

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Curatil is and what it is used for

Curatil contains the active substance carbamazepine.

Curatil is specially formulated to release the active ingredient gradually. Carbamazepine, the active ingredient, can affect the body in several different ways. It is an anti-convulsant medicine (prevents fits), it can also modify some types of pain and can 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 think you may be hypersensitive (allergic) to carbamazepine or similar drugs such as oxcarbazepine, or to any of a related group of drugs known as tricyclic antidepressants (such as amitriptyline or imipramine) or to any of the other ingredients of Curatil . Signs of a hypersensitivity reaction include swelling of the face or mouth (angioedema), breathing problems, runny nose, skin rash, blistering or peeling.
- you have heart block,
- you have ever had decrease in bone marrow activity resulting in reduced production of blood cells,
- you have or have had a blood disorder called porphyria,

- you have taken drugs called monoamine oxidase inhibitors (MAOIs), used to treat depression, within the last 14 days.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Curatil

- A small number of people being treated with anti-epileptics such as carbamazepine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- Serious skin rashes (Stevens- Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of carbamazepine (see section 4). These serious skin reactions can be more common in people from some Asian countries. The risk of these reactions in patients of Han Chinese or Thai origin 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 carbamazepine.
- If you develop a rash or these skin symptoms, stop taking carbamazepine and contact your doctor immediately.
- If you experience dizziness, drowsiness, decrease in blood pressure, confusion, due to carbamazepine treatment, this may lead to falls.
- Your doctor may want you to have a number of blood tests before you start taking carbamazepine and from time to time during your treatment. This is quite usual and nothing to worry about.

You should also ask yourself these questions before taking Curatil If the answer to any of these questions is YES, discuss your treatment with your doctor or pharmacist because Curatil might not be the right medicine for you.

- Are you pregnant or planning to become pregnant
- Are you breastfeeding
- Do you suffer from the sort of epilepsy where you get mixed seizures which include absences
- Do you have any mental illness
- Are you allergic to an epilepsy medicine called phenytoin, primidone or phenobarbital
- Do you have liver problems
- Do you have kidney problems associated with low sodium blood level or do you have kidney problems and you are taking certain medicines that lower sodium blood levels (diuretics such as hydrochlorothiazide, furosemide)
- Are you elderly
- Do you have any eye problems such as glaucoma (increased pressure in the eye) or do you have difficulty retaining your urine

Other medicines and Curatil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell the doctor if you are taking:

- Hormone contraceptives, e.g. pills, patches, injections or implants.

Carbamazepine affects the way the contraceptive works in your body, and you may get breakthrough bleeding or spotting. It may also make the contraceptive less effective and there will be a risk of getting pregnant.

Your doctor will be able to advise you about this, and you should think about using other contraceptives.

- Hormone Replacement Therapy (HRT). Carbamazepine can make thyroid replacement therapy less effective.
- medicines for depression or anxiety such as fluoxetine, fluvoxamine, paroxetine, trazodone.
- Corticosteroids ('steroids') such as prednisolone, dexamethasone. You might be taking these for inflammatory conditions such as asthma, inflammatory bowel disease, muscle and joint pains.
- Anticoagulants to stop your blood clotting (e.g warfarin, acenocoumarol, rivaroxaban, dabigatran, apixaban and edoxaban).
- Antibiotics to treat infections including skin infections, TB (e.g isoniazid, rifampicin) and other medicines such as erythromycin, clarithromycin, ciprofloxacin, doxycycline and rifabutin.
- Antifungals to treat fungal infections (e.g . itraconazole, ketoconazole, fluconazole, voriconazole)
- Painkillers containing paracetamol, dextropropoxyphene, tramadol, methadone or buprenorphine.
- Other medicines to treat epilepsy such as vigabatrin, clobazam, clonazepam, ethosuximide, lamotrigine, eslicarbazepine, oxcarbazepine, primidone, tiagabine, topiramate, valproic acid, zonisamide.
- Medicines for high blood pressure such as diltiazem, verapamil, calcium channel blockers (dihydropyridine group, e.g felodipine, digoxin, simvastatin, atorvastatin, lovastatin, cerivastatin, ivabradine).
- Antihistamines (medicines to treat allergy such as hayfever, itch, etc) such as loratidine.
- Diuretics (water tablets) such as hydrochlorothiazide, furosemide.
- medicines to treat gastric ulcers (cimetidine or omeprazole).
- a medicine for the treatment of acne (isotretinoin).
- anti-sickness medications (metoclopramide or aprepitant).
- a medicine to treat glaucoma - increased pressure in the eye (acetazolamide).
- treatments for endometriosis (danazol or gestrinone).
- medicines used in the treatment of asthma (theophylline or aminophylline).
- immunosuppressants, used after transplant operations, but also sometimes in the treatment of arthritis or psoriasis (ciclosporin, tacrolimus or sirolimus).
- Drugs to treat schizophrenia (e.g. paliperidone, aripiprazole).
- Cancer drugs (e.g. temsirolimus, cyclophosphamide, lapatinib).
- The anti-malarial drug, mefloquine.
- Drugs to treat HIV (ritonavir, indinavir, ritonavir, saquinavir).
- drug used to treat hypothyroidism (levothyroxine).
- medicine used to treat impotence (tadalafil).
- medicine used to treat worms (albendazole).
- medicine used to help stop smoking (bupropion).
- A herbal remedy called St John's Wort or Hypericum.
- Drugs or supplements containing Vitamin B (nicotinamide).

