

# Levetiracetam SZ tablets

levetiracetam tablets

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about this medicine.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medication against the benefits it is expected to have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What Levetiracetam SZ is used for

Levetiracetam SZ 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.

Levetiracetam SZ 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.

Levetiracetam SZ may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe Levetiracetam SZ in addition to your current therapy.

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

There is no evidence that Levetiracetam SZ is addictive.

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

The safety and effectiveness of Levetiracetam SZ have not been established in patients less than 4 years of age.

### Before you take Levetiracetam SZ

#### When you must not take it

**Do not take Levetiracetam SZ if you have an allergy to:**

- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to Levetiracetam SZ may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**If you are unsure whether any of the above conditions apply to you, ask your doctor.**

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

Like most antiepileptic medicines, Levetiracetam SZ 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 Levetiracetam SZ, your doctor can help you decide whether or not to take it during pregnancy.

**Do not breastfeed while taking Levetiracetam SZ.**

Levetiracetam SZ passes into breast milk.

**Do not take Levetiracetam SZ after the expiry date (EXP) printed on the pack.**

**Do not take Levetiracetam SZ tablets if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.**

**If Levetiracetam SZ has expired or is damaged, return to your pharmacist for disposal.**

**If you are not sure whether you should start taking Levetiracetam SZ, talk to your doctor or pharmacist.**

*Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines, especially barbiturates or any other anticonvulsant medicines
- any other substances, such as foods, preservatives or dyes

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

- kidney problems (renal damage, renal insufficiency, impaired renal function)
- liver problems

**Tell your doctor if you are pregnant or intend to become pregnant.**

Levetiracetam SZ 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 Levetiracetam SZ, your doctor can help you decide whether or not to take it during pregnancy.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

It is recommended that you do not breastfeed while taking Levetiracetam SZ.

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

#### Taking other medicines

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

Levetiracetam SZ does not interact with the oral contraceptive pill. However, you may be given Levetiracetam SZ together with other antiepileptic drugs that do interact and they may compromise contraceptive efficacy.

Your doctor may advise you to use an additional method of contraception if you take Levetiracetam SZ with other antiepileptic drugs.

### How to take Levetiracetam SZ

#### How much to take

For patients 12 years of age and older, the dosage is generally between 1000mg and 3000mg 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 Levetiracetam SZ for patients less than 4 years of age.

Your doctor will tell you how much Levetiracetam SZ 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 Levetiracetam SZ 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 carefully.**

They may differ from the information contained in this leaflet.

**If you believe that the effect of Levetiracetam SZ is too weak, talk to your doctor.**

**If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.**

#### How to take it

**Swallow Levetiracetam SZ tablets whole with a glass of water.**

#### When to take it

**Levetiracetam SZ must be taken two times a day, once in the morning and once in the evening, at about the same time each day.**

Taking Levetiracetam SZ at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take Levetiracetam SZ before or after food.

#### 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 that you missed.**

This may increase the chance of you getting an unwanted side effect.

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

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

#### How long to take it

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

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

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

Stopping Levetiracetam SZ 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 (tel: 131 126) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Levetiracetam SZ. Do this even if there are no signs of discomfort or poisoning.**

If you take too much Levetiracetam SZ you may feel drowsy.

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## While you are using Levetiracetam SZ

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### *Things you must do*

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

**Tell your doctor immediately if you have symptoms of depression or thoughts of self harm.**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Levetiracetam SZ.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Levetiracetam SZ.**

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

**Tell your doctor if you feel Levetiracetam SZ is not helping your condition.**

Your doctor may need to change your medicine.

**Tell your doctor if, for any reason, you have not taken Levetiracetam SZ exactly as prescribed.**

Otherwise, your doctor may change your treatment unnecessarily.

**If you become pregnant while taking Levetiracetam SZ, tell your doctor.**

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

### *Things you must not do*

**Do not give Levetiracetam SZ to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.**

**Do not take Levetiracetam SZ to treat any other complaints unless your doctor tells you to.**

**Do not stop using it unless your doctor tells you to.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Levetiracetam SZ affects you.**

As with other anticonvulsant medicines, Levetiracetam SZ may cause drowsiness in some people.

This is more frequent at the beginning of treatment or at dosage increase.

**Make sure you know how you react to Levetiracetam SZ before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy.**

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

Levetiracetam SZ may cause drowsiness and affect alertness.

**Be careful when drinking alcohol while taking Levetiracetam SZ. Combining Levetiracetam SZ and alcohol can make you more drowsy.**

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

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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 Levetiracetam SZ.**

Levetiracetam SZ helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. 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.**

**If you get any side effects, do not stop taking Levetiracetam SZ without first talking to your doctor or pharmacist.**

**Tell your doctor or pharmacist 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 Levetiracetam SZ. Mostly these are mild and short-lived.

Other side-effects reported include:

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

You may not experience any of these side-effects.

**If you experience any other side-effects, tell your doctor immediately.**

**If you experience more frequent or more severe seizures (fits), or thoughts of self harm tell your doctor immediately or go to Accident and Emergency at your nearest hospital.**

**Tell your doctor if you notice anything else that is making you feel unwell.**

Other side effects not listed above may happen in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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## After using Levetiracetam SZ

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### *Storage*

**Keep this medication in the pack until it is time to take it.**

If you take the tablets out of their packs they will not keep well.

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

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

**Do not leave it on a window sill or in the car on hot days.**

Heat and dampness can destroy some medicines.

**Keep it 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.

### *Disposal*

**If your doctor or pharmacist tells you to stop taking Levetiracetam SZ or it has passed its expiry date, ask your pharmacist what to do with any that is left over.**

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## Product description

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### *What it looks like*

Levetiracetam SZ tablets are available in three strengths:

- 250 mg - blue, marked Lev 250 on one side with central score on both faces;
- 500 mg - yellow, marked Lev 500 on one side with central score on both faces;
- 1,000 mg - white, marked Lev 1000 on one side with central score on both faces.

### *Ingredients*

Each Levetiracetam SZ tablet contains either 250mg, 500mg or 1000mg of levetiracetam as the active ingredient.

Other ingredients in Levetiracetam SZ tablets include:

- starch - maize
- povidone
- talc
- magnesium stearate
- silica colloidal anhydrous

Levetiracetam SZ tablets are film-coated. The coating for each tablet strength contains Macrogol 3350, polyvinyl alcohol, talc and titanium dioxide. The following strengths also contain:

- 250mg - Indigo carmine CI73015
- 500mg - Iron oxide yellow CI77492

Levetiracetam SZ tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

#### **Southern Cross Pharma Pty Ltd**

56 Illabunda Drive  
Malua Bay NSW 2536  
ABN 47 094 447 677

### *Distributor*

#### **Sandoz Pty Ltd**

ABN 60 075 449 553  
19 Harris Street  
Pyrmont NSW 2009  
Australia  
Tel: 1800 634 500

### **Date of Information:**

February 2012

### **AUST R Number**

250mg - 159268  
500mg - 159269  
1000mg - 159271