Package leaflet: Information for the patient

Tegretol® 100mg/5ml Oral Suspension
carbamazepine

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 Tegretol Oral Suspension is and what it is used for

Tegretol Oral Suspension contains a medicine called carbamazepine.
Carbamazepine can affect the body in several different ways. Tegretol Oral Suspension helps to control messages passed from the brain to muscles along the nerve pathways in the body. It is an anti-epileptic medicine (prevents fits). It can also modify some types of pain and can control mood disorders.
Tegretol Oral Suspension is used in adults to treat the following:
• some forms of epilepsy
• a painful condition of the face called "trigeminal neuralgia" and some other nerve pains
• serious mood disorders when other medicines have not worked
• alcohol withdrawal problems.
Tegretol Oral Suspension is also used in children to treat some forms of epilepsy.

2. What you need to know before you take Tegretol Oral Suspension

Do not take Tegretol Oral Suspension if:
- you are allergic to carbamazepine or similar medicines such as oxcarbazepine (Trileptal), or to any of a related group of medicines called tricyclic antidepressants (such as amitriptyline or imipramine).
- you are allergic to any of the other ingredients of Tegretol Oral Suspension (listed in section 6). Signs of an allergic reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling
- you have severe heart disease or have had any abnormalities of heart rate or rhythm.
- you have had serious blood illnesses in the past.
- you have ever had problems with your bone marrow
- you have a blood problem called porphyria
- you have taken medicines called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days
- Newborn babies below 4 weeks of age, unless no other treatment option is available (see Warnings and Precautions).
- you are taking herbal preparations containing St. John's wort (Hypericum perforatum).

Do not take Tegretol Oral Suspension if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tegretol Oral Suspension.

Warnings and precautions

Thoughts of harming or killing yourself
A small number of people being treated with anti-epileptics, such as carbamazepine, have had thoughts of harming or killing themselves. If you have these thoughts, talk to your doctor straight away (or ask someone else to).

Look out for signs of serious blood or bone marrow problems
Tell your doctor straight away (or ask someone else to) if you get signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin.

Look out for allergic reactions
If an allergic reaction happens, such as swelling of lips, eyelids, face, throat, mouth, or sudden breathing problems, fever with lymph nodes swelling, rash or skin blistering, tell your doctor immediately or go to the emergency department at your nearest hospital.

Look out for serious skin reactions
Tell your doctor straight away (or ask someone else to) if you get serious skin reactions when taking this medicine such as skin rash, with blistering or peeling, mouth or genital ulcers often with flu-like symptoms or a reduction in blood cells leading to unexplained bruising or bleeding (these may be signs of Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalised Exanthematous Pustulosis (AGEP)). These types of reactions are more likely in the first few months of treatment. Serious skin reactions are more likely in certain groups of people (such as people of Han Chinese, Thai, Japanese or European origin). This can be predicted in a blood test before treatment starts. Your doctor will be able to advise you whether this blood test is necessary for you.

Patients at risk of hyponatraemia
Hyponatremia is a condition that occurs when the level of sodium in your blood is abnormally low. It is known to occur with carbamazepine. If you have kidney problems associated with low sodium blood level or if you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide, furosemide), then you should discuss your treatment with your doctor or pharmacist because Tegretol might not be the right medicine for you.

Seizures
If you experience an increase in the number of seizures, tell your doctor immediately.

Talk to your doctor or pharmacist before taking Tegretol Oral Suspension if:
• you have blood problems (including those caused by other medicines)
• you are allergic to phenytoin (a medicine used to treat epilepsy)
• you have the form of epilepsy where you have mixed fits which include absences
• you have ever had any heart, liver or kidney problems
• you are over 65 years of age
• you have an under-active thyroid (hypothyroidism)
• you have any eye problems such as glaucoma (increased pressure in the eye)
• you have difficulty emptying your bladder (urinary retention)
• you have problems with your mental health
• you have thinning of the bones (osteopenia or osteoporosis)
• you experience dizziness, drowsiness, decrease in blood pressure, confusion, due to Tegretol treatment, which may lead to falls.
• you are pregnant or plan to become pregnant. Your doctor will discuss with you the potential risk of taking Tegretol during pregnancy since it may cause harm or cause abnormalities in the unborn child (See section Pregnancy and contraception).
• you are a female of childbearing age as you should use an effective method of contraception throughout your treatment and for 2 weeks after your last dose

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Tegretol Oral Suspension.