Curatil with drink and alcohol

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

Pregnancy and breast-feeding

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

You must discuss your epilepsy treatment with your doctor well before you become pregnant. If you do get pregnant while you're taking Curatil you must tell the doctor straightaway.

It is important that your epilepsy remains well controlled, but, as with other anti-epilepsy treatments, there is a risk of harm to the foetus. The risk will be weighed against the benefit by the doctor.

Women of child bearing potential should be advised to use alternative contraceptive methods while on treatment with carbamazepine and for 2 weeks following the last dose.

Breast-feeding

The benefits of breast-feeding should be weighed against the risk of adverse effects in the infant. Breast-fed infants of mothers treated with carbamazepine should be carefully observed for side effects such as excessive sleepiness, skin reaction or yellow skin and eyes, dark urine or pale stools.

Driving and using machines:

Curatil can make you feel dizzy or drowsy, or may cause blurred vision, double vision, or you may have a lack of muscular coordination, 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.

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.

Your doctor will usually start Curatil at a lower dose which can then be increased to suit you individually. It is important to follow the doctor's ordination, especially if you have epilepsy. The dose needed varies between patients. You can take Curatil during, after or between meals. **Swallow the tablets with a drink. Do not chew them.**

You are usually told to take a dose two or three times a day.

To treat epilepsy the usual doses are:

Adults: 800-1,200 mg a day, although higher doses may be necessary. If you are elderly you might require a lower dose.

Children:

Aged 5-10 years: 400-600 mg a day

Aged 10-15 years: 600-1,000 mg a day.

Carbamazepine is not recommended for children under 5.

To treat trigeminal neuralgia the usual dose is: 600-800 mg a day. The maximum dose is 1200mg a day. If you are elderly you might require a lower dose.

To treat mood swings the usual dose is: 400-600 mg a day

If you forget to take Curatil

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, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

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

Some side effects can be serious

Stop taking Curatil and tell your doctor straight away if you notice:

- hypersensitivity reaction (serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, or skin peeling accompanied by fever). These reactions may be more frequent in patients of Chinese or Thai origin (*Very rare*)
- Mouth ulcers (*very rare*) or unexplained bruising or bleeding (*common*)
- Sore throat or fever-high temperature (*rare*), or both
- Jaundice (yellowing of your skin or the whites of your eyes) (*rare*)
- oedema (Swollen ankles, feet or lower legs) (*common*)
- Any signs of nervous illness (depression, restlessness, agitation, aggression) or confusion (*rare*)
- Lupus erythematosus (pain in your joints and muscles, a rash across the bridge of the nose and cheeks and problems with breathing) (*rare*)
- multi-organ sensitivity disorder (fever, skin rash, joint pain, and abnormalities in blood and liver function tests) (*rare*)
- Bronchospasm with wheezing and coughing, difficulty in breathing, feeling faint, rash, itching or facial swelling (these may be the signs of a severe allergic reaction) (*very rare*)
- abdominal pain (pain in the area near the stomach) (*rare*).
- you experience a fall due to dizziness, drowsiness, decrease in blood pressure, confusion (*not known*).

The side effects listed below have also been reported:

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

- Leucopenia (a reduced number of the cells which fight infection making it easier to catch infections)
- dizziness and tiredness;
- feeling unsteady or finding it difficult to control movements;
- feeling or being sick;

- changes in liver enzyme levels (usually without any symptoms);
- skin reactions which may be severe.

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

- Changes in the blood including an increased tendency to bruise or bleed;
- fluid retention and swelling;
- weight increase;
- low sodium in the blood which might result in confusion;
- headache;
- double or blurred vision;
- dry mouth.

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;
- hallucinations;
- loss of appetite;
- speech disorders;
- numbness or tingling in the hands and feet;
- 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, confused, having blurred vision);
- changes to heart beat;

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

- Changes to the composition of the blood including anaemia;
- Porphyria (severe abdominal pain, red urine, severe constipation or hallucinations);
- meningitis;
- swelling of the breasts and discharge of milk which may occur in both male and females;
- abnormal thyroid function tests;
- osteomalacia (softening of the bones);
- osteoporosis (medical condition in which the bones become brittle and fragile);
- increased blood fat 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;
- severe skin reactions including Stevens-Johnson syndrome (These reactions may be more frequent in patients of Chinese or Thai origin); Frequently, the rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes are often preceded by influenza-like symptoms fever, headache, body ache (flu-like symptoms). The rash may progress to widespread blistering and peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first months of treatment.
- sore tongue;
- liver failure;
- increased sensitivity of the skin to sunlight;
- alterations in skin pigmentation;
- acne;
- excessive sweating;
- hair loss;
- increased hair growth on the body and face;
- muscle pain or spasm;
- sexual difficulties which may include reduced male fertility, loss of libido or impotence;
- kidney failure;
- blood spots in the urine;
- increased or decreased desire to pass urine or difficulty in passing urine.

The following have also been reported, but the frequency cannot be estimated from the available information:

- Severe skin reactions, accompanied by feeling unwell and changes in blood results.
- Diarrhoea, abdominal pain, and fever (signs of inflammation of colon)
- reactivation of herpes virus infection (can be serious when immune system is depressed),
- complete loss of nails,
- fracture,
- decrease in the measure of the bone density,
- drowsiness,
- memory loss,
- purple or reddish-purple bumps that may be itchy.

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 the

national reporting system listed in the Yellow Card Scheme 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 '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

The active substance is carbamazepine.

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

Prolonged-Release Tablet

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 come in blister packs of 30, 50, 56, 100 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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