1. **WHAT FINLEPSIN 400 RETARD IS AND WHAT IT IS USED FOR**

Finlepsin 400 retard is a drug for treatment of epileptic convulsive diseases and other convulsive diseases, of certain painful states as well as for prevention of certain psychic disorders.

Finlepsin 400 retard is used in the treatment of:
- **Epilepsies:** Seizures originating in a circumscribed brain area (focal seizures). The seizures may occur without disturbances of consciousness (simple partial seizures) or with disturbances of consciousness (complex partial seizures, psychomotor seizures).
- Seizures affecting both halves of the brain (generalized seizures), in particular seizures originating in a circumscribed brain area (nocturnal epilepsy, diffuse epilepsy); mixed forms of epilepsy.
- Attacks of facial pain (trigeminal neuralgia).
- Attacks of pain in the throat of unknown origin (genuine glossopharyngeal neuralgia).
- Painful states due to injury of nerves caused by diabetes (painful diabetic neuropathy).
- Non-epileptic seizures in people suffering from multiple sclerosis, such as trigeminal neuralgia, tonic seizures (characterized by normal muscular tone), seizures of speech disorders and movement disorders, abnormal sensations (paroxysmal dysarthria and ataxia, paroxysmal paraesthesias) and attacks of pain.
- Prevention of attacks in the alcohol withdrawal syndrome.
- Prevention of manic-depressive phases (certain mental disturbances with mood swings) if a lithium therapy has failed, if patients have undergone rapid phase changes under lithium or if lithium is contraindicated.

2. **BEFORE YOU TAKE FINLEPSIN 400 RETARD**

*Finlepsin 400 retard should not be taken in the following cases:*
- If you are hypersensitive (allergic) to carbamazepine, to tricyclic antidepressants or any of the other ingredients of Finlepsin 400 retard.
- Damage to the bone marrow.
- Conduction disorders of the heart (atrioventricular block).
- acute intermittent porphyria (a hereditary metabolic defect)
- simultaneous treatment with a monoamine oxidase inhibitor (antidepressant)
- simultaneous treatment with voriconazole (a drug used to treat fungal infections), since treatment with this drug may be rendered ineffective.

**Particular caution is required taking Finlepsin 400 retard:**

As Finlepsin 400 retard may cause absences (states of clouded consciousness) or intensify existing ones, it should not be given to patients suffering from this type of seizure.

In the following cases Finlepsin 400 retard should only be administered after a stringent benefit/risk assessment and after taking the necessary precautions to patients with:
- diseases of the blood-forming organs (haematological diseases)
- a disordered sodium metabolism
- serious functional disturbances of the heart, liver and kidneys (see "3. How to take Finlepsin 400 retard" and "4. Possible side effects")
- myotonic dystrophy (a degenerative disease of the muscles), as these patients frequently suffer from cardiac conduction disorders.

If symptoms such as fever, a sore throat or allergic skin reactions like rashes with lymph node enlargement and / or influenzal symptoms occur under a Finlepsing 400 retard therapy, a doctor should be seen at once and a blood count taken.

In case of serious allergic reactions, Finlepsin 400 retard should be discontinued at once.

Certain changes in the blood picture (in particular leucocytopenia and thrombocytopenia) may require Finlepsin 400 retard to be discontinued. This is definitely the case if they are accompanied by allergic symptoms, fever, a sore throat or skin bleeding.

If symptoms of hepatitis occur, such as sluggishness, lack of appetite, nausea, yellowing of the skin and enlargement of the liver, you should see a doctor without delay.

In view of the adverse drug reactions listed under "Possible side effects" and the hypersensitivity reactions that may possibly occur, the blood picture as well as the kidney and liver functions should be regularly checked, particularly in a long-term therapy.

In a combination therapy it is necessary to check the plasma concentrations of carbamazepine and the other anti-epileptic agents and to reduce the daily doses, if required.

