PACKAGE LEAFLET

Package leaflet: Information for the patient

Curatil 200 mg Prolonged-Release Tablets

Curatil 400 mg Prolonged-Release Tablets

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 Curatil is and what it is used for

Carbamazepine, the active ingredient in Curatil, is an anti-convulsant medicine (prevents fits), it can also treat some types of pain and help to control mood disorders.

Curatil is used:
• To treat some forms of epilepsy
• To treat a painful condition of the face called trigeminal neuralgia
• To help control serious mood disorders when some other medicines don't work.

2. What you need to know before you take Curatil

Do not take Curatil:

- if you are allergic to carbamazepine or to any of a related group of drugs known as tricyclic antidepressants or any of the other ingredients of this medicine (listed in section 6). If signs or symptoms of a hypersensitivity reaction occur, Curatil should be discontinued immediately;
- if you have a history of bone marrow damage or a disorder of the bone marrow;
- if you have a disorder of the heart rhythm (atrioventricular block);
- if you have an inherited or acquired disorder where there is a problem with the production of haem (used to make haemoglobin in red blood cells) within the body (porphyria);
- if you have also taken a monoamine oxidase inhibitor (MAOI), used to treat depression, within the last 14 days.

Warnings and precautions

Talk to your doctor or pharmacist before taking Curatil

- If you suffer from epilepsy which includes absences, you should not take carbamazepine, as it can cause these types of seizures or intensify existing ones.

- If you suffer from a mental illness.
- If you suffer from liver inflammation or yellowing of the skin and/or eyes.
- If you have kidney problems associated with low levels of sodium in your blood or if you have kidney problems and you are taking medicines that lower sodium levels in your blood (diuretics such as hydrochlorothiazide, furosemide).
- If you have muscle loss and weakness disorder (myotonic dystrophy), as heart conduction disorders maybe more common.
- If you have increased pressure in the eye (glaucoma).
- If you have difficulty or pain when urinating.
- If you experience dizziness, light-headedness, drop in blood pressure or confusion due to taking carbamazepine, as this can lead to falls.
- There is a risk of harm to the unborn baby, if carbamazepine is used during pregnancy. Women of childbearing potential should use effective contraception during treatment with carbamazepine and for two weeks after the last dose (see pregnancy and breast-feeding section).
- Inform your doctor immediately if you experience irregular vaginal bleeding or spotting.
- A small number of people being treated with anti-epileptics such as Curatil have had thoughts of harming or killing themselves. If at any time you have such thoughts, contact your doctor immediately.
- Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis), which can be life-threatening, have been reported with the use of carbamazepine. The rash can result in widespread blistering or peeling of the skin. Additional symptoms to look out for include open, sore spots (ulcers) in the mouth, throat, nose, and genitals, and red and swollen eyes (conjunctivitis). These skin reactions are often accompanied by flu-like symptoms (headache, fever and body aches).

  The highest risk of these severe skin reactions occurring is in the first few weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis in connection with the use of carbamazepine, you must never be treated with carbamazepine again.

  If you develop a skin rash or any of the other skin symptoms listed, seek medical attention immediately. Let them know that you are taking carbamazepine.

  The severe skin reactions described may be more common in people from certain Asian countries. If you belong to the Han Chinese or Thai population, your doctor can do a blood test to determine if you are at increased risk of these serious skin reactions. Your doctor can tell you if a blood test is needed before taking carbamazepine.

  Due to the possibility of increased sensitivity of the skin to light (photosensitisation), you should protect yourself from strong sunlight during treatment with carbamazepine.

Other medicines and Curatil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Treatment with MAO inhibitors (medicines used to treat depression) must have been stopped at least 2 weeks before starting treatment with carbamazepine.

