

Kevtam

contains the active ingredient levetiracetam

CONSUMER MEDICINE INFORMATION

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.

What Kevtam is used for

Kevtam 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.

Kevtam 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 is used alone in the treatment of partial seizures in patients from 16 years of age.

Kevtam is used in patients who are already taking another antiepileptic medicine in the treatment of:

- partial seizures in adults and children from 4 years of age

- myoclonic seizures in patients from 12 years of age with Juvenile Myoclonic Epilepsy
- primary generalised tonic-clonic seizures in adults and children from 4 years of age.

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.

Kevtam is available only with a doctor's prescription.

Kevtam is not addictive.

Before you take Kevtam

When you must not take it

Do not take Kevtam if you have an allergy to:

- any medicine containing levetiracetam
- 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 give this medicine to children under the age of 4 years.

Safety and effectiveness in children younger than 4 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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, foods, preservatives or dyes.

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

- kidney problems
- liver problems.

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

Kevtam may affect your unborn baby if you take it during pregnancy, but it is still important that you control your fits while you are pregnant. Your doctor will discuss the risks and benefits of taking Kevtam during pregnancy and help you decide whether or not you should take this medicine.

It is recommended that women on antiepileptic drugs receive pre-pregnancy counselling with regard to the risk on their unborn child.

It is recommended that you take a folate supplement, e.g. 5mg folate daily, 4 weeks before becoming pregnant and during the first 12 weeks of your pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not recommended to breastfeed while taking Kevtam.

The active ingredient passes into breast milk and there is a possibility that your baby may be affected.

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 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 Kevtam with other antiepileptic drugs.

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 pack, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

Your doctor will decide the right dose for you. This may depend on your condition, age, other medicines you are taking and how you respond to Kevtam.

Monotherapy

The recommended starting dose is 500 mg each day, increased to 1,000 mg each day after two weeks. This

dose may be gradually increased up to 3,000 mg daily.

Adjunctive therapy

Dosage in adults and adolescents (12 to 17 years) weighing 50 kg or more:

The usual dose is between 1,000 mg and 3,000 mg each day.

Dosage in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:

The usual dose is between 20 mg/kg and 60 mg/kg each day.

Your doctor may recommend that you start with a low dose of Kevtam and slowly increase the dose to the lowest amount needed to control your epilepsy.

How to take it

Swallow the tablet whole with a glass of water.

Do not crush or chew the tablets.

When to take it

Kevtam must be taken twice a day, once in the morning and once in the evening, at 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 Kevtam with or without food.

How long to take it

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

Continue taking Kevtam 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

If it has only been a few hours since your missed dose, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for the next dose, skip the dose you missed and take your next dose when you are meant to.

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.

If you take too much Kevtam you may feel drowsy, sleepy, agitated or even lose consciousness.

While you are taking Kevtam

Things you must do

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.

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

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Kevtam may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while taking Kevtam, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability, or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

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

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

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 Kevtam exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

Your doctor may do some tests from time to time. This helps 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 your medicine or lower the dosage without checking with your doctor.

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

Your doctor will slowly reduce your dose before you can stop taking it completely.

Things to be careful of

Be careful driving or operating machinery until you know how Kevtam affects you.

This medicine may cause drowsiness in some people. This is more frequent at the beginning of treatment or at dosage increase.

If you feel drowsy or sleepy, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

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

Combining Kevtam and alcohol can make you more drowsy.

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

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.

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

- sleepiness
- dizziness
- unusual weakness, fatigue
- common cold and upper respiratory tract infections
- digestive disorders, such as vomiting, diarrhoea, constipation
- anorexia (loss of appetite)
- skin rash, pruritus
- hair loss
- aching muscles, muscle tenderness or weakness, not caused by exercise.

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

- double or blurred vision
- memory loss
- problems with muscle coordination (problems walking and moving)
- mood and behaviour changes such as aggression, agitation, anger, anxiety, mood swings, depression, nervousness, confusion, hostility and irritability.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- psychotic symptoms such as hallucinations (seeing or hearing things that are not there) or delusions (false or strange thoughts or beliefs)
- more frequent or more severe seizures (fits)
- suicide thoughts or attempts (see Things you must do)

- tiredness, being short of breath and looking pale
- bleeding or bruising more easily than normal.

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.

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 come in 3 strengths:

- Kevtam 250 mg - A blue, film-coated, oblong-shaped biconvex tablet, debossed with "LV 250" on one side and blank on the other side.
- Kevtam 500 mg - A yellow, film-coated, oblong-shaped biconvex tablet, debossed with "LV 500" on one side and blank on the other side.
- Kevtam 1000 mg - A white, film-coated, oblong-shaped biconvex tablet, debossed with "LV 1000" on one side and blank on the other side.

Each blister pack contains 60 tablets.

Ingredients

The active ingredient in Kevtam is levetiracetam:

- each Kevtam 250 mg tablet contains 250mg of levetiracetam
- each Kevtam 500 mg tablet contains 500 mg of levetiracetam
- each Kevtam 1000 mg tablet contains 1000 mg of levetiracetam

The tablets also contain the following inactive ingredients:

- starch - pregelatinised maize
- povidone
- silicone dioxide
- cellulose - microcrystalline
- magnesium stearate
- hypromellose
- titanium dioxide,

and additional ingredients listed below:

Kevtam 250 mg:

- macrogol 400
- indigo carmine CI73015
- polysorbate 80

Kevtam 500 mg:

- macrogol 400
- quinoline yellow CI47005
- sunset yellow FCF CI15985

Kevtam 1000 mg:

- lactose

- glycerol triacetate

The tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Kevtam is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Cnr. Wentworth Park Road & Bay Street

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Kevtam 250 mg: AUST R 152772

Kevtam 500 mg: AUST R 152769

Kevtam 1000 mg: AUST R 152770

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