Package leaflet: Information for the user

Trileptal® 60 mg/ml Oral Suspension

oxcarbazepine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Trileptal is and what it is used for

What Trileptal is

Trileptal contains the active substance oxcarbazepine.

Trileptal belongs to a group of medicines called anticonvulsants or antiepileptics.

What Trileptal is used for

Medicines such as Trileptal are the standard treatment for epilepsy.

Epilepsy is a brain disorder that causes people to have recurring seizures and convulsions. Seizures happen because of a temporary fault in the brain's electrical activity. Normally brain cells coordinate body movements by sending out signals through the nerves to the muscles in an organised, orderly way. In epilepsy, brain cells send out too many signals in a disorderly fashion. The result can be uncoordinated muscular activity that is called an epileptic seizure.

Trileptal is used to treat partial seizures with or without secondarily generalised tonic-clonic seizures.

Partial seizures involve a limited area of the brain, but may spread to the whole brain and may cause a generalised tonic-clonic seizure. There are two types of partial seizures: simple and complex. In simple partial seizures, the patient remains conscious, whereas in complex partial seizures, patients consciousness is altered.

Trileptal works by keeping the brain's "overexcitable" nerve cells under control. This suppresses or reduces the frequency of such seizures.

Trileptal 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. Trileptal is for use in adults and in children of 6 years of age and above.

If you have any questions about how Trileptal works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Trileptal

Follow all your doctor's instructions carefully, even if they may differ from the general information contained in this leaflet.

Monitoring during your treatment with Trileptal
Before and during your treatment with Trileptal, your doctor may perform blood tests to determine the dose for you. Your doctor will tell you when to have the tests.

Do not take Trileptal

- if you are allergic to oxcarbazepine or any of the other ingredients of this medicine (listed in section 6) or if you are allergic to eslicarbazepine.

If this applies to you, tell your doctor before taking Trileptal. If you think you may be allergic, ask your doctor for advice.

Warnings and precautions
Talk to your doctor or pharmacist before taking Trileptal:

- 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 could also have an allergic reaction to oxcarbazepine (Trileptal).
- if you have **kidney disease**.
- if you have serious **liver 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 **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 birth-control pill), Trileptal may stop your contraceptive from working. Use a different or extra (non-hormonal) method of contraception while taking Trileptal. 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 professional.

The risk of serious skin reactions in patients of Han Chinese or Thai origin associated with carbamazepine or chemically-related compounds may be predicted by testing a blood sample of these patients. Your doctor should be able to advise if a blood test is necessary before taking oxcarbazepine.

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

- if you experience an **allergic reaction** after starting Trileptal. 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 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 Trileptal 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 heartbeat.**

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

Other medicines and Trileptal
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This applies especially to:
- Hormonal contraceptives, such as the pill (see Warnings and precautions).
- Other antiepileptic medicines and enzyme inducing medicines, such as carbamazepine, phenobarbital, phenytoin or lamotrigine and rifampicin.
- Medicines that reduce the level of sodium in your blood, such as diuretics (used to help the kidneys get rid of salt and water by increasing the amount of urine produced), desmopressin and non-steroidal anti-inflammatory medicines, such as indometacin.
- Lithium and 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.

Trileptal with food and alcohol
Trileptal can be taken with or without food.
Alcohol may increase the sedative effects of Trileptal. Avoid alcohol as much as possible and ask your doctor for advice.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 antiepileptic medicines during pregnancy.

Birth defects
Studies have not shown an increased risk of birth defects associated with oxcarbazepine use during pregnancy, however, a risk of birth defects for your unborn child cannot be completely ruled out.

Neurodevelopmental disorders
Some studies have shown that exposure to oxcarbazepine in the womb negatively affects the development of brain function (neurodevelopment) in children, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

Birth weight

If you use Trileptal during pregnancy, your child may be smaller and weigh less than expected at birth [born small for gestational age (SGA)]. Among women with epilepsy, in one study, around 15 out of every 100 children born to mothers who had taken oxcarbazepine during pregnancy were smaller and weighed less than expected at birth, compared to around 11 out of every 100 children born to women not taking anti-seizure medication during pregnancy.

Your doctor will tell you the benefits and potential risks involved and help you to decide whether you should take Trileptal.
Do not stop your treatment with Trileptal during pregnancy without first checking with your doctor.

Breast-feeding
If you are taking this medicine, ask your doctor for advice before starting breastfeeding. The active substance in Trileptal passes into breast milk. Although available data suggest that the amount of Trileptal that passes to a breastfed baby is low, a risk of side effects for the baby cannot be ruled out.
Your doctor will discuss with you the benefits and potential risks of breastfeeding while taking Trileptal. If you are breastfeeding while taking Trileptal and you think your baby is having side effects such as excessive sleepiness or poor weight gain, tell your doctor immediately.