Carbamazepine may affect the following medicinal products:

- Pain relievers, anti-inflammatory medicines: buprenorphine, fentanyl, methadone, paracetamol (long-term use of carbamazepine and paracetamol may result in hepatotoxicity and can reduce the effectiveness of paracetamol), phenazone, tramadol, dextropropoxyphene / propoxyphene, ibuprofen
- Anti-parasite medicines: praziquantel, albendazole
- Anticoagulants (used to thin the blood): warfarin, phenprocoumon, dicoumarol, acenocoumarol, rivaroxaban, dabigatran, apixaban, edoxaban, ticlopidine. Simultaneous use of carbamazepine and direct-acting oral anticoagulants should be avoided or used with caution
- Medicines for treating depression (including tricyclic antidepressants): citalopram, mianserin, nefazodone (it is recommended not to use carbamazepine in combination with nefazodone as carbamazepine can lead to a significant reduction in the nefazodone plasma level up to a loss of effect), sertraline, trazodone, imipramine, amitriptyline, nortriptyline, clomipramine, fluoxetine, fluvoxamine, paroxetine, viloxazine, possibly also desipramine. Simultaneous use of antidepressants of the serotonin reuptake inhibitor type (such as fluoxetine) can lead to toxic serotonin syndrome
- Medicines to treat nausea and vomiting: aprepitant
- Antiepileptics and other medicines used to treat seizure disorders: clonazepam, ethosuximide, felbamate, eslicarbazepine, oxcarbazepine, primidone, lamotrigine, tiagabine, topiramate, valproic acid, zonisamide, phenytoin (the plasma level of phenytoin may be increased or decreased), stiripentol, vigabatrin, methosuximide, phenobarbital, phensuximide, fosphenytoin, progabid and possibly clonazepam, valpromide, valnoctamide, brivaracetam. It is advisable to check plasma levels and, if necessary, adjust the dosage of carbamazepine, especially when several antiepileptic medicines are administered at the same time
- Medicines used to treat fungal infections: caspofungin, azole-type antifungals: e.g. itraconazole, ketoconazole, fluconazole, voriconazole. Alternative anticonvulsants are recommended for patients treated with voriconazole or itraconazol
- Medicines for viral illnesses/HIV: e.g. indinavir, ritonavir, saquinavir
- Anxiety medicines: alprazolam, midazolam, clobazam
- Medicines used to treat respiratory illnesses: theophylline, aminophylline
- Medicines used to treat heart disorders: digoxin, simvastatin, atorvastatin, lovastatin, cerivastatin, ivabradine, quinidine (used to treat cardiac arrhythmias), propranolol (beta-blocker, antihypertensive medicine)
- Medicines used after organ transplants, immunosuppressant: ciclosporin, tacrolimus, sirolimus, everolimus
- Calcium antagonists (medicines to treat high blood pressure): felodipine, flunarizine, diltiazem, verapamil
- Medicines to prevent pregnancy: hormonal contraceptives e.g. pills, patches, injections or implants. Carbamazepine may affect how hormonal contraceptives work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking carbamazepine.
- Corticosteroids (anti-inflammatory medicines): e.g. prednisolone, dexamethasone
- Medicines for the treatment of mental illnesses or psychiatric disorders: haloperidol, bromperidol, clozapine, olanzapine, risperidone, quetiapine, ziprasonide, zotepine (accelerate metabolism), aripiprazole, paliperidone, loxapine. Simultaneous use of carbamazepine and lithium or neuroleptics (haloperidol, thioridazine) can promote the occurrence of neurological side effects including neuroleptic malignant syndrome. It is advisable to check plasma levels and, if necessary, adjust the dosage of carbamazepine
- Thyroid hormones: levothyroxine (carbamazepine seems to increase the excretion (elimination) of thyroid hormones and increase the need for them in patients with hypothyroidism. If necessary, the dose of the thyroid hormone should be adjusted
- Antibiotics: rifabutin, tetracyclines e.g. doxycycline

