

EPSYLAM DT DISPERSIBLE TABLETS

Lamotrigine (50mg, 100mg)

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What EPSYLAM DT is used for

EPSYLAM DT is used for the treatment of two types of the diseases: seizures and bipolar disorder.

How EPSYLAM DT works

EPSYLAM DT works to prevent the depression in bipolar disorder. It is not known how Lamotrigine works in the brain to provide the above effects.

Before you use EPSYLAM DT

- When you must not use it

Do not take EPSYLAM DT if:

- If you are allergic to lamotrigine or any other ingredient in the product.

Pregnancy and lactation

Do not take EPSYLAM DT if you are pregnant, trying to get pregnant or think you may be pregnant. However, in therapy with Lamotrigine is considered necessary during pregnancy, the lowest possible therapeutic dose is recommended.

Do not take EPSYLAM DT if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Inform your doctor if you have any of the following conditions:

- you have ever had a rash while taking lamotrigine
- you have suicidal behavior or thoughts
- you are taking hormonal contraceptives to prevent pregnancies
- you suffer from kidney failure

- you have bipolar disorder
- you have a condition called Brugada syndrome (a genetic disease that affects the heart)

- Taking other medicines

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

Tell your doctor if you are particularly taking:

- Valproate (medicine used to treat epilepsy and bipolar disorder and to prevent migraine headaches)
- Carbamazepine, phenytoin, primidone, phenobarbitone (medicines used to prevent and control seizures)
- Rifampicin (medicine used to treat bacterial infections)
- Lopinavir, ritonavir, atazanavir (antiviral medication)
- Ethinyloestradiol/levonorgestrel combination (medicine used to prevent pregnancy)
- Lithium, bupropion, olanzapine (psychiatric medication)
- Oxcarbazepine (medicine used to treat epilepsy and bipolar disorder)
- Gabapentin, levetiracetam, pregabalin, topiramate, zonisamide (medicine used to treat seizure)

How to use EPSYLAM DT

- How much to use

Always use EPSYLAM DT tablets exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure. Your doctor will start your treatment with a low dose and gradually increase it to achieve the suitable dose of EPSYLAM DT for you. Take the exact dose as recommended by your doctor.

The usual effective dose of EPSYLAM DT for adults over 16 years is between 100mg to 200mg per day given once a day or in two divided doses.

For children aged 2 to 12 years, the effective dose depends on body weight, with a maintenance dose of 1 to 5mg per day

given once a day or in two divided doses with maximum of 200mg per day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking EPSYLAM DT for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose:

- Nystagmus (condition in which the eyes make repetitive, uncontrolled movements)
- Ataxia (lack of muscle control or coordination of voluntary movements)
- Impaired consciousness
- Coma

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking EPSYLAM DT.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give EPSYLAM DT to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, EPSYLAM DT can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

A small number of people who take lamotrigine have potentially severe allergic or skin reactions. If not treated, these reactions can become worse and may even be fatal. These reactions include:

- Skin rashes or redness, which may develop into severe skin reactions including red spots or patches that may look like a target or “bull’s-eye” with a dark red centre surrounded by paler red rings (Erythema multiforme)
- Ulcers and pain in the mouth or eyes,
- High temperature (fever), symptom similar to flu or somnolence
- Swelling around the face or inflammation of the glands in the neck, armpits or groin
- Bleeding or unexpected bruises, or fingers turning blue
- Sore throat or more infections (such as colds) than normal

In many cases, these symptoms may be signs of less severe adverse effects. But you should realize that they are potentially serious – if you suffer any of these symptoms, see a doctor immediately.

Very Frequent Adverse Effects

- Headache
- Dizziness
- Sensation of sleep or somnolence
- Clumsiness and loss of coordination (ataxia)
- Double-vision or blurred vision
- Nausea or vomiting
- Rash

Frequent Adverse Effects

- Aggression, irritability
- Rapid and uncontrollable eye movements (nystagmus)
- Spasms or tremor
- Difficulty in sleeping
- Diarrhoea
- Dry mouth
- Tiredness
- Pain in the back, joints or other areas.

Hemophagocytic lymphohistiocytosis (HLH)

There have been reports of a rare but very serious immune system reaction, in patients taking lamotrigine.

- Contact your doctor or pharmacist immediately if you experience any of the following symptoms while taking lamotrigine: fever, rash, neurological symptoms (e.g. shaking or tremor, confusional state).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of EPSYLAM DT

Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

EPSYLAM DT 50:

White to off-white, rounded square shaped uncoated tablets debossed with ‘H’ on multifaceted side and ‘79’ on flat side.

EPSYLAM DT 100:

White to off-white, rounded square shaped uncoated tablets debossed with ‘H’ on multifaceted side and ‘78’ on flat side.

- Ingredients

- Active ingredient
Lamotrigine

- Inactive ingredients

Cellulose microcrystalline,
magnesium carbonate,
polacrillin potassium,
sucralose, povidone, blackcurrant
flavor, magnesium stearate and purified
water.

- MAL numbers:

EPSYLAM DT 50:
MAL17085020AZ

EPSYLAM DT 100:
MAL13115207AZ

Manufacturer

Aurobindo Pharma Limited
(Unit III), Sy No. 313 & 314,
Bachupally (V), Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State, India.

Product Registration Holder

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