Pregnancy
There is a risk of harm to the unborn child if Tegretol Oral Suspension is used during pregnancy. Women of childbearing age should use effective contraception during treatment with Tegretol Oral Suspension and for two weeks after the last dose (see Pregnancy and breast-feeding).

Children (4 weeks of age or above), adolescents (below 18 years) and older people (65 years of age or above)
Tegretol may be safely used in children 4 weeks of age or above and in elderly patients, keeping to the doctor's instructions. If necessary, special information will be given, such as on the need for careful dosage and close observation (see also sections 3 “How to take Tegretol” and 4 “Possible side effects”).

Other medicines and Tegretol Oral Suspension
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because of the way Tegretol Oral Suspension works. It can affect and be affected by lots of other things that you might be eating or medicines you are taking. It is very important to make sure that your doctor knows all about what else you are taking, including anything you have bought from a chemist or health food shop. It may be necessary to change the dose of some medicines or stop taking them altogether.
In particular, **do not take** Tegretol Oral Suspension and tell your doctor if you are taking:
• monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.
• herbal preparations containing St. John’s wort (Hypericum perforatum).

Do not take Tegretol Oral Suspension if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Tegretol Oral Suspension.

Tell your doctor or pharmacist if you are taking:
• hormone contraceptives, e.g. pills, patches, injections or implants. Tegretol Oral Suspension may affect how hormonal contraceptives work and make them less effective at preventing pregnancy. You may also get breakthrough bleeding or spotting. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Tegretol Oral Suspension.
• any other medicines for depression or anxiety such as desipramine, fluoxetine, viloxazine, imipramine, lithium, haloperidol, thioridazine
• corticosteroids (“steroids”) such as prednisolone, dexamethasone. You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease or muscle and joint pains
• anticoagulants to stop your blood clotting such as warfarin
• antibiotics to treat infections including tuberculosis (TB) such as erythromycin, ciprofloxacin, doxycycline, isoniazid, rifampicin
• antifungals to treat fungal infections such as itraconazole, ketoconazole, fluconazole
• painkillers containing paracetamol, dextropropoxyphene, tramadol or methadone
• other medicines to treat epilepsy such as phenytoin, oxcarbazepine, phenobarbitone, clobazam, clonazepam, ethosuximide, primidone, valproic acid and brivaracetam.
• medicines for high blood pressure or heart problems such as verapamil, diltiazam, digoxin, felodapine
• antihistamines (medicines to treat allergy such as hay fever or itching) such as loratadine, terfenadine
• diuretics (water tablets)
• cimetidine or omeprazole (medicines to treat gastric ulcers)
• analgesics or anti-inflammatory medicines such as ibuprofen, paracetamol
• isotretinoin (a medicine for the treatment of acne)
• metoclopramide or aprepitant (anti-sickness medications)
• acetazolamide (a medicine to treat glaucoma – increased pressure in the eye)
• danazol or gestrinone (treatments for endometriosis)
• theophylline or aminophylline (used in the treatment of asthma)

• ciclosporin (an immunosuppressant, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis)
• everolimus (an immunosuppressant)
• medicines to treat schizophrenia such as olanzapine, clozapine, risperidone
• cancer medicines such as cisplatin, doxorubicin, imatinib
• the anti-malarial medicine, mefloquine
• medicines to treat HIV such as indinavir, saquinavir, ritonavir
• levothyroxine (used to treat hypothyroidism)
• muscle relaxant medicines such as oxybutynin, dantrolene
• bupropion (used to help stop smoking)
• medicines for erectile dysfunction such as tadalafil
• medicines or supplements containing vitamin B (e.g. nicotinamide)
• ticlopidine (an anti-platelet drug)
• praziquantel or albendazole (used to treat worms)
• any other medicine that lowers the salt (sodium) level in your blood (your doctor can advise).
If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Tegretol Oral Suspension.