- Medicines used to treat cancer: imatinib, cyclophosphamide, lapatinib, temsirolimus, cisplatin, doxorubicin
- Hormones: oestrogens, progesterone derivatives
- Methylphenidate (medicine used to treat attention deficit disorders)
- Medicines used to treat erectile dysfunction: tadalafil
- Carbamazepine can reduce plasma levels of bupropion (a medicine to help you stop smoking) and increase levels of the breakdown product hydroxybupropion
- Anti-tuberculosis medicine: rifampicin, isoniazid (carbamazepine can increase the liver damage caused by isoniazid)
- Medicines for skin conditions: isotretinoin. If isotretinoin and carbamazepine are given at the same time, the carbamazepine plasma level should be checked
- St. John's Wort (Hypericum perforatum, herbal remedy for depressive moods)
- Medicines that inhibit the sex hormone gonadotropin: danazol
- Antibiotics, agents used to treat bacterial infections: macrolide antibiotics (e.g., erythromycin, troleandomycin, josamycin, clarithromycin, ciprofloxacin)
- Medicines used to treat allergic reactions: loratadine, terfenadine
- Medicines used to treat glaucoma: acetazolamide
- Muscle relaxants: oxybutynin, dantrolene. Carbamazepine may reduce the effectiveness of certain medicines used during anaesthesia (non-depolarising muscle relaxants such as pancuronium). Patients treated with muscle relaxants should be monitored and their dosage increased if necessary
- Medicines used to treat gastrointestinal ulcers: omeprazole, possibly cimetidine
- Nicotinamide (B group vitamin, in high doses)
- Simultaneous use of carbamazepine and levetiracetam may increase carbamazepine toxicity
- Simultaneous use of carbamazepine and metoclopramide (medicines used to treat gastrointestinal disorders) can promote the occurrence of neurological side effects
- The combined administration of carbamazepine and some diuretics (hydrochlorothiazide, furosemide) can lead to a reduced sodium content in the blood serum.

Curatil with food, drink and alcohol

- Drinking alcohol may affect you more than usual. Discuss with your doctor whether you should stop drinking alcohol.
- Eating grapefruit, or drinking grapefruit juice, may increase your chance of experiencing side effects.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Please inform your doctor immediately if you experience irregular vaginal bleeding or spotting.

Curatil can cause major birth defects. If you take carbamazepine 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 include 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, heart defects, birth defect of the penis involving the urinary opening (hypospadias) and finger defects have been reported. Your unborn baby should be closely monitored if you have taken Curatil while pregnant.

Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used Curatil 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 carbamazepine. Curatil may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. You may 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 Curatil. If treatment with Curatil is discontinued you should continue using effective contraception for 2 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 Curatil 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.

Breast-feeding

Carbamazepine passes into breast milk. The benefits of breast-feeding should be weighed against the risk of side effects in the infant such as poor weight gain, excessive sleepiness or allergic skin reaction.

Fertility

There have been isolated cases of sexual dysfunction, such as impotence or decreased libido. Reduced male fertility and/or abnormal sperm production have been reported very rarely.

Driving and using machines:

Curatil can make you feel dizzy, drowsy, may cause blurred vision or double vision or cause a lack of muscular co-ordination, especially at the start of treatment or when the dose is changed. If you are affected in this way, or if your eyesight is affected, you should not drive or operate machinery.

Curatil contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Curatil contains sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Curatil

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

- The prolonged-release tablets should be swallowed whole and not chewed or crushed.

- Take the prolonged-release tablets during or after meals with sufficient liquid (e.g. 1 glass of drinking water).
- When changing to treatment with carbamazepine, the dose of the anti-seizure medicine to be discontinued should be reduced gradually.
- A lower dosage may be necessary in patients with severe cardiovascular disease, liver or kidney disorders, during pregnancy and in the elderly.
- A gradual increase in dosage up to the optimal effective dose is recommended.
- You must not make any changes to the treatment or dose without first consulting your doctor.
- Please talk to your doctor or pharmacist if you have the impression that the effect of carbamazepine is too strong or too weak.

Recommended dosage for the treatment of epileptic seizure disorders:

<table>
<tr><th></th><th>Daily starting dose in mg</th><th>Daily maintenance dose in mg</th><th>Recommended maximum dose</th></tr>
<tr><td>Adults</td><td rowspan="3">200 mg in the evening</td><td>200 mg to 600 mg in the morning

400 mg to 600 mg in the evening</td><td>1,600 mg/day</td></tr>
<tr><td>Children*
Aged 6 to 10 years</td><td>200 mg in the morning

200 mg to 400 mg in the evening</td><td>1,000 mg/day</td></tr>
<tr><td>Children
Aged 11 to 15 years</td><td>200 mg to 400 mg in the morning

400 mg to 600 mg in the evening</td><td>1,000 mg/day</td></tr>
<tr><td>Children
Aged over 15 years</td><td colspan="2">Adult dose</td><td>1,200 mg/day</td></tr>
</table>

*Additional information for use in children

In general, the maintenance dose for children is an average of 10 to 20 mg carbamazepine/kg body weight/day.