Before starting the Finlepsin 400 retard therapy, it is advisable to check the blood picture and the liver parameters. Then in the first month of treatment checks should take place at weekly intervals and later at monthly intervals. After 6 months of treatment 2 or 4 checks a year may be sufficient.

Patients with glaucoma should be regularly tested for their intra-ocular pressure.

Epileptic patients treated with Finlepsin 400 retard should not be abruptly changed over to another therapy. If a changeover is required, the Finlepsin 400 retard dose should be gradually reduced and replaced by another agent.

For "Prevention of attacks during the alcohol withdrawal syndrome", Finlepsin 400 retard should always be taken under hospital conditions.

Please note that the side effects of carbamazepine during treatment of the alcohol withdrawal syndrome may be similar to the withdrawal symptoms and could easily be confused with them.

If Finlepsin 400 retard is combined with lithium to prevent manic-depressive phases (which may be necessary if lithium alone is not sufficiently effective), adverse drug reactions (as described below under "Combination of Finlepsin 400 retard with other medicinal products") should be avoided by making sure that a certain carbamazepine plasma concentration (8 µg/ml) is not exceeded, that the lithium level is kept within a low therapeutic range (0.3 to 0.8 mval/l) and that the patient has not been treated with neuroleptics (drugs used in the treatment of psychoses) in the last 8 weeks and is not currently being treated with them.

During treatment with carbamazepine patients should avoid exposure to intense sunlight as there is a danger of photosensitization (increased sensitivity of the skin to light).

A small number of people being treated with anti-epileptics such as Finlepsin 400 retard have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
Serious skin side effects can rarely occur during treatment with Finlepsin 400 retard. This risk can be predicted with blood sample in people of Chinese and Thai origin. Discuss this with your doctor before taking Finlepsin 400 retard if you are of such origin.

**Combination of Finlepsin 400 retard with other drugs**

Please inform your doctor or pharmacist if you take any other drugs – even drugs available without prescription – or have taken them until recently.

Treatment with MAO inhibitors (antidepressants) should have stopped at least two weeks before a course of treatment with Finlepsin 400 retard is due to begin.

Please bear in mind that the following may also apply to drugs taken until recently.

**Finlepsin 400 retard affecting the plasma concentration of other drugs:**

Finlepsin 400 retard may increase the activity of certain liver enzymes and thereby lower the plasma levels of other drugs. This may weaken or even annul the effect of some other concurrently administered drugs that are broken down the same way as carbamazepine.

If the following active substances from various fields of application are administered together with Finlepsin 400 retard, their dosage may have to be adapted to clinical requirements:

- clonazepam, ethosuximide, felbamate, primidone, lamotrigine, tiagabine, topiramate, valproic acid (anti-epileptics, other anticonvulsants)
- alprazolam, clobazam (anti-anxiety agents)
- haloperidol, bromperidol, clozapine, olanzapine, risperidone, quetiapine (antipsychotic agents)
- imipramine, amitryptiline, nortryptilnine, clomipramine (antidepressants)
- tetracyclines, such as doxycycline (antibiotics)
- agents for treatment of (systemic) fungal infections: caspofungine, azole-type antimycotics (such as voriconazole, itraconazole)
- alprazolam, clobazam (anti-anxiety agents)
- haloperidol, bromperidol, clozapine, olanzapine, risperidone, quetiapine (antipsychotic agents)
- imipramine, amitryptiline, nortryptilnine, clomipramine (antidepressants)
- tetracyclines, such as doxycycline (antibiotics)
- agents for treatment of (systemic) fungal infections: caspofungine, azole-type antimycotics (such as voriconazole, itraconazole)
- indinavir (antiviral agent/HIV)
- praziquantel (antiparasitic agent)
- fentanyl (anaesthetic agent), midazolam (narcotic agent / tranquilizer)
- methylphenidate (psychostimulant, agent for treatment of attention disorders)
- phenazone (analgesic), methadone (analgesic)
- flunarizine (calcium antagonist; agent for treatment of dizziness, migraine)
- theophylline (agent for treatment of serious respiratory diseases)
- quinidine (agent for treatment of cardiac arrhythmias)
- digoxin (agent for treatment of heart diseases)
- propranolol (beta blocker, antihypertensive agent)
- felodipine (antihypertensive agent)
- corticosteroids (such as prednisolone, dexamethasone)
- ciclosporine (inhibitor of defence mechanisms after organ transplantation, immunosuppressive agent)
- tacrolimus (immunosuppressive agent)
- anticoagulants such as warfarin, phenprocoumon, dicumarol
- hormonal contraceptives.

