Consumer Medicine Information

Everet[®] Tablets

Levetiracetam tablets 250mg, 500mg, 750mg, 1,000mg 60 TABLETS

What is in this leaflet

The information enclosed answers several general questions about Everet tablets. This leaflet does not include all accessible information on Everet tablets. All medication has benefits and risks. Your doctor would have considered the risks of you using Everet tablets against the benefits expected. Discuss with your doctor or pharmacist any concerns you may have.

What Everet is used for

Everet tablets are used to manage epilepsy.

Epilepsy is a group of associated disorders characterized by a predisposition of regular seizures. Seizures can range from mild to severe.

Everet tablets are part of a medication group named antiepileptics. This medication is believed to control the brain chemicals which transmit signals to the nerves to prevent seizures happening.

Everet tablets can be used on their own, or along with other medication, to manage your condition.

Everet tablets may be prescribed by your doctor as an extra form of treatment to your existing therapy.

If you have any concerns about your Everet tablets or why they have been prescribed, please discuss this with your doctor.

Everet tablets contain medication that is not addictive.

Everet tablets are only available with a prescription from your doctor.

Before you take Everet tablets

If you have any concerns about using Everet tablets, discuss with your doctor.

Do not use Everet tablets if you are allergic to:

- Levetiracetam or any of the other ingredients mentioned at the end of this leaflet.
- Any other medication, in particular any other anticonvulsant medication or barbiturates.
- Any other materials, for example; preservatives, foods or dyes.

Seek immediate medical attention if you experience any of the following side effects, as you may be allergic to this medicine:

- o Itching, rash or reddened skin
- Swelling of the eye lids, lips, face or throat,
- o Increase in wheezing and shortness of breath.

Pregnancy and breast feeding

If you are pregnant, think you might be pregnant, planning to get pregnant or breastfeeding, you must talk to your doctor before starting to take Everet tablets.

Everet tablets are not recommended to be taken while pregnant like most other antiepileptic medication as it may have an effect on the development of the baby. However, controlling your seizures while pregnant is crucial and if it is essential for you to take Everet tablets, your doctor will be able to assist to help your decision in whether to take Everet tablets or not during pregnancy.

Everet tablets should not be taken while breastfeeding as Levetiracetam is known to pass into the breast milk.

Do not use after the expiry date. The expiry date can be found on the blister and on the carton.

If the packaging of the Everet carton or blister displays signs of damage or tampering do not use.

Please inform your doctor before using Everet tablets if you are currently being treated or have in the past been treated for any other medical conditions, in particular the following:

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

Make sure your doctor is fully informed of the above information before you start to take Everet tablets.

Using other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines obtained without a prescription from your pharmacy, health store or supermarket.

Everet tablets do not affect the oral contraceptive pill. However, Everet tablets may be prescribed simultaneously with further antiepileptic medicines that do interact and in turn may compromise the contraception efficacy.

An additional method of contraception may be advised by your doctor if you take Everet tablets with additional antiepileptic drugs.

Using Everet Tablets

Adults and adolescents aged 12 years and over (>50kg):

The usual dose is usually between 500mg and 1,500mg twice a day.

Children aged 6 to 11 years (25-50kg):

The usual dose is usually between 250mg and 750mg twice a day.

Children ages less than 6 years:

Everet tablets are not recommended in children under 6 years of age due to insufficient clinical data.

Your doctor will inform you of the Everet tablet dosage you will be required to take each day. This will be determined by your age, other medication you may be taking and your condition.

It may be recommended by your doctor that you start Everet tablets on a low dosage and increase your dosage slowly to the smallest dosage required to manage your seizures.

Abide by all instructions given by your doctor carefully as they may be different from the information provided in this leaflet.

If you observe that Everet tablets are not working as they should, or are less effective, discuss with your doctor immediately.

Ask your doctor or pharmacist for assistance if you have difficulty understanding the instructions on the pack or in this leaflet.

How to take Everet tablets

Everet tablets must be taken orally, with a glass of water. Everet tablets can be taken with or without food at approximately the same time each day (once in the morning and once at night). Do not divide the tablet.

Taking Everet tablets at approximately the same time each day will help you to remember when to take your tablets and will give you the best effect of the medication.

If you forget to take your Everet tablets

If you have missed one or more of your Everet tablet doses, contact your doctor as soon as possible.

Do not take a double dose of Everet tablets at any given time if you have missed a dose as this can increase the likelihood of experiencing side effects.

If you are unsure of what to do, contact your doctor or pharmacist.

If you have difficulty remembering when the next dose of your Everet tablets are due, talk to your pharmacist for advice.

How long should you take Everet tablets

Do not be discouraged if you do not feel an improvement with Everet tablets immediately, as most anticonvulsant medication takes some time to become effective.

Continue to use Everet tablets for as long as your doctor has advised.

Everet tablets help to manage your epilepsy condition, but does not cure it. For that reason it is important that you take your Everet medication every day, even if you feel better.

Do not change the dosage or stop taking Everet tablets under any circumstances unless you have approval from your doctor.