For children under 6 years of age, the administration of prolonged-release tablets cannot be recommended due to insufficient knowledge.

Dose reduction and discontinuation:

The antiepilepsy treatment is a long-term therapy. In general, a dose reduction and discontinuation of the medication should be considered after two to three years free from seizures, at the earliest.

Discontinuation must take place in gradual dose reductions over one to two years; children can outgrow the dose per kg body weight instead of age-appropriate dose adjustment.

Paroxysmal facial pain (trigeminal neuralgia):

The usual dose is 400-800 mg a day. The maximum recommended dose is 1200mg a day. In some instances, doses of 1600mg carbamazepine daily may be needed. However, once pain relief has been achieved, the dosage should be gradually reduced to the lowest possible maintenance dose.

In the treatment of neuralgia, it has proven useful to carry out the therapy over a period of a few weeks with a maintenance dose that is just about sufficient for relief from pain. Careful dose reduction should be used to determine whether remission has occurred. If pain attacks recur, the original maintenance dose should be continued.

Prophylaxis of manic-depressive phases:
The starting dose, which is usually also sufficient as a maintenance dose, is 200 to 400 mg carbamazepine daily.

If necessary, the dose can be increased to 800 mg carbamazepine twice daily.

The prophylaxis of manic-depressive phases is a long-term treatment.

If you forget to take Curatil

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you take more Curatil than you should

If you accidentally take too many tablets, contact your doctor or your nearest hospital emergency department immediately. Remember to take any remaining tablets or this leaflet with you.

Symptoms of an overdose of carbamazepine, may include the following:

Nervous system disorders, seizures of the brain (tonic-clonic convulsions), changes in brain activity, slurred speech, low body temperature.

Consciousness disorders including drowsiness, sleepiness, coma, dizziness, disorientation, restlessness, agitation, confusion, hallucinations.

Movement disorders including involuntary movements, rigidity/stupor, unsteadiness, muscle twitching, shaking, severely abnormal posture, increased or weakened reflexes.

Eye disorders including blurred vision, involuntary movement of the eyes, dilated pupils of the eyes.

Difficulty in breathing including water in the lungs, blue discolouration of the face, respiratory arrest.

Heart disorders including increased heart rate, change in blood pressure, ECG changes, arrhythmias, AV block, fainting, cardiac arrest, flushing.

Gastrointestinal disturbances including nausea and vomiting.

Urinary disorders including reduced or no urine output, retention of water in the body, excretion of sugar in the urine, increase in a specific metabolic product in the urine (acetonuria).

Blood disorders including low levels of sodium in the blood, increased acidity of the blood, increased blood sugar, increased muscle creatine phosphokinase, increased or decreased white blood cell count.

If you stop taking Curatil

Do not stop treatment with carbamazepine suddenly as you may trigger an epileptic seizure. Curatil should be discontinued 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, this medicine can cause side effects, although not everybody gets them.

The following side effects can have serious consequences:
Contact your doctor **immediately** if you experience any of the following adverse reactions as you may require urgent medical attention.

- If you develop flu-like symptoms, fever, sore throat, skin rash, mouth ulcers, swelling of the lymph glands or increased susceptibility to infection (signs of certain changes in the blood count, in particular a reduction in white blood cells)
- If you develop a red, blotchy rash mainly on the face and simultaneous exhaustion, fever, nausea, loss of appetite (signs of systemic lupus erythematosus)
- In the event of yellow discoloration of the skin or whiteness in the eye, dark urine (signs of liver problems)
- In the event of reduced passing of urine due to kidney failure or blood in the urine
- In the event of severe pain in the upper abdomen, vomiting, loss of appetite (signs of pancreatitis)
- In the event of skin rash, skin redness, blisters on lips, eyes or in the mouth, peeling of the skin and simultaneous fever, chills, headache, cough, pain all over the body (signs of severe skin reactions)
- In the event of swelling of the face, eyes or tongue, difficulty swallowing, wheezing, hives or itching all over your body, skin rash, fever, abdominal cramps, chest discomfort or tightness around the chest, difficulty breathing, loss of consciousness (signs of angioedema or severe allergic reactions)
- In the event of fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to light (signs of meningitis)
- In the event of muscle stiffness, high fever, changes in consciousness, high blood pressure, excessive salivation (signs of neuroleptic malignant syndrome)
- Fever, general ill feeling, swollen/enlarged lymph nodes and skin eruption (Drug Rash with Eosinophilia and Systemic Symptoms [DRESS])
- Small raised bumps on the skin that fill with fluid or pus caused by a hypersensitivity (allergy) to medicine (Acute Generalised Exanthematous Pustulosis [AGEP]).

