

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **EIZUREX 150 ,300 & 600**

Dosage form and strength: **Each film coated tablet contains 150 mg of oxcarbazepine USP**
Each film coated tablet contains 300 mg of oxcarbazepine USP
Each film coated tablet contains 600 mg of oxcarbazepine USP

APPROVED PATIENT INFORMATION LEAFLET FOR EIZUREX

SCHEDULING STATUS

S3

EIZUREX 150 (film coated tablets)

EIZUREX 300 (film coated tablets)

EIZUREX 600 (film coated tablets)

Oxcarbazepine

Sugar free

Read all of this leaflet carefully before you start taking EIZUREX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- EIZUREX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- 1.What EIZUREX is and what it is used for
- 2.What you need to know before you take EIZUREX
- 3.How to take EIZUREX
- 4.Possible side effects
- 5.How to store EIZUREX
- 6.Contents of the pack and other information

1.What EIZUREX is and what it is used for

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EIZUREX contains the active substance oxcarbazepine. EIZUREX belongs to a group of medicines called anticonvulsants or antiepileptics.

EIZUREX is used to treat epilepsy (a brain disorder that causes people to have recurring seizures and convulsions). EIZUREX is used to treat partial seizures [a condition that causes temporary abnormalities in muscle tone or movements (stiffness, twitching or limpness), behaviours, sensations or states of awareness, with or without secondarily generalised tonic-clonic seizures.

EIZUREX can be used alone or in combination with other antiepileptic medicines. Usually, the doctor will try to find the one medicine that works best for you or for your child. However, with more severe epilepsy, a combination of two or more medicines may be needed to control seizures.

EIZUREX is for use in adults and in children aged 1 month and above

2.What you need to know before you take EIZUREX

Do not take EIZUREX:

- If you are hypersensitive (allergic) to oxycarbazepine, eslicarbazepine or any of the other ingredients of EIZUREX (listed in section 6).

Warnings and precautions

Take special care with EIZUREX:

- if you have ever shown an allergic reaction (rash or any other signs of allergy) to carbamazepine or to any other medicines. If you are allergic to carbamazepine, the chances are that you could also have an allergic reaction to oxcarbazepine (EIZUREX).
- if you have low levels of sodium in the blood (see section 4).
- If you have a condition in which your thyroid gland doesn't produce enough of certain crucial hormones (hypothyroidism).
- if you have serious liver disease.

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- if you have kidney disease.
- If you are taking diuretics (medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced).
- If you suffer from a heart failure, shortness of breath and/or swelling of the feet or legs due to fluid build-up.
- if you have thoughts of harming or killing themselves.
- if you are a woman taking and you are taking hormonal contraceptive (birth-control pills), EIZUREX may render this contraceptive ineffective. Therefore, you should use a different or additional non-hormonal method of contraception while you are taking EIZUREX. This should help to prevent an unwanted pregnancy. Tell your doctor at once if you get irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or healthcare professional.
- if you drink alcohol.

If any of the above applies to you, tell your doctor before you take EIZUREX.

Do not stop your treatment with EIZUREX without first checking with your doctor. To prevent sudden worsening of your seizure, do not discontinue your medicine abruptly.

If you develop any of the following symptoms after starting EIZUREX, tell your doctor immediately or go to the emergency department at your nearest hospital:

- If you have an allergic reaction after starting EIZUREX. Symptoms include swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with swollen glands, rash or skin blistering.
- If you notice symptoms of hepatitis, such as jaundice (yellowing of skin or the whites of the eyes).
- If you experience an increase in the frequency of seizures. This is particularly important for

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children but may also occur in adults.

- If you notice possible symptoms of blood disorders such as tiredness, being short of breath when exercising, looking pale, headache, chills, dizziness, frequent infections leading to fever, sore throat, mouth ulcers, bleeding or bruising more easily than normal, nose bleeds, reddish or purplish patches, or unexplained blotches on the skin.
- A small number of people being treated with antiepileptics such as EIZUREX have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- If you have a fast or unusually slow heart beat.

Children and adolescents

In children, your doctor may recommend thyroid function monitoring before therapy and during therapy.

Other medicines and EIZUREX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Hormonal contraceptives, such as the pill (see warnings and precautions).
- other antiepileptic and enzyme inducing medicines such as phenobarbitone, phenytoin, carbamazepine, lamotrigine, rifampicin and valproic acid.
- medicines that can lower sodium levels in the blood (e.g., diuretics (used to help the kidneys get rid of salt and water by increasing, desmopressin and non-steroid anti-inflammatory medicines such as indomethacin and ibuprofen).
- monoamine oxidase inhibitors (medicines used to treat mood swings and some types of depression).
- medicines that control the body's immune system, such as ciclosporin and tacrolimus.

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EIZUREX with food, drink and alcohol

EIZUREX can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

It is important to control epileptic seizures during pregnancy. However, there may be a risk to your baby if you take EIZUREX during pregnancy. Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take EIZUREX.

Do not stop your treatment with EIZUREX during pregnancy without first checking with your doctor.

