **Convulex**[®] exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. The total daily dose should be taken in divided dosages. **Convulex**[®] capsules should be taken whole, with some liquid, during or after meals.

The usual dose is

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).

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 overdose, 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 physician. If you have any further questions on the use of **Convulex**[®], ask your doctor or pharmacist.

SIDE-EFFECTS

Convulex[®] may cause side effects.

You may need medical treatment if you get some of the side effects:

Nausea and minor gastric irritation, especially when starting treatment.

Shakiness (tremor), drowsiness

Skin reactions such as rashes

Transient hair loss

Changes in women's period

Allergic reactions

Swelling of the feet and legs (oedema)

Weight gain

Kidney problems , bedwetting or increased need to pass urine

Tell your doctor immediately if you notice any of the following side effects. You may need urgent attention:

Bizzare behaviour associated with or not with more frequent or more severe fits, loss of drive particularly if phenobarbital 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

Not all side effects reported for **Convulex**[®] are included in this leaflet should your general health worsen while taking **Convulex**[®], please consult your doctor, pharmacist or other healthcare professional for advice.

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, pharmacist or other healthcare professional.

STORING AND DISPOSING OF CONVULEX®:

Keep out of the reach and sight of children.

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.

PRESENTATION OF CONVULEX®:

Convulex® Syrup:	100ml amber glass bottle
Convulex® 150:	Blister packs containing 100 capsules
Convulex® 300:	Blister packs containing 100 capsules
Convulex® 500:	Blister packs containing 100 capsules

IDENTIFICATION OF CONVULEX®

Convulex® Syrup is sugar-free, clear, slightly yellow syrup, with a peachy smell and taste

Convulex® 150 is a pinkish, enteric-coated, oval, soft gelatin capsule with a “150” imprint.

The capsule contains a clear, slightly yellow liquid.

Convulex® 300 is a pinkish, enteric-coated, oval, soft gelatin capsule with a ‘300’ imprint.

The capsule contains a clear, slightly yellow liquid.

Convulex® 500 is a pinkish, enteric-coated, oval, soft gelatin capsule with a ‘500’ imprint.

The capsule contains a clear, slightly yellow liquid.

REGISTRATION NUMBER

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

NAME AND ADDRESS OF REGISTRATION HOLDER

For more information about the product, telephone or write to:

TAKEDA (PTY) LTD

Building A, Monte circle
Montecasino Boulevard
Fourways
2191

DATE OF PUBLICATION

To be determined