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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about KEVTAM.

It does not contain all 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 KEVTAM against the benefits expected 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.

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### What Kevtam is used for

KEVTAM levetiracetam is used to treat epilepsy.

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

This medicine 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.

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

Your doctor may have prescribed this medicine in addition to your current therapy.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive

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

The safety and effectiveness of KEVTAM has not been established in patients less than 4 years of age.

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### Before you take KEVTAM

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

**Do not take KEVTAM if you have an allergy to:**

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

Some of the symptoms of an allergic reaction 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

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

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

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

- any other medicines, especially barbiturates (such as phenobarbital (phenobarbitone)) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or valproate)
- any other medicines, foods, preservatives or dyes,

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

- kidney problems
- liver problems

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

Your doctor can discuss with you the risks and benefits involved.

KEVTAM may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will outline and weigh up all the risks and benefits of taking KEVTAM during pregnancy to help decide whether or not you should take it.

KEVTAM passes into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss the risks and benefits of using KEVTAM if you are breastfeeding.

**If you have not told your doctor about any of the above, tell him/her before you start taking KEVTAM.**

#### *Taking other medicines*

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

KEVTAM does not interact with the oral contraceptive pill. However, you may be given KEVTAM together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptive.

Your doctor may advise you to use an additional method of contraception if you take KEVTAM with other antiepileptic medicines.

You may need different amounts of your medicines, or you may need to take different medicines.

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

#### *How to take KEVTAM*

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

They may differ from the information contained in this leaflet.

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

#### *How much to take*

Your doctor will tell you how much KEVTAM 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.

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

For children 4 to 11 years of age the doctor will calculate the dosage based on the child's weight and tell you how much to give. The medicine is to be given twice daily.

Your doctor may start you on a low dose of KEVTAM first. Your doctor will slowly increase the amount of medicine until you are taking enough to control your epilepsy and you are not having seizures.

#### *How to take it*

**Swallow the tablets whole with a glass of water.**

#### *When to take it*

**Take KEVTAM twice a day, once in the morning and once at night. Take it about the same time each day.**

Taking it 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 this medicine before or after food.

#### *How long to take it*

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

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

#### *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.**

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.**

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

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

You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy.

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### While you are taking KEVTAM

#### *Things you must do*

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

**Tell your doctor immediately if you have symptoms of depression or thought of harming yourself.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking KEVTAM. Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

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

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

*Things you must not do*

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

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

**Do not stop taking KEVTAM, or change the dosage, without checking with your doctor.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

*Things to be careful of*

**Be careful driving or operating machinery until you know how KEVTAM affects you. Children should be careful when riding bicycles or climbing trees**

As with other antiepileptic medicines, KEVTAM may cause dizziness or drowsiness in some people. This is more frequent at the beginning of treatment or after an increase in the dose.

If you are feeling dizzy or drowsy 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 dizzy or drowsy.

**Be careful when drinking alcohol while you are taking this medicine.**

Combining KEVTAM and alcohol can increase drowsiness. Your doctor may suggest you avoid alcohol while you are being treated with KEVTAM.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

## Side effects

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

This medicine helps most people with epilepsy, but it may have unwanted side effects in some people.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following list of side effects.**

You may not experience any of them.

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

**If you get any side effects, do not stop taking KEVTAM 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
- headache
- common cold
- upset stomach
- diarrhoea
- feeling tired, drowsy or sleepy.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability
- feelings of depression
- upper respiratory tract infections
- recurrent infections
- high temperature or fever
- weight loss.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- thoughts of harming yourself
- more frequent or more severe = seizures
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, mouth, throat or tongue or other parts of the body
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

If you noticed any other side effects, check with your doctor. Other side effects may be

only seen by blood tests. Your doctor will carry out any necessary tests.

## After taking KEVTAM

### Storage

**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 KEVTAM or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## Product description

### What it looks like

KEVTAM tablets are available in three strengths:

- 250mg - Light blue, capsule shaped, biconvex film coated tablets plain on both sides
- 500mg - Yellow, capsule shaped, biconvex film coated tablets plain on both sides
- 1000mg - capsule shaped, biconvex film coated tablets plain on both sides

### Ingredients

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

It also contains the following inactive ingredients:

- croscarmellose sodium
- magnesium stearate
- silica colloidal anhydrous
- povidone
- starch maize

KEVTAM tablets are film-coated. The strengths also contain:

- 250mg - Opadry complete film coating system 03B50643 BLUE (PI 109251)
- 500mg - Opadry complete film coating system 03B52573 YELLOW (PI 109246)
- 1000mg - Opadry complete film coating system 04F58804 WHITE (PI 11793)

### Supplier

Kevtam is supplied in Australia by:

**Alphapharm Pty Ltd**

Level 1, 30 The Bond

30-34 Hickson road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Australian registration numbers:

KEVTAM 250: AUST R 278843

KEVTAM 500: AUST R 278842

KEVTAM 1000: AUST R 278841

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