Please read this entire leaflet carefully before you start to take your medicine. It contains important information on what you should observe before taking this medicine. If you have more questions, please contact your doctor or pharmacist.

Patients information leaflet  Please, read carefully!

Qualitative and Quantitative Composition

Active ingredient:
One tablet contains as active ingredient carbamazepine 200 mg

Other ingredients:
Gelatin, Magnesium stearate, Croscarmellose sodium, Microcrystalline cellulose

Name and Address of The Marketing authorisation holder

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Clinical particulars

Antiepileptic drug

Therapeutic Indications

− Epilepsy: Partial seizures with complex symptomatology (psychomotor attacks; uncomplicated partial seizures (focal attacks); grand mal, especially of focal genesis, sleep grand mal, diffuse grand mal; mixed forms of epilepsy
− Prevention of attacks in case of alcohol withdrawal syndrome under hospital conditions
− Trigeminal neuralgia
− Genuine glossopharyngeal neuralgia
− Pain in case of diabetic neuropathy
− Non-epileptic attacks in case of multiple sclerosis such as trigeminal neuralgia, tonic spasms, paroxysmal dysarthria and ataxia, paroxysmal paraesthesia and attacks of pain
− Treatment of Acute mania and Prophylaxis of Bipolar Affective Disorders

Contraindications

In what cases you should not take these tablets?

You should not take Finlepsin® 200 in one of the following cases: bone marrow damage, atrioventricular block, known hypersensitivity against Carbamazepine or tricyclic antidepressants or against some of the other ingredients (see Qualitative and Quantitative Composition).

Finlepsin® 200 should not be taken together with MAOI or within 14 days after discontinuing MAOI-therapy

Finlepsin® 200 should not be taken in combination with Lithium (see Interactions).

Finlepsin® 200 may trigger or exacerbate a certain type of convulsions (absences). It should therefore not be used in patients suffering from absences.

In what cases you should take Finlepsin® 200 only after consulting your doctor?

The cases when one should take Finlepsin® 200 only very carefully under certain conditions are described below. In these cases you should ask the doctor before starting the treatment. The same applies if these particulars were applicable to you formerly.
- haematological disturbances (changes of blood count),
- severe cardiac, liver and kidney dysfunction (see Undesirable effects and Posology and method of administration),
- disturbed sodium metabolism.

Note: In children below 6 years of age Finlepsin® 200 should only be applied after a careful assessment of the risk/benefit ratio.

**Interactions**

Due to the undesirable effects on the central nervous system Finlepsin® 200 should not be taken together with MAOI (drugs used in depressive disorders). Or it should be taken within 14 days after discontinuing MAOI-therapy.

The simultaneous intake of Finlepsin® 200 with other antiepileptic drugs (as phenytoin, phenobarbital, primidon) may lead to a decrease of antiepileptic effects, or in rare cases may increase these effects. A monitoring of carbamazepine and other epileptics blood levels is strongly advisable. Combinations with valproic acid may lead in exceptional cases to coma and orientation loss.

The concomitant use of Finlepsin® 200 and oral anticoagulants may decrease their effectiveness therefore when starting and/or ending the carbamazepine treatment the anticoagulant dose must be set in conformity to the clinical tests.

Finlepsin® 200 as other anticonvulsive drugs may decrease the action of hormonal contraceptives. In patients taking the pill breakthrough bleeding or spotting may appear suddenly due to a decreased activity of the contraceptive. Therefore some alternative non-hormonal method of contraception should be sought.

Concurrent use of Finlepsin® 200 and neuroleptic drugs (medicines for the treatment of psychiatric disorders) may increase the occurrence of neurological side effects.

In patients receiving neuroleptic treatment, Finlepsin® 200 can decrease the plasma level and thus worsen the symptoms. Therefore if necessary, the doctor should increase the dose of the neuroleptic.

Neurotoxic effects may be increased with concurrent use of Lithium (drug for treatment of psychiatric disorders) and Finlepsin® 200. Their blood levels should be closely monitored. The following neurotoxic symptoms can be noted: unsteady gait, ataxia, horizontal nystagmus, increased involuntary muscle reflexes, muscle twitching.

The following drugs may increase the plasma levels of carbamazepine: macrolide antibiotics (erythromycin); isoniazid; calcium antagonists (verapamil; diltiazem); dextropropoxyphen; viloxacin and most probably cimetidine. In rare cases the effects of propoxyphene might be increased. The therapeutical effects of tetracyclines may be diminished.

