Levisat 500mg Film Coated Tablet

Levetiracetam 500mg Film Coated Tablet

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What Levisat 500mg Film Coated Tablet is used for

- on its own in adults and adolescents from 16 years of age with a certain typeof newly diagnosed epilepsy. Epilepsy is acondition where the patients haverepeated fits (seizures). Levetiracetam isused for the epilepsy form in which thefits initially affect only one side of thebrain, but could thereafter extend tolarger areas on both sides of the brain(partial onset seizures with or withoutsecondary generalization). Levisat hasbeen given to you by your doctor toreduce the number of fits.

- as an add-on to other antiepileptic medicines to treat:

- partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy.
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- primary generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

Levisat 500mg Film Coated Tablet works

Levisat is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Before you take Leviat 500mg Film Coated Tablet

-<u>When you must not take it</u>

If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Levisat can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor.

You should not stop your treatment without discussing this with your doctor. A risk of birth defects for your unborn child cannot be completely excluded. Levisat shown unwanted reproductive effects in animal studies.

Breast-feeding is not recommended during treatment.

Children and adolescents

Keppra is not indicated in children and adolescents before 16 years on its own (monotherapy).

- <u>Before you start to take it</u>

Talk to your doctor before taking Levisat

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slowdown in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as Levisat have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.
- If you notice any abnormal and aggressive behaviours, or if you or your family and friends notice important changes in mood or behaviour,immediately contact your doctor.
- If you have a family or medical history of heart problems, for example disturbance in heart rhythm (visible on an electrocardiogram) or if you are taking any other medicine that makes you prone to have disturbance in heart rhythm or unusual amount of salt in the body.

- <u>Taking other medicines</u>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

How to take Levisat 500mg Film Coated Tablet

- <u>How much to take</u>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the number of tablets following your doctor's instructions.

- <u>When to take it</u>

Follow your doctor's advice

- <u>How long to take it</u>

Do not stop taking Levisat 500mg Film Coated Tablet without your doctor's advice.

- <u>If you forget to take it</u>

It is important not to miss a dose of Levisat 500mg Film Coated Tablet.

If you miss a dose, take it as soon as you remember it, and then take the next dose at its regular time.

If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a forgotten tablet.

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-If you take too much (overdose)
If you have accidentally taken too many Levisat 500mg Film Coated Tablet you may be at increased risk of experiencing possible side effects with this medicine.

Immediately contact your doctor or go to the nearest hospital for immediate medical attention.

While you are using Levisat 500mg Film Coated Tablet
- Things you must do
Follow your doctor's advice.

-Things you must not do
Do not stop taking Levisat 500mg Film Coated Tablet without consulting your doctor first.
Do not give your medicine to other people who experience the same symptoms as you.

- Things to be careful of
Driving and using machines
Levisat may impair your ability to drive or operate any tools or machinery, as Levisat may make you sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.

Your seizures may rarely become worse or happen more often, mainly during the first month after starting the treatment or increase of the dose of Levisat. If you notice any of these symptoms while taking Levisat, immediately contact your doctor.

Side effects
Like all medicines, this medicine can cause side effects although not everybody gets them. Possible serious side effects:
Common side effects include headache, dizziness and sleepiness.
Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reactions Monitoring by visiting the website http://npra.moh.gov.my
Reporting Side Effects to Medicine (ConSERF) or Vaccines (Public(AEFI)).

Storage and Disposal of Levisat 500mg Film CoatedTablet
- Storage
Store below 30˚C.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

- Disposal
Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description
- What it looks like
Yellow colored, oblong-shaped biconvex film coated tablets, debossed with "L" and "U" on either side of break line on one side and "X02" on the other side.

- Ingredients
- Active ingredient used is Levetiracetam
- Inactive ingredients:
Corn Starch, Microcrystalline Cellulose 102, Crosspovidone, Colloidal Silicon Dioxide, Purified Talc, Povidone, Magnesium Stearate and OpadryYellow 05F82955

MAL:

Manufacturer and Product Registration Holder
SM Pharmaceuticals Sdn. Bhd.
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