Driving and using machines
Trileptal 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.

Trileptal contains sorbitol (E420), propylene glycol (E1520), parahydroxybenzoates, sodium and ethanol
Trileptal oral suspension contains:
- Sorbitol (E420): This medicine contains 175 mg sorbitol in each 1 ml of oral suspension. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect
- Propylene glycol (E1520): This medicine contains 25 mg propylene glycol in each 1 ml of oral suspension.
- Parahydroxybenzoates: Propylparahydroxybenzoate (E216) and Methylparahydroxybenzoate (E218) may cause allergic reactions (possibly delayed).
- Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.
- Ethanol: This medicine contains 0.8 mg of alcohol (ethanol) in each 1 ml of oral suspension. The amount in 1 ml of this medicine is equivalent to less than 0.02 ml beer or 0.01 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Trileptal

Always take this medicine exactly as your doctor or pharmacist has told you, even if this differs from the information given in this leaflet. Check with your doctor or pharmacist if you are not sure.

Your dose must be given in millilitres (ml)
The dose your doctor prescribes you must be given in **millilitres (ml)** and not in milligrams (mg). This is important because the oral dosing syringe used to withdraw the correct dose from the bottle is

marked in ml. **If your prescription is in mg, do not take your medicine and contact as soon as possible your pharmacist or doctor for advice.**

How much to take

Use in adults

- The **usual starting dose** of Trileptal for adults (including elderly patients) is 10 ml oral suspension (600 mg oxcarbazepine) per day.
- Take one 5 ml dose oral suspension (300 mg oxcarbazepine) twice daily.
- Your doctor may increase the dose gradually to find the best dose for you. The best results are usually with doses between 10 ml and 40 ml oral suspension (600 mg to 2,400 mg oxcarbazepine) per day.
- If you take another antiepileptic medicine, the dose is the same.
- 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.

Use in children and adolescents

Trileptal can be taken by children aged 6 years or above.
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. For example, a 30 kg child would start treatment with one 150 mg dose (2.5 ml oral suspension) twice daily.
- 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.

How to take Trileptal

For full instructions on how to take Trileptal, see section Instructions for use at the end of this leaflet.

When and for how long to take Trileptal

Take Trileptal twice a day, every day, at about the same time of day, unless the doctor tells you otherwise. This will have the best effect on controlling epilepsy. It will also help you to remember when to take the oral suspension.

Your doctor will tell you how long your or your child’s treatment with Trileptal 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 Trileptal than you should

If you have taken more oral suspension than your doctor prescribed, contact the nearest hospital or your doctor immediately. Symptoms of overdose with Trileptal may include:

- drowsiness, dizziness, problems with coordination and/or involuntary movement of the eyes, muscular twitching or significant worsening of convulsions, headache, loss of consciousness, coma,
- feeling sick (nausea), being sick (vomiting), increased uncontrolled movements,
- lethargy, double vision, narrowing of black part of the eye, blurred vision,
- tiredness,
- short and shallow breathing (respiratory rate depression),
- irregular heart beat (QTc prolonged interval),
- trembling, headache, coma, decreased consciousness, uncontrollable movements of mouth, tongue and limbs,
- aggression, agitation, confusion
- low blood pressure
- breathlessness

If you forget to take Trileptal
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 a forgotten dose.
If you are unsure or have forgotten to take several doses, contact your doctor.

If you stop taking Trileptal
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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or go to the emergency department at your nearest hospital if you get any of the following side effects:
The following are signs of potentially serious side effects that may require urgent medical treatment. The doctor will also decide whether Trileptal has to be stopped immediately and how to continue further medical care.
Uncommon (may affect up to 1 in 100 people):
- Weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of under active thyroid gland).
- Fall

Rare (may affect up to 1 in 1,000 people):
- 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 Generalized 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).

Very rare (may affect up to 1 in 10,000 people):
- 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 pancreatitis).

Tell your doctor as soon as possible if you get any of the following side effects, they may require medical attention:

Common (may affect up to 1 in 10 people):

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

Very rare (may affect up to 1 in 10,000 people):

- 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 Trileptal. Most of these effects are transient and usually diminish over time.

Very common (may affect more than 1 in 10 people):

- tiredness; headache; dizziness; drowsiness; feeling sick (nausea); being sick (vomiting); double vision.

Common (may affect up to 1 in 10 people):

- 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.

Uncommon (may affect up to 1 in 100 people):

- high blood pressure; hives.
- you may also have raised levels of liver enzymes while taking Trileptal.