Raised plasma levels of Finlepsin® 200 retard may lead to the symptoms listed under 'side effects' (e.g. dizziness, tiredness, unsteady gait, double vision). The Carbamazepine plasma level should be checked and the dosage reduced, if necessary, if these symptoms appear.

**What should you observe during pregnancy?**

Carbamazepine should not be used during pregnancy, but in female patients with seizures it’s use can’t be avoided. The risk of malformations in the foetus is increased in pregnant women who are treated with antiepileptics including carbamazepine. If you are planning to get pregnant, please seek advice from your doctor. Finlepsin® 200 may be used during pregnancy only after careful risk/benefit evaluation. Primarily during days 20 to 40 of pregnancy the lowest effective dose should be used. The daily dose should be taken in several small doses spread over the day. Monitoring of plasma levels is recommended.

Combination therapy with other antiepileptics as well as other medicines is not advisable, as it increases the risk of malformations. Administration of vitamin K1 to the mother during the last weeks of pregnancy and to the new-born post-partum to prevent coagulation complaints is advisable.
What should you observe during breastfeeding?
Finlepsin® 200 is excreted in breast milk, but in low concentrations, which at therapeutic dose levels do not usually put the baby at risk. Breast feeding should be stopped only, if the baby's weight increases pathologically or the baby is sedated.

Effects on the ability to drive and operate machines
Finlepsin® 200 impairs the ability to react quickly to such an extent, independent of the symptoms of the illness, that the ability to actively participate in road traffic, to operated machinery or work without secure hold may be impaired.
You would not be capable to react quickly enough to sudden and unexpected situations. Do not drive! Do not work with electrical instruments and machinery! Do not work without secure hold!
Please note that this is even more pronounced when alcohol is used.

How many tablets and how often should you take Finlepsin® 200 tablets?
Treatment is started with a low dose set individually according to the type and severity of symptoms. The dose is then slowly increased to the optimal maintenance dose to suit the patient.
Doses should be established from plasma level measurements in particular, if combination therapy is used. When changing the therapy to Finlepsin® 200, the dose of the other anticonvulsive drug should be reduced gradually. The treatment with anticonvulsants should be carried out as monotherapy and should be strictly monitored by a specialist.
The usual dosage is 400-1200 mg per day divided into 3-4 intakes.

Therapeutic levels of Finlepsin® 200 are between 4-12 µg/l. The dose required by some patients may differ substantially from the recommendation for initial and maintenance dose below, due to increased metabolism caused by auto-induction of hepatic enzymes or drug interactions during combination therapy.
In general the exceeding of a total dose of 1200 mg is not appropriate. In some cases the division of the daily dose in 4-5 daily intakes may prove efficient. Patients with severe cardiovascular diseases, liver and renal impairments as well as elderly patients require lower dosing.
Take Finlepsin® 200 exactly in accordance with the doctor’s instruction, otherwise it may not act properly. Unless otherwise advised by the doctor, the usual doses are as follows:
The daily maintainance dose is 10-20 mg/kg.

<table>
<thead>
<tr>
<th>Age</th>
<th>Daily starting dose</th>
<th>Daily maintainance dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>200 mg once</td>
<td>3 times x 200-400 mg</td>
</tr>
<tr>
<td>Children*: till 1 year of age</td>
<td>виж. указанията</td>
<td>1-2 times x 100 mg</td>
</tr>
<tr>
<td>from 1-5 years</td>
<td>виж. указанията</td>
<td>1-2 times x 200 mg</td>
</tr>
<tr>
<td>from 5-10 years</td>
<td>2 times x 100 mg</td>
<td>2-3 times x 200 mg</td>
</tr>
<tr>
<td>from 10-15 years</td>
<td>2 times x 100 mg</td>
<td>3-5 times x 200 mg</td>
</tr>
</tbody>
</table>

* For children under the age of 4 years it is recommended that the treatment starts with 20-60 mg daily. It can be increased with 20-60 mg as a daily dose every second day until the optimum dosage is reached. In children above 4 years of age the starting dose may be 100 mg daily. It can be increased with a daily dose of 100 mg every second day until the optimum dosage is reached.

Prevention of seizures during alcohol withdrawal:
The average daily dose is 200 mg three times daily. In severe cases it can be increased up to 400 mg three times daily. The concomitant use of Finlepsin® 200 with sedative/hypnotic drugs is not recommended in case of delirium tremens. The Carbamazepine blood level should be checked regularly. The treatment should be stopped after 7-10 days by gradual decreasing of the dosing.

