**SCHEDULING STATUS: S3**

**OXCARBAZEPINE 150 VIATRIS** film-coated tablets
**OXCARBAZEPINE 300 VIATRIS** film-coated tablets
**OXCARBAZEPINE 600 VIATRIS** film-coated tablets
Oxcarbazepine
Contains sugar: (lactose monohydrate 1,23 mg, 2,46 mg or 4,92 mg)

**Read all of this leaflet carefully before you start taking OXCARBAZEPINE VIATRIS.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other health care provider.
- OXCARBAZEPINE VIATRIS 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 OXCARBAZEPINE VIATRIS is and what it is used for.
2. What you need to know before you take OXCARBAZEPINE VIATRIS.
3. How to take OXCARBAZEPINE VIATRIS.
4. Possible side effects.
5. How to store OXCARBAZEPINE VIATRIS.
6. Contents of the pack and other information.

## 1. What OXCARBAZEPINE VIATRIS is and what it is used for

OXCARBAZEPINE VIATRIS belongs to a group of medicines called anticonvulsants or anti-epileptics and is used for the treatment of epilepsy.
OXCARBAZEPINE VIATRIS is used to treat partial seizures with or without secondarily generalised tonic-clonic seizures.
OXCARBAZEPINE VIATRIS can be used alone or in combination with other anti-epileptic medicines.

OXCARBAZEPINE VIATRIS is for use in adults and in children from the age of 6 years and older. However, OXCARBAZEPINE VIATRIS are film-coated tablets and must only be used in children

who are able to swallow tablets. If they are unable to swallow tablets an oral suspension must be used.

## 2. What you need to know before you take OXCARBAZEPINE VIATRIS

**Do not take OXCARBAZEPINE VIATRIS:**

- if you are hypersensitive (allergic) to oxcarbazepine (the active substance of OXCARBAZEPINE VIATRIS), eslicarbazepine or to any other ingredients of OXCARBAZEPINE VIATRIS tablets listed in section 6.

If you are not sure whether any of the above applies to you, ask your pharmacist or your doctor.

**Warnings and precautions**

Take special care with OXCARBAZEPINE VIATRIS:

- if you have ever shown unusual sensitivity (rash or any other signs of allergy) to carbamazepine or to any other medicines. If you are allergic to carbamazepine, the chances are approximately 1 in 4 (25 %) that you may also develop an allergic reaction to oxcarbazepine (OXCARBAZEPINE VIATRIS).
- if you have serious liver disease.
- if you have a 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 have ~~a~~ heart disease, shortness of breath and/or swelling of the feet or legs due to fluid build-up.
- if your blood level of sodium is low as shown by blood tests (see section 4 Possible side effects).
- if you are a woman taking a hormonal contraceptive, such as the pill, OXCARBAZEPINE VIATRIS may stop your contraceptive from working. Use a different or extra (non-hormonal) method of contraception while taking OXCARBAZEPINE VIATRIS. This should help to prevent an unwanted pregnancy. Tell your doctor immediately if you get irregular vaginal bleeding or spotting. If you have any questions about this, ask your doctor or health care professional.

If any of the above apply to you, tell your doctor before you take OXCARBAZEPINE VIATRIS.

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

- if you experience an allergic reaction after starting OXCARBAZEPINE VIATRIS: 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 and/or the whites of the eyes).
- if you experience an increase in the frequency of seizures. This is particularly important for 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 anti-epileptics such as OXCARBAZEPINE VIATRIS 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 OXCARBAZEPINE VIATRIS**

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

Tell your doctor if you are already taking any of the following medicines as they may interact:

- other anti-epileptic medicines, such as phenobarbitone, phenytoin, carbamazepine or lamotrigine and rifampicin;
- hormonal contraceptives, such as the birth-control pill (see Warnings and precautions);
- medicines to treat mental illness such as lithium, MAOIs (monoamine oxidase inhibitors);

- medicines that can lower sodium levels in your blood, e.g. diuretics (used to help the kidneys get rid of salt and water by increasing the amount of urine produced), anti-inflammatory medicines such as indomethacin;
- medicines which control the body's immune system, e.g. ciclosporin and tacrolimus.

**OXCARBAZEPINE VIATRIS with food, drink and alcohol**

OXCARBAZEPINE VIATRIS can be taken with or without food.