Operations or tests
• Your doctor may want you to have a number of blood tests before you start taking Tegretol Oral Suspension and from time to time during your treatment. This is quite usual and nothing to worry about.
• Before having any kind of blood tests or surgery, including dental or emergency treatment, tell the doctor in charge that you are taking Tegretol Oral Suspension.

Tegretol Oral Suspension with food, drink and alcohol
• Do not drink alcohol while you are taking this medicine. This is because it may affect you more than usual. Talk to your doctor if you have any questions about drinking alcohol.
• Do not eat grapefruit or drink grapefruit juice while you are taking this medicine. This is because it may increase your chance of experiencing side effects.

Pregnancy, breastfeeding and fertility
Tegretol Oral Suspension can cause major birth defects. If you take Tegretol Oral Suspension during pregnancy your baby has up to 3 times the risk of having a birth defect than women not taking an antiepileptic medication. Major birth defects including neural tube defect (opening in the spine), birth defect of the face such as cleft of the upper lip and palate, birth defect of the head, smaller head (microcephaly), heart defects, birth defect of the penis involving the urinary opening (hypospadias) and finger defects have been reported. If you use Tegretol Oral Suspension 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 13 out of every 100 children born to mothers who had taken carbamazepine 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 unborn baby should be closely monitored if you have taken Tegretol Oral Suspension while pregnant.

Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used Tegretol Oral Suspension during pregnancy. Some studies have shown that carbamazepine negatively affects neurodevelopment of children exposed to carbamazepine in the womb, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Tegretol Oral Suspension. Tegretol Oral Suspension may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. You may also get breakthrough bleeding or spotting. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Tegretol Oral Suspension. If treatment with Tegretol Oral Suspension is discontinued you should continue using effective contraception for two more weeks following discontinuation.

If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to carbamazepine.

If you are or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment.

If you take Tegretol Oral Suspension during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this.

Seizures, breathing problems, vomiting, diarrhoea and decreased feeding have also been reported in newborn babies whose mothers received Tegretol Oral Suspension during pregnancy. Make sure you are very clear about the risks and benefits of taking Tegretol Oral Suspension.

Mothers taking Tegretol Oral Suspension can breast-feed their babies, but you must tell the doctor as soon as possible if you think that the baby is having side effects such as excessive sleepiness, skin reactions or gets yellowish skin or eyes because you are taking Tegretol Oral Suspension.

Driving and using machines
Tegretol Oral Suspension can make you feel dizzy or drowsy, have a lack of coordination or balance, especially at the start of treatment or when your dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive, cycle or operate machinery.
The condition you are taking Tegretol Oral Suspension for may also affect your ability to drive, cycle or operate machinery.

Important information about some of the ingredients of Tegretol
This medicine contains 125 mg propylene glycol in each 5 mL of Tegretol oral suspension which is equivalent to 25 mg per ml. If your baby is less than 4 weeks old, your baby should not receive this medicine before a thorough evaluation from your doctor and unless no other treatment option is available. At this age, your baby may not be able to metabolise propylene glycol, which can lead to serious side effects including kidney and liver problems. The risk is increased if the baby is given other medicines that contain propylene glycol or other alcohols. If treatment with this medicine is needed, your baby will be monitored for these side effects. Talk to your doctor if your baby was born preterm (early).

This medicine contains 875 mg sorbitol in each 5 mL of Tegretol oral suspension which is equivalent to 175 mg per ml. 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, 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.

This medicine contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) in each millilitre, that is to say essentially “sodium-free”.

3. How to take Tegretol Oral Suspension

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
Your doctor will usually start Tegretol Oral Suspension at a fairly low dose which can then be increased to suit you individually. The dose needed varies between patients. You are usually told to take a dose two or three times a day.

To treat epilepsy the recommended doses are:
Adults
Treatment of epilepsy in adults is usually started at 100 to 200 mg (5 to 10 ml of medicine) once or twice a day.
The dose is then slowly increased to between 800 and 1,200 mg a day (40 to 60 ml of medicine), until the best dose for you is found. Higher doses such as 1,600 mg (80 ml) or even 2,000 mg (100 ml) may be necessary. Older patients might require a lower dose.