If you are taking the "pill" (a hormonal contraceptive), a decrease in its effectiveness may result in sudden intermenstrual bleeding. Together with your doctor you should therefore consider using other – nonhormonal – methods of contraception.

Finlepsin 400 retard may both increase and reduce the plasma concentration of phenytoin; in exceptional cases this may cause states of confusion up to the point of coma.

Finlepsin 400 retard may lower the plasma level of bupropione (an agent supporting nicotine withdrawal) and increase that of its breakdown product hydroxbupropione, thus reducing the clinical efficacy and reliability of bupropione.

Finlepsin 400 retard may lower the plasma level of trazodone (antidepressant), but seems to intensify its antidepressant effect.

It is possible that Finlepsin 400 retard speeds up the breakdown of zotepine (an agent used in the treatment of psychic disorders).
Other drugs reducing the plasma concentration of Finlepsin 400 retard:
The plasma levels of Finlepsin 400 retard may be reduced by:
phenobarbital, phenytoin, primidone, valproic acid (other anti-epileptics), theophylline (agent used in
the treatment of serious respiratory diseases), rifampicin (antibiotic), doxorubicin, cisplatin (agents
used in the treatment of cancerous diseases), St. John’s wart (herbal antidepressant). But the plasma
levels of its pharmacologically active breakdown product (carbamazepine-10,11-epoxide) may be
raised by valproic acid as well as by primidone.
By comedication with felbamate, the carbamazepine plasma level may be lowered and the
carbamazepine-10,11-epoxide plasma level raised, which lowers the felbamate level.
In view of this mutual interaction, the plasma levels should be checked – particularly in a combination
therapy involving several anti-epileptics – and, if required, the Finlepsin 400 retard dose adapted.

Other drugs increasing the plasma concentration of Finlepsin 400 retard:
The following active substances may increase the plasma concentration of Finlepsin 400 retard:
- macrolide antibiotics such as erythromycin, troleandomycin, josamycin, clarithromycin
  (substances for treatment of bacterial infections)
- isoniazid (agent for treatment of tuberculosis)
- antifungal activities of the azole type, such as itraconazole, ketoconazole, fluconazole (agents for
treatment of fungal infections)
- ritonavir (agent for treatment of viral diseases / HIV)
- calcium antagonists such as verapamil, diltiazem (substances for treatment of angina
  pectoris)
- acetazolamide (agent for treatment of glaucoma)
- dextropropoxyphene / propoxyphene (pain killer)
- viloxazine, nefazodone, fluoxetine (antidepressants)
- danazol (inhibitor of the sexual hormone gonadotropin)
- cimetidine (agent for treatment of gastro-intestinal ulcers)
- large doses of nicotine in adults (vitamin B group)
- terfenadine, loratadine (agents for treatment of allergic reactions)
- possibly also desipramine and fluvoxamine (antidepressants)
Increased plasma levels of Finlepsin 400 retard may cause symptoms such as are mentioned under
"Possible side effects" (dizziness, tiredness, unsteadiness of gait, double vision). If such symptoms
occur, the carbamazepine concentration should be checked and the dose reduced, if necessary.