Alcohol may increase the sedative effects of OXCARBAZEPINE VIATRIS. Avoid alcohol as much as possible and ask your doctor for advice

**Pregnancy and breastfeeding**

**Pregnancy:**

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.

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

Anti-epileptic medicines, including OXCARBAZEPINE VIATRIS, can cause harmful effects to your unborn baby.

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

Ask your doctor, pharmacist or health care professional for advice before taking any medicine during pregnancy.

**Breastfeeding:**

You should not breastfeed while taking OXCARBAZEPINE VIATRIS**.** The active ingredient in OXCARBAZEPINE VIATRIS passes into the breast milk. This could cause side effects for breastfed babies. Ask your doctor or pharmacist for advice before taking any medicine while you are breastfeeding.

**Driving and using machines:**

OXCARBAZEPINE VIATRIS 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 if you can drive a vehicle or operate machines while taking OXCARBAZEPINE VIATRIS.

**OXCARBAZEPINE VIATRIS contains lactose**

OXCARBAZEPINE VIATRIS tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take OXCARBAZEPINE VIATRIS

Do not share medicines prescribed for you with any other person.

- Always take OXCARBAZEPINE VIATRIS tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- If necessary, the tablets can be broken in half to help swallow them.
- Swallow the tablet with a glass of water. Your doctor will probably start treatment with a low dose and gradually increase it to suit your own needs. Ask your pharmacist if you are unsure about the correct dose but the usual doses are as follows:

*Dose for adults:*

OXCARBAZEPINE VIATRIS should be taken twice a day, every day, at about the same times of the day, unless the doctor tells you otherwise. Taking the medicine at the same time each day will have the best effect on controlling epilepsy. It will also help you to remember when to take the medicine.

The usual starting dose of OXCARBAZEPINE VIATRIS for adults (including elderly patients) is 600 mg daily, divided into two doses. Your doctor will increase the dose gradually until your epilepsy is controlled. The best results are usually with doses between 600 mg and 2400 mg of OXCARBAZEPINE VIATRIS.

If you are also taking another anti-epileptic medicine, your doctor may need to reduce the dose of this to stop unwanted side effects.

If you have kidney problems your doctor will give you a lower dose than that stated above and will monitor your kidney function closely.

If you have severe liver disease, your doctor may adjust your dose.

*Dose for children:*

OXCARBAZEPINE VIATRIS can be taken by children aged 6 years and older.

However, OXCARBAZEPINE VIATRIS 150, 300 and 600 are film-coated tablets and must only be used in children who are able to swallow tablets. If they are unable to swallow tablets an oral suspension must be used.
The dosage for children will be calculated by your doctor and depends on your child's weight.
The starting dose is 8 to 10 milligrams per kilogram of bodyweight per day given in two divided doses.
Your doctor may increase the dose gradually to find the best dose for your child. The best results are usually with a dose of 30 milligrams per kilogram of bodyweight per day. The maximum dose for a child is 46 milligrams per kilogram of bodyweight per day.
Your doctor will tell you how long your or your child's treatment with OXCARBAZEPINE VIATRIS will last. The length of treatment will depend on your or your child's seizure type. Treatment may be needed for many years to control the seizures. Do not change the dose or stop treatment without talking to your doctor.

**If you take more OXCARBAZEPINE VIATRIS than you should:**
In the event of overdosage, consult your doctor or pharmacist. If neither is available**,** contact the nearest hospital or poison centre. Take the container and any remaining tablets with you.

**If you forget to take OXCARBAZEPINE VIATRIS:**
If you have forgotten one dose, take it as soon as you remember. However, if it is time for your next dose, do not take the missed dose. Go back to your regular dosing timetable.
Do not take a double dose to make up for forgotten doses.

**If you stop taking OXCARBAZEPINE VIATRIS**
Do not stop taking your medicine unless your doctor tells you to.
To prevent sudden worsening of your seizures, never discontinue your medicine abruptly.
If your treatment is stopped, it should be done gradually as instructed by your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**
OXCARBAZEPINE VIATRIS can have side effects.
Not all side effects reported for OXCARBAZEPINE VIATRIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking

OXCARBAZEPINE VIATRIS, please consult your doctor, pharmacist or other health care provider for advice.