Very common: may affect more than 1 in 10 people

- Drowsiness, dizziness, tiredness, sleepiness, fatigue
- Gait and movement disorders (ataxia)
- Blood count changes such as a reduced count of white blood cells (leukopenia)
- Nausea and vomiting
- Allergic skin reactions, including severe ones, with and without fever and hives (urticaria)
- Increased gamma-glutamyltransferase (detected in blood test).

Common: may affect up to 1 in 10 people

- An increased count of a certain type of white blood cell (eosinophilia) or a reduced count of blood platelets (thrombocytopenia)
- Swelling of parts of the body (oedema), decreased fluid excretion, weight gain, decreased blood serum sodium levels (hyponatraemia) and decreased electrolyte–water balance in the body

- Headache
- Double vision, blurred vision
- Loss of appetite, dry mouth
- Increase in blood alkaline phosphatase.

Uncommon: may affect up to 1 in 100 people

- A delayed multi-organ hypersensitivity disorder with fever, rashes, inflammation of blood vessels, swollen/enlarged lymph nodes, skin disorders, joint pain, blood disorders, enlargement of both the spleen and the liver, abnormal liver function tests and vanishing bile duct syndrome occurring in various combinations
- In elderly patients, states of confusion and restlessness (agitation)
- Involuntary movements (e.g. tremor, inability to maintain a position [asterixis], muscle spasms and contractions, tics)
- Uncontrollable eye movement
- Heart rate and rhythm disorders, in some cases with fainting
- Diarrhoea, constipation
- Skin rash or inflammation (dermatitis exfoliative), peeling of the skin over large areas of the body (erythroderma)
- Kidney disorders (e.g. too much albumin in the urine, blood in the urine, decreased passing of urine, increased blood urea nitrogen, increase of creatinine in the blood [detected by blood tests])
- Increase in liver enzymes (transaminases).

Uncommon to Rare

- Slower heartbeat (bradycardia), abnormal heart rhythm (cardiac arrhythmia)
- Heart failure
- Worsening of pre-existing coronary artery disease.

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

- An increased count of other white blood cells (leukocytosis) or swelling of the lymph nodes (lymphadenopathy)
- Folic acid deficiency
- Loss of appetite
- Visual and/or audio hallucinations
- Mood changes such as depression, low or manic moods, restlessness, aggressive behaviour
- Involuntary movements or movement disorders, including the mouth and face area (such as grimacing, twisted movements), speech disorders (e.g. difficulty with or slurred speech), damage or disease affecting peripheral nerves (ones outside the brain and spinal cord), disorders of the nervous system (e.g. “creeping” sensation and other sensory disorders affecting hands and/or feet), tingling or numbness in the hands or feet and impaired or partial loss of movement
- High or low blood pressure (hypertension or hypotension)
- Abdominal pain
- Jaundice or liver inflammation (hepatitis in various forms) and liver disease with destruction and wasting of the intrahepatic bile ducts. Life-threatening acute hepatitis or liver failure can occur, especially within the first months of therapy
- Severe itching (pruritus)
- Muscle weakness.