Other interactions:
The combined use of Finlepsin 400 retard with neuroleptics (drugs used in the treatment of
psychoses) or metoclopramide (agent for treatment of gastrointestinal disorders) may trigger the
occurrence of neurological side effects. The administration of Finlepsin 400 retard to patients treated
with neuroleptics may, on the other hand, reduce the plasma levels of these drugs and thus cause a
deterioration of the clinical picture. The attending physician may therefore think it necessary to
increase the dose of the neuroleptic.
It should be pointed out that the simultaneous administration of lithium (agent for treatment and
prevention of certain mental diseases) and Finlepsin 400 retard may intensify the harmful effects of
both active substances on the nervous system. The blood levels of both substances should be carefully
monitored. The use of neuroleptics during an eight-week period preceding the Finlepsin 400 retard
treatment and during treatment should be ruled out. The following symptoms should be watched for:
an unsteady gait (ataxia), drifting and flicking back of the eyes (horizontal nystagmus), an increase in
muscular reflexes and muscle twitching (fasciculation).
There are indications in the literature that the taking of carbamazepine by patients treated with
neuroleptics increases the risk of a malignant neuroleptic syndrome (a potentially life-threatening
condition with increased body temperature and muscular stiffness) or a Stevens-Johnson syndrome
(serial skin reaction).

The hepatotoxic effect of isoniazid (agent for treatment of tuberculosis) may be increased by Finlepsin
400 retard.
The combined administration of Finlepsin 400 retard with a number of diuretic agents
(hydrochlorothiazide, furosemide) may result in a reduced sodium content of the blood serum.
The efficacy of muscle relaxant agents such as pancuronium may be impaired by Finlepsin 400 retard, resulting in the earlier lifting of the neuromuscular blockade. This effect should be watched for in patients treated with muscle relaxants and the dosage of the drug should be increased, if necessary. If Finlepsin 400 retard is administered together with isotretinoin (an anti-acne agent), the carbamazepine plasma levels should be watched.

The combined administration of Finlepsin 400 retard with paracetamol (a pain killer and antipyretic) may reduce the bioavailability and thus the efficacy of paracetamol.

Carbamazepine seems to intensify the elimination of thyroid hormones and to increase the need of hypothyroid patients for these hormones. The thyroid parameters of patients undergoing a hormone-substitution therapy should therefore be determined at the start and at the end of a Finlepsin 400 retard therapy. If necessary, the dose of the thyroid hormone preparations has to be adapted.

The combined administration of Finlepsin 400 retard with antidepressants of the type of serotonin re-uptake inhibitors (such as fluoxetine) may trigger a toxic serotonin syndrome.

Finlepsin 400 retard should not be used in combination with nefazodone (an antidepressant) as it may cause a marked reduction in the nefazodone plasma level and possibly render it completely ineffective. Simultaneous administration of nefazodone and Finlepsin 400 retard increases moreover the carbamazepine plasma level and lowers the plasma level of its active breakdown product, carbamazepine-10,11-epoxide.

The risk of cardiac conduction disorders (disturbed stimulus conduction at the heart) is increased if carbamazepine is combined with other drugs that may cause such disorders, such as antiarrhythmics (for treatment of disordered heart rhythm), cyclic antidepressants (for treatment of depression) or erythromycin (an antibiotic).

An increase in the carbamazepine plasma level after drinking grapefruit juice has been reported. Like other substances that act on the central nervous system, carbamazepine may reduce the patients’ alcohol tolerance. You should therefore abstain from drinking alcohol during a therapy with Finlepsin 400 retard.

Taking Finlepsin 400 retard together with food and drink
During treatment with Finlepsin 400 retard you should abstain from drinking alcohol, as the effect of Finlepsin 400 retard may be changed and intensified in an unforeseeable way.

Pregnancy and breast-feeding period
During pregnancy carbamazepine should only be prescribed after a careful benefit-risk assessment by the attending physician. Women longing for a baby should seek the advice of their doctor and ensure that they receive regular medical attention during their pregnancy.

