

# LEVITAM

levetiracetam

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about LEVITAM. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking LEVITAM against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.** You may need to read it again.

### What LEVITAM is used for

LEVITAM is used to control epilepsy.

Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

LEVITAM belongs to a group of medicines called antiepileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

LEVITAM may be used alone, or in combination with other medicines, to treat your condition. Your doctor may prescribe this medicine in addition to your current therapy.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

LEVITAM is not recommended for use in children under the age of 4, as there have been no studies of its effects in children of this age group.

This medicine is available only with a doctor's prescription.

There is no evidence that it is addictive.

### Before you take it

#### *When you must not take it*

**Do not take LEVITAM if you are allergic to medicines containing levetiracetam or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

**Do not take LEVITAM if you are pregnant or intend to become pregnant, without talking to your doctor first.**

Like most antiepileptic medicines, LEVITAM is not recommended for use during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take this medicine, your doctor can help you decide whether or not to take it during pregnancy.

**Do not take it if you are breastfeeding.**

LEVITAM passes into breast milk and may affect your baby.

**Do not take it if the expiry date (Exp.) printed on the pack has passed.**

**Do not take it if the packaging is torn or shows signs of tampering.**

#### *Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

Tell your doctor if you are pregnant or plan to become pregnant.

LEVITAM may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take LEVITAM, your doctor can help you decide whether or not to take it during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

It is recommended that you do not breastfeed while taking LEVITAM.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- kidney problems
- liver problems.

Your doctor may want to take special care if you have any of these conditions.

**If you have not told your doctor about any of the above, tell them before you start taking LEVITAM.**

#### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking LEVITAM.

### How to take it

#### *How much to take*

For patients 12 years of age and older, the dosage is generally between 1000 mg and 3000 mg each day.

For children 4 to 11 years of age the dose is 20 mg/kg to 60 mg/kg each day.

There is no data to support the use of LEVITAM for patients less than 4 years of age.

Your doctor will tell you how much LEVITAM you will need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of LEVITAM and slowly increase the dose to the lowest amount needed to control your epilepsy/seizures (fits).

**Follow all directions given to you by your doctor and pharmacist carefully.**

#### *How to take it*

Swallow the tablets with a glass of water.

#### *If you forget to take it*

**Contact your doctor if you have missed one or more doses.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

#### *How long to take it for*

Most anticonvulsant medicines take time to work, so do not be discouraged if you do not feel better straight away.

**Continue taking LEVITAM for as long as your doctor tells you to.**

This medicine helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

**Do not stop taking LEVITAM, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**

Stopping treatment suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

#### *If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much LEVITAM. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much LEVITAM, you may feel drowsy.

### While you are taking it

#### *Things you must do*

**Tell your doctor immediately if you notice an increase in seizures.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking LEVITAM.**

**Before starting any new medicine, tell your doctor or pharmacist that you are taking LEVITAM.**

**Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking LEVITAM.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.** Otherwise, your doctor may change your treatment unnecessarily.

**Visit your doctor regularly so they can check on your progress.**

Your doctor may also want to take some tests from time to time. This helps to prevent unwanted side effects.

#### *Things you must not do*

**Do not stop taking LEVITAM, or lower the dose, without checking with your doctor.**

**Do not use it to treat any other conditions unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

#### *Things to be careful of*

**Be careful driving or operating machinery until you know how LEVITAM affects you.** It may cause drowsiness, in some people, especially in the beginning of treatment. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

**Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.**

Be careful when drinking alcohol while taking LEVITAM.

Combining it with alcohol can make you drowsier.

Your doctor may suggest you avoid alcohol while you are being treated with LEVITAM.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LEVITAM.**

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- dizziness
- feeling weak
- common cold and upper respiratory tract infections
- feeling tired, drowsy or sleepy.

These are the more common side effects of LEVITAM and are usually short-lived.

Other side effects reported are:

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

**If you experience more frequent or more severe seizures, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.**

**Tell your doctor immediately if you experience any of the following:**

- suicidal thoughts
- suicidal attempts.

**Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.**

- LEVITAM 500 - yellow, oval shaped film coated tablet marked 'LE 500' on one side and a scoreline on the other
- LEVITAM 1000 - white, oval shaped film coated tablet marked 'LE 1000' on one side and a scoreline on the other

Each pack contains 60 tablets.

### *Ingredients*

The active ingredient in LEVITAM is levetiracetam.

- each LEVITAM 250 tablet contains 250 mg of levetiracetam
- each LEVITAM 500 tablet contains 500 mg of levetiracetam
- each LEVITAM 1000 tablet contains 1000 mg of levetiracetam.

The tablets also contain:

- maize starch
- povidone
- purified talc
- colloidal anhydrous silica
- magnesium stearate
- Opadry II 85F60833 Blue (250 mg tablets)
- Opadry II 85F62663 Yellow (500 mg tablets)
- Opadry II 85F18378 White (1000 mg tablets).

Tablets are gluten, lactose and sucrose free.

### *Sponsor*

**Aspen Pharma Pty Ltd**  
34-36 Chandos Street  
St Leonards NSW 2065  
Australia

### **Australian registration numbers:**

LEVITAM 250 - AUST R 143659  
LEVITAM 500 - AUST R 143695  
LEVITAM 1000 - AUST R 143700

Date of preparation:

April 2010.

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## After using it

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### *Storage*

**Keep your medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store LEVITAM or any other medicine in the bathroom or near a sink.**

**Do not leave LEVITAM in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

**If your doctor tells you to stop taking LEVITAM, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### *What it looks like*

LEVITAM comes in 3 strengths of tablets:

- LEVITAM 250 - blue, oval shaped, film coated tablet marked 'LE 250' on one side and a scoreline on the other