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

- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (agranulocytosis, aplastic anaemia, pancytopenia)
- A rare disorder in which the bone marrow does not make enough red blood cells
- Spleen enlargement
- A reduction in the level of gamma globulins in the blood (laboratory test)
- Excessive delopment of the male breast (gynaecomastia) or milky secretion from the breasts not due to breast-feeding (galactorrhea)
- A group of rare inherited or acquired disorders where there is a problem with the production of haem (used to make haemoglobin in red blood cells) within the body (porphyria)
- Anxiety disorders, difficulty thinking. Concealed mental illnesses can be activated during treatment with carbamazepine
- Lack of drive
- A group of symptoms together e.g. rigidity, fever, sweating, high blood pressure, agitation, delirium, coma (neuroleptic malignant syndrome)
- Serious inflammation of the linings of the brain (aseptic meningitis, not caused by bacteria and viruses) with muscle twitching (myoclonus)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- Taste disturbances (dysgeusia)
- Infection that causes inflammation of the eye, red eyes, itchiness and discharge (conjunctivitis), eye lens becomes opaque or clouded, damage to the retina (retinotoxicity) which resolved after discontinuation of carbamazepine, increased pressure in the eye
- Hearing disorders such as ringing in the ears (tinnitus), excessive or reduced hearing sensitivity and changes in pitch perception
- Blood circulation disorders including blockages in the blood vessels (circulatory collapse, pulmonary embolism)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombophlebitis)
- Shortness of breath or difficulty in breathing, inflammation of the lungs (pneumonitis, pneumonia, alveolitis) and some cases of scarring of the lungs (pulmonary fibrosis)
- Inflammation of the mouth (stomatitis), gums (gingivitis), tongue (glossitis)
- Liver disease
- Severe blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome, Lyell's syndrome, toxic epidermal necrolysis), abnormal sensitivity of the skin to sunlight (photosensitivity), fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme) inflammatory condition that causes red, tender lumps to form just below the skin surface that usually affects the lower legs (erythema nodosum), pigmentation disorder, skin rash caused by small blood vessels bleeding into the skin (purpura), acne
- Increased sweating
- Hair loss (alopecia), excessive hair growth (hirsutism)
- Inflammation of blood vessels (vasculitis)

- Softening of the bones (osteomalacia), weak, fragile bones, more likely to break (osteoporosis), joint pain (arthralgia), muscle pain (myalgia), muscle spasms/cramps
- Inflammation of the kidney tissue (interstitial nephritis), kidney failure, urinary problems (frequent urination, pain when urinating, urge to urinate frequently without increased urination, urinary retention)
- Sexual disorders, decreased libido, erectile dysfunction, decreased male fertility, and /or decreased sperm count and/or motility
- Increased level of fats in the blood (cholesterol, high density lipoprotein, triglycerides)
- Abnormal thyroid function test, increased level of cortisol in the blood, increased prolactin level in the blood.

Not known: frequency cannot be estimated from the available data

- Reactivation of a herpes virus infection
- Abnormal condition of the bone marrow in which it is unable to produce normal amounts of red blood cells, white blood cells, and platelets leaving the immune system in a weakened state and vulnerable to infection
- High levels of ammonia in the blood (hyperammonaemia). The symptoms of hyperammonaemia may include irritability, confusion, vomiting, loss of appetite, and sleepiness
- Memory loss
- Inflammation which causes abdominal pain or diarrhoea (colitis)
- Skin rash that may be itchy (lichenoid keratosis)
- Nail fallout
- Fractures
- Falls.

Other possible side effects:

- There is evidence that carbamazepine can worsen symptoms of multiple sclerosis
- There is evidence of reduced vitamin B12 levels and increased serum homocysteine levels.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Curatil

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 pack carton after 'Exp'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicine 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 Curatil contains

Each prolonged-release tablet contains 200 mg carbamazepine.
Each prolonged-release tablet contains 400 mg carbamazepine.

The other ingredients are: microcrystalline cellulose, ammonio methacrylate copolymer**,** lactose monohydrate, maize starch, sodium starch glycolate type A, magnesium stearate, talc, triethyl citrate.

What Curatil looks like and contents of the pack

Curatil 200 mg Prolonged-Release Tablets: White to off-white, round, biconvex tablets, debossed with "297" on one side and "HP" on the other side.

Curatil 400 mg Prolonged-Release Tablets: White to off-white, round, biconvex tablets, debossed with "298" on one side and "HP" on the other side.

They are available in blister packs of 30, 50, 56, 100 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

Manufacturer

MIAS Pharma Limited
Suite 2, Stafford House
Strand Road
Portmarnock, Co. Dublin
Ireland

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton
LU2 8DL
UK

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