As for other anti-epileptics, various malformations have also been described for carbamazepine. Studies show that the risk of developing clefts of the spinal column (bifid spine) has increased to about 1 %. It is still unclear to what extent the carbamazepine treatment is responsible for these malformations, as a causal relation with the basic disease or genetic factors cannot be ruled out. Diagnostic measures such as ultrasonic and alpha-foetoprotein tests are recommended for early detection of possible damage to the foetus.

If possible, women of child-bearing age should use carbamazepine as a monotherapy, particularly during a pregnancy, as a combination therapy involving other anti-epileptics increases the risk of malformation.

If a pregnancy occurs under a carbamazepine therapy or if a carbamazepine therapy becomes necessary during pregnancy, the doctor should carefully weigh the need to keep seizures under control against the possible risk of this therapy to the unborn child. During the first three months of pregnancy, when the risk of malformations is greatest, and especially between the 20th and 40th day after fertilization, the lowest effective dose should be used, as malformations are probably caused by high plasma concentrations of the active substance. Checks of the plasma levels are recommended. In no case should you stop taking the tablets without consulting your doctor, as epileptic seizures may injure the child. A deficiency of folic acid caused by carbamazepine activating liver enzymes may be an additional factor for the development of malformations. The administration of folic acid before and during pregnancy makes therefore sense. Vitamin K₁ may be administered to the mother in the last
few weeks of pregnancy and, after birth, to the newborn child as a prophylactic measure to avoid blood-clotting disorders.
Only small amounts of carbamazepine pass into the mother’s milk. Breast feeding is therefore usually possible during treatment. Weaning the infant should only be considered, if the baby does not sufficiently gain in weight or shows an abnormal sleep requirement (sedation).

_Before taking / using any drugs, ask your doctor or pharmacist for advice._

**Children**
Finlepsin 400 retard is unsuitable for children under 6 years of age on account of its high drug content and a general lack of experience with prolonged release tablets in this age group.

**Elderly people**
A lower dose is indicated for elderly patients (see also "How to take Finlepsin 400 retard").

**Effects on the ability to drive and to operate machines**
At the start of treatment, after an increase in dosage and / or in combination with other drugs that also act on the central nervous system, Finlepsin 400 retard – even when used in accordance with instructions – may cause central nervous side effects, such as dizziness, drowsiness or tiredness that affect the patients’ reactivity to such an extent – irrespective of the effects of the basic disease to be treated – as to impair, for example, their ability to drive a car, to operate machines or to work without secure support. These effects are heightened in conjunction with alcohol.
You are no longer in a position to react swiftly and appropriately to unexpected and sudden events. Do not drive a car or other vehicle. Do not operate electrical tools and machines. Do not work without secure support. Remember in particular that your ability to drive is bound to be further impaired by alcohol.

### 3. HOW TO TAKE FINLEPSIN 400 RETARD

*Always take Finlepsin 400 retard exactly the way your doctor has told you to. Check with your doctor or pharmacist if you are not quite sure.*

**The usual dosage, unless otherwise prescribed by your doctor:**
The dosage will be individually determined and checked by a specialist physician with the aim of achieving freedom from seizures with the lowest possible dose, particularly during pregnancy.
So as not to jeopardise therapeutical success, do not make any changes in your course of treatment or dose without consulting your doctor first.
A gradual dose buildup is recommended until the optimal response is achieved.
The daily dose is usually administered as 1 or 2 single doses and ranges from 400 to 1200 mg of carbamazepine.
A total daily dose of 1600 mg of carbamazepine should not be exceeded, as larger doses tend to have more side effects.
Particularly in a combination therapy the therapeutic dose should be fixed by determining the plasma levels, taking the efficacy of the drugs into account. Experience shows that the therapeutic carbamazepine level ranges from 4 to 12 µg/ml. In individual cases the required dose may considerably differ from the indicated initial and maintenance doses (due, perhaps, to an accelerated metabolism caused by enzyme induction or by interactions with other drugs in a combined therapy).
In the treatment of epilepsy Finlepsin 400 retard should preferably be used on its own (monotherapy).
The therapy should be supervised by a specialist experienced in the treatment of epilepsy.
When changing over to Finlepsin 400 retard, the dose of the previous anti-epileptic should be gradually reduced.
The following general dosage scheme is recommended for treatment of epileptic convulsive disorders:
### Convulsive disorders (epilepsy):