Breastfeeding

You should not breast-feed while taking EIZUREX. The active substance in EIZUREX passes into breast milk. This could cause side effects for breastfed babies. Ask your doctor or pharmacist for advice before taking this medicine while you are breastfeeding.

Driving and using machines

EIZUREX may make you feel sleepy or dizzy, or may cause blurred vision, double vision, lack of muscle coordination or a depressed level of consciousness, especially when starting treatment or increasing the dose.

It is important to discuss with your doctor whether you can drive a vehicle or operate machines while taking this medicine.

3. How to take EIZUREX

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Do not share medicines prescribed for you with any other person. Always take EIZUREX exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if not sure.

Dose for adults and elderly patients

- The usual starting dose of EIZUREX is 600 mg per day (8-10 mg/kg/day) given in 2 divided doses.
- The maintenance doses are usually with doses between 600 mg and 2400 mg per day.
- If you have kidney disease (with impaired kidney function), the starting dose is half the usual starting dose.
- If you have severe liver disease, your doctor may adjust your dose.

Dose for children

The dosage for children depends on their weight.

- The starting dose is 8 to 10 milligrams per kilogram of bodyweight per day given in two divided doses. For example, a 30-kg child would start treatment with one 150 mg tablet twice daily. The maximum dose for a child is 60 mg per kg bodyweight per day.

Swallow the tablets with a little water. If necessary, the tablets can be broken in half to help swallow them.

If you take more EIZUREX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to take EIZUREX

Do not take a double dose to make up for forgotten individual doses.

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4. Possible side effects

EIZUREX can have side effects.

Not all side effects reported for EIZUREX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EIZUREX, please consult your health care provider for advice.

If any of the following happens, stop taking EIZUREX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EIZUREX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- signs of recurrent infections such as fever or sore throat.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- trembling,
- coordination problems,

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- involuntary movement of the eyes,
- tiredness,
- headache,
- dizziness,
- drowsiness,
- feeling sick (nausea),
- being sick (vomiting),
- double vision,
- weakness,
- memory disturbances,
- confusion,
- constipation,
- diarrhoea,
- stomach pain,
- hair loss,
- weight increased,
- speech disorder.

Less frequent side effects:

- irregular heartbeat or a very fast or slow heart rate,
- High blood pressure,
- raised level of liver enzymes,
- osteoporosis (thinning of the bone).

If you notice any side effects not mentioned in this leaf, please inform your doctor or pharmacist.

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. or to the Holder of certificate of registration through the mail: pvg.cdma@hererodrugs.com. By reporting side effects, you can help provide more information on the safety of EIZUREX.

5. How to store EIZUREX

Store all medicines out of reach of children

Store at or below 25 °C

Store in the original package

Protect from light/ moisture

Do not use after the expiry date stated on the label

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EIZUREX contains

- The active substance is oxcarbazepine
- The other ingredients are microcrystalline cellulose, hypromellose, colloidal silicon dioxide, crospovidone, magnesium stearate,

Composition of Opadry II Brown 85F565266

- polyvinyl alcohol-part hydrolyzed E1203, macrogol/PEG E1521, talc E553b, titanium dioxide E171, iron oxide yellow E172, iron oxide red E172, ferrosoferric oxide NF/ black iron oxide E172

What EIZUREX looks like and contents of the pack

EIZUREX 150

Brown colored, oval shaped, biconvex, film coated tablets debossed with 'V' on one side and '7'

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and '6' on another side separated by a score line on both sides.

EIZUREX 300

Brown colored, oval shaped, biconvex, film coated tablets debossed with 'V' on one side and '7' and '7' on another side separated by a score line on both sides.

EIZUREX 600

Brown colored, oval shaped, biconvex, film coated tablets debossed with 'V' on one side and '7' and '8' on another side separated by a score line on both sides.

EIZUREX 150

100's count

High Density Polyethylene Container 60 cc with 33 mm Neck (Heavy weight) with child resistant plastic caps with pulp liners 33 mm

10's count

Clear (250 µ PVC/25 µ PE/90 GSM PVdC) width 172 mm (ACG), with plain aluminium foil 0,025 x 168 mm -7GSM HSL coat

EIZUREX 300

100's count

High Density Polyethylene Container 100 cc with 38 mm Neck (Heavy weight) with child resistant plastic caps with pulp liners 38 mm

14's count

Clear film width 251 mm (250 µ PVC/25 µ PE/90 GSM PVdC), with 25µ plain aluminium foil (Hard Tempered) with 7GSM HSL coating on bright side width 245 mm

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EIZUREX 600

100's count

High Density Polyethylene Container 150 cc with 38 mm Neck (Heavy weight) with child resistant plastic caps with pulp liners 38 mm

10's count

Clear triplex film width 222 mm (250 µ PVC/25 µ PE/90 GSM PVdC), with plain aluminium foil 0,025 x 216 mm -7GSM HSL coat

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

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Midrand, 2066

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Registration numbers

EIZUREX 150: 57/2.5/0209

EIZUREX 300: 57/2.5/0210

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Access to the corresponding Professional Information

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Building No.2, First Floor,

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