Rare (may affect up to 1 in 1,000 people):

- 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 antiepileptic medication, have a history of osteoporosis or take steroids.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trileptal

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton and the bottle. The expiry date refers to the last day of that month.
- Use within 7 weeks after first opening the bottle.
- After 7 weeks, return any unused oral suspension to your pharmacy for safe disposal.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trileptal contains

- The active substance of Trileptal is oxcarbazepine. Each ml of the oral suspension contains 60 mg of oxcarbazepine.
- The other ingredients are purified water, sorbitol (E 420) 70% liquid (non-crystallising), propylene glycol (E 1520), dispersible cellulose (containing microcrystalline cellulose and carmellose sodium), ascorbic acid (E 300), yellow-plum-lemon flavour (containing ethanol),

methylparahydroxybenzoate (E 218), macrogol stearate 400, sorbic acid (E 200), saccharin sodium, propyl parahydroxybenzoate (E 216).

What Trileptal looks like and contents of the pack

Trileptal oral suspension is supplied as an off white to slightly brown or slightly red suspension. Discoloration of the oral suspension to a slightly reddish brown colour is normal and does not affect the quality of the product.

Trileptal oral suspension is supplied in brown glass bottles containing 250 ml of oral suspension. The bottles have a child resistant cap and are packed in a cardboard box together with a 10 ml dosing syringe and press-in bottle adaptor. Each pack contains one bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Novartis Ireland Limited
Vista Building,
Elm Park, Merrion Road,
Ballsbridge, Dublin 4,
Ireland.

Manufacturer

Novartis Farmacéutica, S.A.
Gran Via de les Corts Catalanes, 764,
08013 Barcelona
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Trileptal 60 mg/ml - Suspension zum Einnehmen
Belgium	Trileptal 60 mg/ml suspensie voor oraal gebruik / suspension buvable /Suspension zum Einnehmen
Croatia	Trileptal 60 mg/ml oralna suspenzija
Denmark	Trileptal
Finland	Trileptal 60 mg/ml oraalisuspensio
France	Trileptal 60 mg/ml, suspension buvable
Germany	Trileptal 60 mg/ml Suspension zum Einnehmen
Greece	Trileptal 60mg/1ml Πόσιμο εναιώρημα
Iceland	Trileptal 60 mg/ml mixtúra, dreifa
Ireland	Trileptal
Netherlands	Trileptal 60 mg/ml, orale suspensie
Portugal	Trileptal 60 mg/ml Suspensão Oral
Spain	Trileptal 60 mg/ml suspensión oral
Sweden	Trileptal 60 mg/ml oral suspension

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INSTRUCTIONS FOR USE

Read these instructions carefully so that you know how to use this medicine.

How to use the medicine kit

There are three parts to the medicine kit:

1. A plastic adapter that you push into the neck of the bottle.
The adapter must always stay in the bottle.

2. A bottle containing 250ml of the medicine, with a child resistant cap. Always replace the cap after use.

3. A 10ml oral dosing syringe. This fits into the plastic adapter to withdraw the prescribed dose from the bottle.

How to fit the plastic adapter into a new bottle of medicine

1. Shake the bottle of medicine vigorously for **at least 10 seconds**.
2. Remove the child resistant cap by pushing it down **firmly** and turning it anti-clockwise (as shown on the top of the cap).

Note : Keep the cap nearby to close the bottle after each use.

3. Hold the open bottle upright on a table. Push the plastic adapter **firmly** into the neck of the bottle as far as you can.

Note : You may not be able to push the adapter down fully but it will be forced into the bottle when you screw the cap back on.

To dispense a dose, please follow all instructions in **Preparing a dose of medicine.**

Preparing a dose of medicine

The medicine can be swallowed directly from the oral syringe, or mixed in a small glass of water.

- Shake the bottle vigorously for at least 10 seconds. Prepare the dose immediately afterwards.
- Push and turn the child resistant cap to open the bottle. (Always replace the cap after use)

- Check the plunger is fully down inside the barrel of the oral syringe.
- Keep the bottle upright and insert the oral syringe **firmly** into the plastic adapter.

- Hold the oral syringe in place and carefully turn the bottle upside down.
- Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.

- Withdrawing the prescribed dose: Slowly pull the plunger down. Pull until the top edge of the plunger is exactly level with the marker on the oral syringe barrel that indicates the prescribed dose.

Note: If the prescribed dose is more than 10ml, withdraw the prescribed dose in two steps. Firstly, fill the syringe to the 10 ml mark, and take the 10 ml. Then reload the oral syringe to the required level to take the remaining amount.

Ask your pharmacist if you are unsure.

- Carefully turn the bottle the right way up. Disconnect the oral syringe by gently twisting it out of the plastic adapter.

- The dose of medicine can be swallowed directly from the oral syringe. The patient must be sitting upright and the plunger must be pushed **slowly** to allow the patient to swallow. Alternatively, the dose can be mixed in a small glass of water just prior to administration. Stir and drink the entire mixture right away.
- Replace the child resistant cap after use, leaving the adapter in place.
- **Cleaning:** After use, wipe the outside of the syringe with a dry, clean tissue.