Make sure during holidays that you have plenty of Everet tablets, and you will not run out if you are travelling.

Stopping Everet tablets abruptly may cause unpleasant side effects or may cause your condition to deteriorate. When stopping Everet tablets, your doctor will gradually decrease your dosage before you can stop taking it entirely.

If you take too much of your Everet tablets (overdose):

If you or someone else takes too much of your Everet tablets, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor, even if you do not feel unwell or there are no signs of overdose symptoms. If you have taken too much Levetiracetam you may feel increasingly drowsy.

While you are using Everet Tablets

Contact your doctor immediately if:

- You become aware of an increase in seizures;
- You have any symptoms of thoughts of self harm or depression.

If you are about to start taking any other medicine while you are using Everet tablets, tell your doctor, pharmacist and dentist.

Make sure that all other doctors, pharmacists and dentists who are working with you know that you are taking Everet tablets.

Before any surgery or emergency therapy, make sure your doctor or dentist are aware that you are taking Everet tablets.

Discuss the following with your doctor if:

- You believe that Everet tablets are not assisting with your condition. Your doctor may have to adjust the dosage or change your medication.
- You have for any reason, not taken Everet tablets as prescribed.
- You have become pregnant, or planning to get pregnant.

Make sure you attend all doctor's and/or neurologists appointments in relation to your epilepsy so that your control and management of your condition can be reviewed.

If you have not used Everet tablets as exactly as your doctor has prescribed, advise them of this information. If you do not, your doctor may change your medication unreasonably under the impression that the medicine is not working for you.

To review your progress on Everet tablets, your doctor may carry out some tests at times. This is to help avoid any unnecessary side effects.

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

Everet tablets should not be used to remedy any conditions other than what your doctor has prescribed if for.

Do not change the dosage or stop taking your Everet tablets under any circumstances unless you have approval from your doctor.

Important

Pay extra attention when driving, using machinery or any other dangerous activity until you are well aware of how Everet tablets affect you.

Everet tablets may cause drowsiness. This may be more prevalent at the start of your treatment or if your dosage as recently increased.

As Everet tablets may cause drowsiness in some people this can affect their alertness. Children should take care not to do anything that may be dangerous if they are feeling sleepy or drowsy for example, climbing trees or riding a bike.

Consuming alcohol while taking Everet tablets may cause drowsiness. Your doctor may suggest that you avoid alcohol while taking Everet tablets.

Side effects

If you experience any of the side effects below advise your doctor or pharmacist but do not discontinue taking your Everet tablets.

Everet tablets assists the majority of patients with epilepsy, but it can have unwanted side effects in a small number of people. All medications can have side effects. At times they can be serious, while the majority of the time they are not. Some side effects may require you to have medical treatment.

Discuss with your doctor or pharmacist any questions or concerns you have.

If you experience any of the below side effects and they are causing concern please talk to your doctor or pharmacist:

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

These side effects are the most common of Everet tablets. For most people who experience these they are usually mild and pass after a short time.

Other side-effects are:

• mood changes, for example nervousness, aggression, depression, confusion, anger, anxiety, hallucination and irritability.

You may not encounter any of these side-effects.

If you experience any other side-effects that are not discussed above, tell your doctor without delay.

If your seizures appear more frequently or are more severe, or you experience thoughts of self harm advise your doctor immediately and/or visit the Accident and Emergency Department at your nearest hospital.

If anything else is making you feel in poor health, discuss with your doctor. A number of these side effects can only be investigated when your doctor completes tests to check your progress.

Storage

Store Everet tablets below 25°C.

Keep the Everet tablets in their pack until you are about to take them.

The shelf life of Everet tablets is 36 months.

Keep out of reach of children by storing your Everet tablets in a locked cabinet at a height that children cannot reach them.

Avoid direct sunlight or heat. Do not store your Everet tablets in your car on a hot day or on a window sill.

Disposal

If your doctor advises you to stop taking Everet tablets, or it has exceeded its expiry date, request information from your pharmacist on what to do with any product that is left over.

Product description

Everet tablets are available in four strengths:

- Everet 250mg tablets are light blue, capsule shaped, biconvex film coated tablets, plain on both sides.
- Everet 500mg tablets are yellow, capsule shaped, biconvex film coated tablets, plain on both sides.
- Everet 750mg tablets are light orange, capsule shaped, biconvex film coated tablets, plain on both sides.
- Everet 1000 tablets are white, capsule shaped, biconvex film coated tablets, plain on both sides.

The active ingredient in each Everet tablet contains either 250 mg, 500 mg, 750 mg or 1000 mg of levetiracetam.

Each Everet tablet also contains maize starch, povidone, purified water, croscarmellose sodium, colloidal silicon dioxide and magnesium stearate.

Everet tablets are film-coated. The coating for each tablet strength contains hypromellose, macrogol, and titanium dioxide.

The following strengths also contain:

- 250mg: indigo carmine aluminium lake
- 500mg: iron oxide yellow
- 750 mg: iron oxide red, Sunset yellow FCF aluminium lake, indigo carmine aluminium lake

Everet tablets do not contain lactose, sucrose or gluten.

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