In the treatment of adults the initial dose of ½ - 1 Finlepsin 400 retard prolonged release tablets (equivalent to 200 - 400 mg of carbamazepine a day) should be slowly increased to the maintenance dose of 2 - 3 Finlepsin 400 retard tablets (equivalent to 800 to 1200 mg of carbamazepine a day). The average maintenance dose for children is generally 10 to 20 mg carbamazepine/kg BW/day. Recommended dosage scheme: see above

### Attacks of facial pain (trigeminal neuralgia), attacks of pain of unknown origin in the throat (genuine glossopharyngeal neuralgia):

From an initial dose of ½ - 1 Finlepsin 400 retard prolonged release tablets (equivalent to 200 - 400 mg of carbamazepine) the daily dose is increased to an average of 1 - 2 Finlepsin 400 retard tablets (equivalent to 400 - 800 mg of carbamazepine), to be taken in 1 - 2 single doses a day until the patient is free from pain. In some cases the treatment may be continued with a reduced maintenance dose of ½ Finlepsin 400 retard prolonged release tablet taken twice a day (equivalent to 400 mg of carbamazepine).

For elderly and sensitive patients an initial dose of ½ Finlepsin 400 retard tablet (equivalent to 200 mg of carbamazepine) taken in a single dose in the morning or at night may be sufficient.

### Painful states due to injury of peripheral nerves caused by diabetes (painful diabetic neuropathy):

The average daily dose is ½ Finlepsin 400 retard tablet taken in the morning and 1 taken at night (equivalent to 600 mg of carbamazepine). In exceptional cases the daily dose may be increased to 1½ Finlepsin 400 retard tablets taken twice a day (equivalent to a total of 1200 mg of carbamazepine).

### Non-epileptic seizures in multiple sclerosis:

The average daily dose is ½ - 1 Finlepsin 400 retard prolonged release tablets taken twice a day (equivalent to 400 – 800 mg of carbamazepine).

### Prevention of attacks during hospital treatment of the alcohol withdrawal syndrome:

The average daily dose is ½ Finlepsin 400 retard prolonged release tablet taken in the morning and 1 tablets taken at night (equivalent to 600 mg of carbamazepine).

In serious cases the dose may be increased in the first few days to 1½ Finlepsin 400 retard tablets taken twice a day (equivalent to 1200 mg of carbamazepine).

A combination of Finlepsin 400 retard with sedative-hypnotic agents (tranquillizers/hypnotic agents) is not recommended. Finlepsin 400 retard may, however, be combined with other substances used in the treatment of alcohol withdrawal symptoms, depending on clinical requirements.

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<tr>
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<th>Daily initial dose</th>
<th>Daily maintenance dose</th>
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<tr>
<td><strong>Adults</strong></td>
<td>200 – 300 mg at night</td>
<td>200 – 600 mg in the morning 400 – 600 mg at night</td>
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<tr>
<td><strong>Children</strong>*</td>
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<tr>
<td>6 – 10 years</td>
<td>200 mg at night</td>
<td>200 mg in the morning 200 – 400 mg at night</td>
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<tr>
<td>11 – 15 years</td>
<td>200 mg at night</td>
<td>200 – 400 mg in the morning 400 – 600 mg at night</td>
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*Note: A pharmaceutical form other than prolonged release tablets is available for children under 6 years of age for initial and maintenance dosing. Owing to insufficient experience we cannot recommend administration of prolonged release tablets.
The carbamazepine level should be regularly checked. Careful clinical checks for any central nervous and vegetative side effects are recommended (cf. withdrawal symptoms under "Possible side effects").

