

MEDICATION GUIDE **Eslicarbazepine Acetate** (es" li kar baz' e peen as' e tate) tablets

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).
- antiepileptic 1. Like other drugs, eslicarbazepine acetate tablets 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:

- o thoughts about suicide or dying
- attempt to commit suicide
- o new or worse depression
- new or worse anxiety
- feeling agitated or
 panic attacks
- restless o trouble sleeping (insomnia)
- o new or worse irritability acting on dangerous
- acting aggressive, being angry, or violent

(mania)

o an extreme increase o other unusual in activity and talking 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

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.
 trouble swallowing
- eyes, lips, or tongue or breathing o a skin rash hives $\circ\,$ fever, swollen glands, $\,\circ\,$ painful sores in the

your eyes

o unusual bruising or

- or sore throat that do mouth or around not go away or come and go
- bleeding ○ yellowing of your skin
 ○ severe muscle pain or eyes
- severe fatigue or weakness
- frequent infections or infections that do not go away

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

Eslicarbazepine acetate tablets are a prescription medicine used to treat partial-onset seizures. It is not known if eslicarbazepine acetate tablets is safe and effective in children under 4 years of

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 tablets.
- 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 tablets 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.
- o 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

- oxcarbazepine
- o phenobarbital
- carbamazepine phenytoin
- simvastatin birth control medicine
- o omeprazole o rosuvastatin clobazam o 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

How should I take eslicarbazepine acetate tablets?

pharmacist when you get a new medicine.

- Take eslicarbazepine acetate tablets exactly as your healthcare provider tells you to take it.
- 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 eslicar bazepine 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 o trouble feeling walking or sleepy and tired with
- coordination trouble vision concentrating problems
- **Liver problems.** Eslicarbazepine acetate tablets may affect your liver. Symptoms of liver problems include:
 - o yellowing of o nausea or o loss of your skin or vomiting appetite the whites of
 - your eyes o dark urine stomach

pain

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 eslicarbazepine acetate tablets include:

- dizziness
- vomiting
- sleepiness o feeling tired o nausea
 - o blurred vision
- headache o shakiness double vision
 - o 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 68°F to 77°F (20°C to 25°C).
- 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: colloidal silicone dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose and povidone (K-30).

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 1-800-912-9561

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Manufactured for:

TORRENT PHARMA INC., Basking Ridge, NJ 07920. 8064790

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PRODUCT NAME	:	ESLICARBAZEPINE ACETATE TABLETS	COUNTRY: US	LOCATION: Dahej			Supersedes A/W No.:	
ITEM / PACK	:	Medication Guide	NO. OF COLORS: 1	REMARK:				V. No. : 01
DESIGN STYLE	:	Front / Back	PANTONE SHADE NOS.:	SUBSTRATE:				
CODE	:	8064790	Black	Activities	Department	Name	Signature	Date
DIMENSIONS (MM)	:	150 x 330		Prepared By	Pkg. Dev.			
ART WORK SIZE	:	S/S		Reviewed By	Pkg. Dev.			
DATE	:	12-09-2024	Font Size 6 pt_Med. 10 pt	Approved By	Quality			