Children and adolescents
Treatment of epilepsy in children is usually started based on their body weight. It is usually started at 10 to 20 mg per kg of body weight daily. The dose is then slowly increased based on their age to:
Aged up to 1 year: between 100 and 200 mg a day (5 to 10 ml of medicine)
Aged 1 up to 5 years: between 200 and 400 mg a day (10 to 20 ml of medicine)
Aged 5 up to 10 years: between 400 and 600 mg a day (20 to 30 ml of medicine)
Aged 10 up to 15 years: between 600 and 1,000 mg a day (30 to 50 ml of medicine)
Aged 15 years and older: same as adult dose (see above).

To treat trigeminal neuralgia and other nerve pains the recommended dose is:
Treatment of trigeminal neuralgia is usually started at 200 to 400 mg a day (10 to 20 ml of medicine). The dose is then slowly increased until there is no pain. The usual dose is 200 mg (10 ml of medicine) three to four times a day. The usual maximum dose is 1,200 mg a day (60 ml of medicine), although higher doses may be necessary.
A lower starting dose of 100 mg (5 ml of medicine) twice a day is recommended for older patients.

To treat serious mood disorders the recommended dose is:
Treatment of serious mood disorders is usually started at 100 to 200 mg a day (5 to 10 ml of medicine).
The dose is slowly increased until symptoms are controlled. The usual dose is 400 to 600 mg a day (20 to 30 ml of medicine), although higher doses may be necessary.

To treat alcohol withdrawal problems the recommended dose is:
The usual dose is 600 to 800 mg a day (30 to 40 ml of medicine), although higher doses may be necessary.

Taking this medicine
You can take Tegretol Oral Suspension during or after a meal. Shake the bottle before measuring out your medicine.

If you take more Tegretol Oral Suspension than you should
If you accidentally take too much Tegretol Oral Suspension, tell your doctor or your nearest hospital casualty department straight away. Take your medicine pack with you so that people can see what you have taken. You may have difficulty breathing, a fast or uneven heartbeat, feel faint or shaky, feel or be sick or become unconscious.

If you forget to take Tegretol Oral Suspension
If you forget to take a dose, take one as soon as you remember it. If it is nearly time for your next dose, though, just take the next dose and forget about the one you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tegretol Oral Suspension
Keep taking Tegretol Oral Suspension for as long as you have been told, unless you have any problems. In that case, check with your doctor.
Do not stop taking Tegretol Oral Suspension suddenly. Stopping treatment with Tegretol Oral Suspension suddenly may worsen your seizures. It is recommended that you stop taking your medicine gradually, over a period of 6 months.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Tegretol Oral Suspension can cause side effects, although not everybody gets them.

Tell your doctor straight away (or ask someone else to) if you notice any of the following serious side effects – you may need urgent medical attention:
• thoughts of harming or killing yourself
• serious skin reactions such as skin rash, with blistering or peeling, mouth or genital ulcers often with flu-like symptoms or a reduction in blood cells leading to unexplained bruising or bleeding (these may be signs of SJS, TEN, DRESS or AGEP) (refer to section 2 for further information on serious skin reactions)
• signs of serious blood or bone marrow problems such as fever and sore throat, with possible unexplained bruising or burst blood vessels under your skin
• bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be signs of a serious allergic reaction)
• fever, muscle stiffness with confusion and unusual changes in blood pressure (these may be signs of a serious brain problem)
• fever, feeling or being sick, headache, stiff neck and extreme sensitivity to bright light (these may be signs of meningitis)
• having more fits (seizures)
• yellowing of your skin or the whites of your eyes (these may be signs of liver problems)
• being sick, diarrhoea, weight loss, with changes to or blood in your urine, changes in your heartbeat, muscle cramps or itching (these may be signs of kidney failure)
• any changes in your mental health, including depression, agitation, confusion, loss of appetite, hearing or seeing things which are not there
• pain in your joints and muscles, a rash across the bridge of your nose and cheeks (these may be signs of a rare reaction known as lupus erythematosus)
• fever, skin rash, joint pain, and abnormalities in blood and liver function tests, that could go on to affect other organs as well (these may be signs of a multi-organ sensitivity disorder)
• pain in the area around the stomach
• severe diarrhoea, abdominal pain and fever (these may be signs of an inflamed colon).
• If you experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion.
Tell your doctor straight away (or ask someone else to) if you notice any of the serious side effects above.