**Prophylaxis of manic-depressive phases:**

The initial dose – usually also sufficient as maintenance dose – is ½ - 1 Finlepsin 400 retard prolonged release tablets a day (equivalent to 200 - 400 mg of carbamazepine). If required, the dose may be increased to 1 Finlepsin 400 retard tablets taken twice a day (equivalent to 800 mg of carbamazepine).

**Note:**
A lower dose is indicated for patients with serious cardiovascular diseases, with liver and kidney diseases as well as for elderly patients.
In some cases the division of the daily dose into 4 or 5 single doses proved to be especially effective.
Pharmaceutical forms of carbamazepine other than prolonged release tablets are, however, preferable for this purpose.

**Method of administration**
The prolonged release tablets are divisible.
They are taken during or after meals with sufficient liquid (e.g. a glass of water).
After their disintegration (suspension) in water, the prolonged release tablets may be drunk. Their character as prolonged release tablets is preserved even in the suspended state.

**Duration of administration**
The duration of administration, which depends on the indication and on the patient’s individual response, is fixed by the attending physician.
The anti-epileptic therapy is a long-term therapy.
Questions such as stabilization, duration of treatment and discontinuation of Finlepsin 400 retard should be individually decided by a specialist experienced in the treatment of epilepsy.
A dose reduction and the discontinuation of the medication should generally not be considered before the patient has been free from seizures for two or three years.
To discontinue treatment, the dose has to be gradually reduced over a year or two. Children should be allowed to grow out of the dose in terms of kg BW instead of adapting the dose to their age. Their EEG should not deteriorate in the process.
In the treatment of neuralgia it has proved worthwhile to administer a maintenance dose just sufficient to ensure freedom from pain for a few weeks. Whether or not a spontaneous regression had taken place was verified by a cautious dose reduction. If attacks of pain recurred, treatment was continued with the original maintenance dose.
The duration of treatment in cases of painful diabetic neuropathy and non-epileptic seizures in multiple sclerosis was determined in the same way.
To prevent attacks during treatment of the alcohol withdrawal syndrome, the Finlepsin 400 retard therapy should be terminated with a gradual dose reduction after 7 to 10 days.
Prophylaxis of manic-depressive phases is a long-term treatment.

**If you have taken more Finlepsin 400 retard than you should**
An overdosage requires immediate medical attention.
After administration of an overdose of Finlepsin 400 retard, the undesirable symptoms listed under "Possible side effects" may reappear with a vengeance.
The following symptoms may additionally occur:
tremor, agitation, convulsive seizures of the brain (tonic-clonic convulsions) as well as respiratory and cardiovascular disorders, mostly with low (occasionally also high) blood pressure, an increased heart rate (tachycardia) and conduction disorders of the heart (AV block; changes in the ECG), disturbances of consciousness up to the point of respiratory and cardiac arrest.
In isolated cases the laboratory parameters were found to be changed: leucocytosis, leucopenia, neutropenia (increased or decreased numbers of white blood cells), glucosuria (excess sugar in the urine), acetonuria (increased presence of a certain breakdown product in the urine).
Whenever Finlepsin 400 retard has been wrongly administered (either too much or too little of it), a physician should be immediately informed. If large doses have been taken, emergency measures should be initiated (admission to a hospital).

A specific antidote to acute poisoning with Finlepsin 400 retard does not yet exist. Treatment of an overdose of Finlepsin 400 retard depends on the symptoms and should generally take place in hospital.

If you have forgotten to take your dose of Finlepsin 400 retard
Do not take a double dose if you have forgotten the previous one. Continue to take your medicine as directed.

