Dispense with Medication Guide available at:
www.drreddys.com/pi/Eslicarbazepine.pdf

MEDICATION GUIDE
Eslicarbazepine Acetate Tablets
(ES li kar BAZ e peen)

What is the most important information I should know about eslicarbazepine acetate tablets?

- **Do not stop taking eslicarbazepine acetate tablets without first talking to your healthcare provider.**
  - Stopping eslicarbazepine acetate tablets suddenly can cause serious problems. Stopping a seizure medicine suddenly in a patient who has epilepsy may cause seizures that will not stop (status epilepticus).

1. **Like other antiepileptic drugs, eslicarbazepine acetate may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

   Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:
   - thoughts about suicide or dying
   - attempt to commit suicide
   - new or worse depression
   - new or worse anxiety
   - feeling agitated or restless
   - panic attacks
   - trouble sleeping (insomnia)
   - new or worse irritability
   - acting aggressive, being angry, or violent
   - acting on dangerous impulses
   - an extreme increase in activity and talking (mania)
   - other unusual changes in behavior or mood

   How can I watch for early symptoms of suicidal thoughts and actions?
   - Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
   - Keep all follow-up visits with your healthcare provider as scheduled.
   - Call your healthcare provider between visits as needed, especially if you are worried about symptoms. Suicidal thoughts or actions may be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

2. **Eslicarbazepine acetate tablets may cause allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions.**

   Call your healthcare provider right away if you have any of the following:
   - swelling of your face, eyes, lips, or tongue
   - trouble swallowing or breathing
   - a skin rash
   - hives
   - fever, swollen glands, or sore throat that do not go away or come and go
   - painful sores in the mouth or around your eyes
   - yellowing of your skin or eyes
   - unusual bruising or bleeding
   - severe fatigue or weakness
   - severe muscle pain
   - frequent infections or infections that do not go away

- **Eslicarbazepine acetate may cause the level of sodium in your blood to be low.**
  Symptoms of low blood sodium include:
  - nausea
  - tiredness, lack of energy
  - irritability
  - confusion
  - muscle weakness or muscle spasms
  - more frequent or more severe seizures

Some medicines can also cause low sodium in your blood. Be sure to tell your healthcare provider about all the other medicines that you are taking.

What is eslicarbazepine acetate tablet?
Eslicarbazepine acetate tablet is a prescription medicine used to treat partial-onset seizures.

It is not known if eslicarbazepine acetate tablets are safe and effective in children under 4 years of age.

Who should not take eslicarbazepine acetate tablets?
Do not take eslicarbazepine acetate tablets if you are allergic to eslicarbazepine acetate, any of the other ingredients in eslicarbazepine acetate tablets, or oxcarbazepine. See the end of this Medication Guide for a complete list of ingredients in eslicarbazepine acetate tablets.

What should I tell my healthcare provider before taking eslicarbazepine acetate tablets?

Before taking eslicarbazepine acetate tablets, tell your healthcare provider about all your medical conditions, including if you:
- have or have had suicidal thoughts or actions, depression or mood problems
- have liver, kidney, or blood problems
- are allergic to oxcarbazepine. Some people who are allergic to oxcarbazepine may also be allergic to eslicarbazepine acetate.
- use birth control medicine. Eslicarbazepine acetate tablets may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use.
- are pregnant or plan to become pregnant. Eslicarbazepine acetate may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking eslicarbazepine acetate tablets. You and your healthcare provider will decide if you should take eslicarbazepine acetate tablets while you are pregnant.
  - If you become pregnant while taking eslicarbazepine acetate tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- are breastfeeding or plan to breastfeed. Eslicarbazepine acetate passes into breast milk. You and your healthcare provider should discuss whether you should take eslicarbazepine acetate tablets or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking eslicarbazepine acetate tablets with certain other medicines may cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Especially tell your healthcare provider if you take:
- oxcarbazepine
- carbamazepine
- simvastatin
- omeprazole
- clobazam
- phenobarbital
- phenytoin
- birth control medicine
- rosuvastatin
- primidone

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take eslicarbazepine acetate tablets?

- Take eslicarbazepine acetate tablets exactly as your healthcare provider tells you to take them.
- Do not stop taking eslicarbazepine acetate tablets without talking to your healthcare provider. Stopping eslicarbazepine acetate tablets suddenly can cause serious problems, including seizures that will not stop (status epilepticus).
- Your healthcare provider may change your dose.
- Your healthcare provider will tell you how much eslicarbazepine acetate tablets to take.
- Eslicarbazepine acetate tablets can be taken with or without food.
- Eslicarbazepine acetate tablets can be taken as a whole tablet or crushed.
- If you take too much eslicarbazepine acetate tablets, call your healthcare provider or go to the nearest hospital emergency room right away.
- Talk with your healthcare provider about what you should do if you miss a dose.

What should I avoid while taking eslicarbazepine acetate tablets?

- Do not drive, operate heavy machinery, or do dangerous activities until you know how eslicarbazepine acetate tablets affect you. Eslicarbazepine acetate tablets may slow your thinking and motor skills.

What are the possible side effects of eslicarbazepine acetate tablets?

See **"What is the most important information I should know about eslicarbazepine acetate tablets?"**

Eslicarbazepine acetate tablets may cause other serious side effects including:

- **Nervous system problems.** Eslicarbazepine acetate tablets may cause problems that can affect your nervous system. Symptoms of nervous system problems include:
  - dizziness
  - trouble walking or with coordination
  - feeling sleepy and tired
  - trouble concentrating
  - vision problems
- **Liver problems.** Eslicarbazepine acetate tablets may affect your liver. Symptoms of liver problems include:
  - yellowing of your skin or the whites of your eyes
  - nausea or vomiting
  - loss of appetite
  - stomach pain
  - dark urine

Get medical help right away if you have any of the symptoms listed above or listed in "What is the most important information I should know about eslicarbazepine acetate tablets?"

The most common side effects of eslicarbazepine acetate tablets include:

- dizziness
- sleepiness
- nausea
- headache
- double vision
- vomiting
- feeling tired
- blurred vision
- shakiness
- problems with coordination

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of eslicarbazepine acetate tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store eslicarbazepine acetate tablets?

- Store eslicarbazepine acetate tablets at 20°C to 25°C (68°F to 77°F).
- Safely throw away medicine that is out of date or no longer needed.

Keep eslicarbazepine acetate tablets and all medicines out of reach of children.

What are the ingredients in eslicarbazepine acetate tablets?

Active ingredient: eslicarbazepine acetate

Inactive ingredients: croscarmellose sodium, hydroxyl propyl methyl cellulose, magnesium stearate and microcrystalline cellulose.

General information about the safe and effective use of eslicarbazepine acetate tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use eslicarbazepine acetate tablets for a condition for which it was not prescribed. Do not give eslicarbazepine acetate tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about eslicarbazepine acetate tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about eslicarbazepine acetate tablets that is written for health professionals.

For more information, call Dr. Reddy's Laboratories Inc. at 1-888-375-3784.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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