The following are signs of potentially serious side effects that may require urgent medical treatment. The doctor will also decide whether OXCARBAZEPINE VIATRIS has to be stopped immediately and how to continue further medical care.

*Less frequent:*

- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of underactive thyroid gland).
- Fall
- Swelling of the lips, eyelids, face, throat or mouth, accompanied by difficulty in breathing, speaking or swallowing (signs of anaphylactic reactions and angioedema).
- Skin rash and/or fever which may be manifestations of DRESS (drug rash with eosinophilia and systemic symptoms), AGEP (acute generalised exanthematous pustulosis).
- Tiredness, shortness 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 (signs of a decrease in the number of blood platelets or decrease in the number of blood cells).
- Lethargy, confusion, muscle twitching or significant worsening of convulsions (possible symptoms of low sodium levels in the blood due to inappropriate ADH secretion) (see Warnings and precautions).
- Signs of hypersensitivity reactions such as skin rash, fever and pain in the muscles and joints.
- Severe blistering of the skin and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (signs of serious allergic reaction including Lyell’s syndrome, Stevens-Johnson syndrome and erythema multiforme).
- Red blotchy rash mainly on face which may be accompanied by fatigue, fever, feeling sick (nausea) or loss of appetite (signs of systemic lupus erythematosus).
- Flu-like symptoms with jaundice (yellowing of the skin or the whites of the eyes) (signs of hepatitis).
- Severe upper stomach (abdominal) pain, being sick (vomiting), loss of appetite (signs of inflammation of the pancreas).
- Tell your doctor as soon as possible if you get any of the following side effects, they may require medical attention:

*Frequent:*

- trembling; coordination problems; involuntary movement of the eyes; anxiety and nervousness; depression; mood swing; rash.

*Less frequent:*

- irregular heart beat or a very fast or slow heart rate.

Other side effects that may occur:
These are usually mild to moderate side effects of OXCARBAZEPINE VIATRIS. Most of these effects are transient and usually diminish over time.

*Frequent:*

- tiredness; headache; dizziness; drowsiness; feeling sick (nausea); being sick (vomiting); double vision.
- weakness; memory disturbances; impaired concentration; apathy; agitation; confusion; blurred vision; visual disturbance; constipation; diarrhoea; stomach (abdominal) pain; acne; hair loss; balance disturbances; weight increased; speech disorder.

*Less frequent:*

- High blood pressure; hives.
- You may also have raised levels of liver enzymes while taking OXCARBAZEPINE VIATRIS.
- there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medication, have a history of osteoporosis or take medicines known as steroids.

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

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OXCARBAZEPINE VIATRIS.

## 5. How to store OXCARBAZEPINE VIATRIS

Store all medicines out of reach of children.

Store at or below 30 °C. Protect from moisture.

Store in the original container until required.
Do not use after the expiry date stated on the label.
Return all unused medicines to your pharmacist.
Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What OXCARBAZEPINE VIATRIS contains

The tablets contain either 150 mg, 300 mg or 600 mg of oxcarbazepine.
The other ingredients are crospovidone, hypromellose, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate. The coating contains iron oxides (E172), hypromellose, lactose monohydrate, polyethylene glycol and titanium dioxide (E171).

### What OXCARBAZEPINE VIATRIS looks like and contents of the pack

OXCARBAZEPINE 150 VIATRIS: 5,5 mm x 11,0 mm oblong, normal convex, buff film-coated tablet debossed “OX I 150” on one side and “G I G” on the other side.
OXCARBAZEPINE 300 VIATRIS**:** 6,5 mm x 15,0 mm oblong, normal convex, buff film-coated tablet debossed “OX I 300” on one side and “G I G” on the other side.
OXCARBAZEPINE 600 VIATRIS**:** 8,0 mm x 18,5 mm oblong, normal convex, buff film-coated tablet debossed “OX I 600” on one side and “G I G” on the other side.
All the different strengths of the tablet have a groove so that they can be halved for ease of swallowing.

OXCARBAZEPINE VIATRIS tablets are packed into:
- PVDC coated PVC blister strips and aluminium foil lidding of 10 tablets and placed into unit cardboard outer cartons of 10, 20, 30, 50, 100 or 200 tablets or,
- polypropylene containers with polyethylene caps and an optional polyethylene ullage filler in packs of 100, 200 and 500 tablets.

### Holder of Certificate of Registration

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