Other side effects include:
Talk to your doctor or pharmacist if you get any side effects.

Very common: may affect more than 1 in 10 people
Dizziness and tiredness; feeling unsteady or finding it difficult to control movements; feeling or being sick; low white blood cell count or changes in liver enzyme levels (shown in blood tests); minor skin reactions, including itching, redness, raised bumps and peeling.

Common: may affect up to 1 in 10 people
Weight increase; swollen ankles, feet or lower legs; low sodium in the blood which might result in confusion; headache; double or blurred vision; dry mouth; low platelet count or higher levels of a protein called “ALP” in your body (shown in blood tests).

Uncommon: may affect up to 1 in 100 people
Abnormal involuntary movements including tremor or tics; abnormal eye movements; diarrhoea; constipation.

Rare: may affect up to 1 in 1,000 people
Disease of the lymph glands; folic acid deficiency; speech disorders; numbness or tingling in the hands and feet; a burning, shooting or stabbing pain; muscle weakness; high blood pressure (which may make you feel dizzy, with a flushed face, headache, fatigue and nervousness); low blood pressure

(the symptoms of which are feeling faint, light headed, dizzy or confused); changes to heartbeat; high white blood cell count (shown in a blood test).

Very rare: may affect up to 1 in 10,000 people
Porphyria; swelling of the breasts and discharge of milk which may occur in both males and females; abnormal thyroid function tests; osteomalacia (softening of the bones, which may be noticed as pain on walking and bowing of the long bones in the legs); osteopenia or osteoporosis (thinning of the bones, which may lead to increased fractures); increased blood fat or cholesterol levels; taste disturbances; conjunctivitis; glaucoma; cataracts; hearing disorders; heart and circulatory problems including deep vein thrombosis (DVT), the symptoms of which could include, tenderness,pain, swelling, warmth, skin discoloration and prominent, superficial veins; lung or breathing problems such as a blood clot in the lung or pneumonia; sore mouth or tongue; increased sensitivity of the skin to sunlight; alterations in skin pigmentation; acne; excessive sweating; hair loss; increased hair growth; muscle pain or spasm; sexual difficulties which may include reduced male fertility, loss of libido or impotence; kidney problems; blood spots in the urine; increased or decreased desire to pass urine or difficulty in passing urine; low red blood cell count (anaemia) or low level of all blood cells (shown in blood tests).

Not known: it is not known how often these happen
Feeling drowsy; memory loss; purple or reddish-purple bumps on your skin that may be itchy; complete loss of your nails; reactivation of herpes virus infection (which can be serious when the immune system is depressed). High levels of ammonia in the blood (hyperammonaemia). The symptoms of hyperammonaemia may include irritability, confusion, vomiting, loss of appetite, and sleepiness.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse.
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 Tegretol Oral Suspension

• Keep this medicine out of the sight and reach of children.
• Do not take Tegretol Oral Suspension after the expiry date, which is stated on the carton and bottle label after "EXP". The expiry date refers to the last day of that month.
• Store the bottle in the outer carton in order to protect from light. Do not store above 30°C.
• 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 Tegretol Oral Suspension contains
• The active substance is carbamazepine. There is 100 mg of carbamazepine in each 5 ml of your medicine.
• The other ingredients are saccharin sodium (E 954), hyetellose, microcrystalline cellulose, carmellose sodium, sorbitol liquid (non-crystalising) (E 420), macrogol stearate 400, propylene glycol (E 1520), methylparahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), sorbic acid (E 200), caramel flavour 52.929A and purified water.

What Tegretol Oral Suspension looks like and contents of the pack
Tegretol Oral Suspension is a white, caramel flavoured, liquid. It comes in a 300 ml glass bottle.

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

Manufacturer
Novartis Farmacéutica SA
Gran Via de les Corts Catalanes, 764
08013 Barcelona
Spain

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