Trigeminus neuralgia, genuine glossopharyngeal neuralgia
The initial daily dose is 200-300 mg and can be increased up to 400-800 mg daily, divided as multiple single doses. The dose may be gradually reduced to a lower but still eliminating the pain maintenance dose of 400 – 600 mg Carbamazepine).
In elderly patients a starting daily dose of 200 mg may prove sufficient.

**Pain diabetic neuropathy**

The average daily dose is 200 mg 3 times daily and in exceptional cases 400 mg 3 times daily.

**Non-epileptic attacks in multiple sclerosis**

The average daily dose is 200 mg 2-4 times daily.

**Prophylactic treatment of psychoses and manic-depressive attacks**

The starting dose is 1200 mg daily divided in multiple single doses. The maintainance dose is 200 mg 3 times a day.

In patients with acute schizophrenia Finlepsin® 200 should be applied in combination with neuroleptic.

**Acute mania and Prophylaxis of Bipolar Affective disorders**

Dosage range: 400- 1600 mg/day.

The usual dose is 400-600mg/day in divided doses ; in acute mania – the dose may be gradually increased until symptoms are controlled. In the prophylaxis of bipolar affective disorders- smaller dose increasing to provide optimal patient tolerability.

**How and when should you take Finlepsin® 200?**

Swallow the tablet during or after meal with enough liquid (for example a glass of water).

**How long should you take Finlepsin® 200?**

The duration of the treatment should be decided according to the diagnosis and the individual course of the disease.

Basically the treatment of the convulsive disorders is a long-term treatment. In the individual case a specialist (neurologist, neuropaediatrician) should decide on the dosage regimen.

**Undesirable effects**

Which undesirable effects are possible during the treatment with Finlepsin® 200?

The described side effects are more frequent in combination therapy than in monotherapy. The following side effects appear dependent on the dose in particular at the start of therapy:

**CNS/Psychiatric**

Frequent: dizziness, somnolence, sedation, drowsiness, fatigue, ataxia, (atactic and cerebral disturbances), occasional headache, confusion and agitation in elderly patients.

Psychological effects: occasional: Depressive disorders, aggressive behaviour, thinking difficulties, lack of drive, hallucinations, tinnitus. Latent psychosis may be activated by Finlepsin® 200 treatment.

Rare: Involuntary movements like asterixis, tics or nystagmus. In elderly or patients with cerebral damage dyskinetic disturbances like orofacial dyskinesia (involuntary movements of the face like making faces) and choreoathetotic disorders (screwed up movements) may appear.

Isolated cases: Speech disorders, paraesthesia, muscle weakness, peripheral neuritis, paresis of the legs and taste disorders.

Most of these effects disappear during the first 8-14 days of treatment either spontaneously or after a transient dosage reduction. For this reason treatment should be started with a low dose, which is gradually increased.

**Eyes**
Isolated cases: Conjunctivitis. Rare: Transient visual disturbances, like accommodation disorders, diplopia, lens opacities. The intra-ocular pressure of patients suffering from glaucoma should be checked regularly.

Musculoskeletal system
Isolated cases of arthralgia, muscle pain or cramp are observed which recede after the discontinuation of Finlepsin® 200 tablets.

Skin and mucous membranes
Occasionally to frequent: Allergic skin reactions with or without fever like e.g. urticaria, pruritus, isolated cases of exfoliative dermatitis, erythroderma, Lyell-syndrome, photosensitivity, erythema exsudativum multiforme et nodosum, Stevens-Johnson syndrome, purpura, lupus erythematosides disseminatus were reported.
Occasionally to rarely alopecia, diaphoresis and vasculitis appeared.

Blood and lymphatic system
Occasionally to frequent: Changes in blood count i.e. leucocytosis, eosinophilia, leucopenia, thrombocytopenia. According to literature sources the most frequent disorder is benign leucopenia, 10 % of the cases being of a transient nature, 2 % persistent.
Isolated cases of even life threatening damage of blood cells were reported i.e. agranulocytosis, aplastic anaemia and other forms of anaemia (haemolytic, megaloblastic) and lymphadenopathy, spleen enlargement.
As hypersensitivity reactions enlargement of the lymph nodes, vasculitis, pyrexia and skin rash were reported.
If leucopenia (especially neutropenia), thrombocytopenia, allergic skin rash and fever appear the therapy must be discontinued.

Gastro-intestinal tract
Occasional: Loss of appetite, dry mouth, nausea, vomitting. Rare: Diarrhoea, constipation.
Isolated cases: Abdominal pain, stomatitis, gingivitis, glossitis.
These effects usually disappear during the first 8-14 days of treatment either spontaneously or after a transient dosage reduction. (low initial dose). Literature suggests that Finlepsin® 200 may induce pancreatitis.

Liver and gall bladder
Occasional: Altered liver function test values. Rare: Jaundice. Isolated cases of hepatitis (cholestatic, hepatocellular, granulomatous, mixed type). Two cases of acute intermittent porphyria were reported.

Metabolism (water and minerals), hormone status
Isolated cases of gynaecomastia and galactorrhoea were reported.
Thyroid function parameters T₃, T₄, TSH and FT₄ may be altered in particular during combination therapy.
Due to the antidiuretic effect of Finlepsin® 200 rare cases of hyponatraemia accompanied by vomitting, headache and rarely confusion were observed.
Isolated cases of oedema and weight gain were reported.
Finlepsin® 200 may increase the metabolism of 25-OH-Cholecalciferol leading to a decreased calcium level, which rarely causes osteomalacia.

Respiratory tract
Isolated cases of pulmonary hypersensitivity reactions with fever, dyspnoea, pneumonitis or pneumonia (alveolitis), lung fibrosis.

Urogenital tract
Rarely renal impairment such as proteinuria, haematuria, oliguria are reported, isolated cases of renal failure, which are possibly due to the antidiuretic effect of Finlepsin® 200, additionally other micturition disorders like dysuria, urinary frequency and urinary retention.
Isolated cases of sexual dysfunction like impotence, decreased libido and impaired male fertility.

**Cardiovascular system**

Isolated cases of bradycardia, cardiac arrhythmias and worsening of coronary artery disease in particular in elderly or patients with known disturbance of cardiac function are reported. Rarely an AV-block was observed in isolated cases with syncope and hypertension or hypotension. High dose of Finlepsin® 200 in particular may lead to a fall in blood pressure. Thrombophlebitis and thrombo-embolism have been reported.

**Hypersensitivity reactions**

Rare: delayed multi-organ hypersensitivity disorder with fever, skin rashes, vasculitis, swollen lymph nodes, painful joints (arthritis), leucopenia, eosinophilia, enlargement of liver and spleen or altered liver function test occurring in various combinations. Other organs such as lung, kidney, pancreas and cardiac muscle may also be affected. Isolated cases of a generalised acute allergic reaction and aseptic meningitis with myoclonus and eosinophilia have been observed.

Inform your doctor or pharmacist if you notice any undesirable effects not enlisted in this package insert.

**Overdose and other possible mistakes**

**If you have forgotten to take Finlepsin® 200:**
In case you forget a single dose you should take the medicine immediately when you notice this. If the next regular take is soon after that, you should miss it and try to apply the drug according to the initial dosage scheme. Under no circumstances you should compensate the forgotten dose by taking the double quantity. If you are not sure about anything, please ask your doctor for advice.

**Effects if the treatment with Finlepsin® 200 is discontinued:**
Under no circumstances you should discontinue or permanently terminate the treatment with Finlepsin® 200 without your doctor’s consent because this may endanger your health. This may again induce or exacerbate the symptoms of your disease. Before you discontinue your treatment you must ask your doctor for advice.

**If you have taken a larger quantity of Finlepsin® 200 than you should:**
Emergency measures have to be initiated if high doses were taken (admission to hospital). In connection with an overdose the undesired events as for example tremor, tonic-clonic seizures, agitation, respiratory and cardiovascular disturbances usually linked with hypotension (possibly hypertension), tachycardia, AV-block, ECG-changes, conduction disturbances may occur with a higher intensity. Isolated cases of altered laboratory findings: leucocytosis, leucopenia, neutropenia, glycosuria, acetonuria. There is no specific antidote. Management according to the patients’ clinical condition should be done in a hospital.

**Expiry date:**
The expiry date of Finlepsin® 200 is marked on the blister and the folding box. Do not use the drug after the expiry date.

**Keep the drug out of the reach of children!**
Finlepsin® 200 is packed in blisters that are additionally secured against the reach of children. If you experience difficulties to take out the tablets from the package, try to slightly tear the foil.

**Latest update**
August 2006