Consequences of breaking off treatment with Finlepsin 400 retard
Do not temporarily stop or terminate treatment with Finlepsin 400 retard on your own authority. Please consult the attending physician beforehand if you are faced with incompatibilities or with a changed clinical picture. Otherwise you might jeopardise therapeutical success and trigger new epileptic seizures.

If you have further questions concerning the use of the drug, please consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all drugs, Finlepsin 400 retard may have side effects, which are not bound to occur in every case. The frequency of the occurrence of side effects is based on the following categories:

- **very common** more than 1 patient in 10
- **common** 1 to 10 patients in 100
- **uncommon** 1 to 10 patients in 1000
- **rare** 1 to 10 patients in 10 000
- **very rare** fewer than 1 patient in 10 000
- **not known** frequency cannot be estimated on the basis of the available data

Side effects occurred less frequently when carbamazepine was administered on its own (monotherapy) than when it was combined with other anti-epileptic agents (combination therapy).

The occurrence of many side effects is dose-related, especially at the start of treatment. They mostly disappear on their own after 8 to 14 days or after a temporary dose reduction. Finlepsin 400 retard should therefore be administered using small initial doses and gradually increasing to optimal amounts.

Disorders of the central nervous system / psychiatric disorders:
Very frequent occurrences are somnolence, dizziness, tiredness, sleepiness, gait and movement disorders. Headaches as well as confusion and agitation in elderly patients are occasional side effects. In addition, there have been very rare cases of mood changes, such as depressive or manic mood swings (characterized by depression or euphoria, sometimes combined with violent behaviour), phobic disorders (anxiety disorders), aggressive behaviour, inhibited thinking, lack of drive, misperceptions (hallucinations) and ringing in the ear (tinnitus), increased or reduced hearing (hyperacusis and hypoacusis) as well as changes in the perception of tone pitches. Latent psychoses (subthreshold mental disorders) may be activated under the Finlepsin 400 retard treatment.

Occasional side effects are involuntary movements (such as flapping tremor, muscle twitching), disturbances of ocular motor functions with ocular tremor (nystagmus) and / or double images. Elderly and brain-damaged patients may be affected by movement disorders, e.g. involuntary movements such as grimacing (orofacial dyskinesias) and writhing movements (choreoathetosis). There have also been very rare reports of speech disorders, inappropriate sensations, muscular weakness, nervous diseases (polyneuropathy), inflammation of nerves (peripheral neuritis) as well as paresis (partial paralysis) of the legs, and taste disorders.

There are indications that carbamazepine may aggravate the symptoms of multiple sclerosis.
Cases of an aseptic meningitis (a meningitis not caused by bacteria or viruses) have been reported under carbamazepine treatment (cf. "Hypersensitivity reactions").

Like other anticonvulsants, carbamazepine may increase the incidence of attacks. Absences (a special type of seizure originating in both halves of the brain) may be intensified or may newly occur.

**Eye disorders:**
Conjunctivitis occurred in very rare cases. Clouding of the lenses has been reported. Retinotoxicity (impairment of the retina) was noted in two patients under a long-term carbamazepine therapy. The condition improved when carbamazepine was discontinued.

**Musculoskeletal and connective tissue disorders, disorders of bones:**
Very rare cases of joint and muscle pain (arthralgia and myalgia) as well as of muscular spasm have been reported. They disappeared when Finlepsin 400 retard was discontinued.

**Disorders of the skin, subcutaneous tissue and vascular system:**
Allergic skin reactions with and without fever, such as nettle rash (urticaria) or intense itching (pruritus) are common to very common occurrences. There have been isolated reports of inflammation of the skin with large patches peeling off (exfoliative dermatitis, erythrodermia), the so-called scalded-skin syndrome (Lyell’s syndrome), light sensitivity (photosensitivity), reddening of the skin with disk-shaped or nodular changes and suffused patches (erythema exudativum et nodosum, Stevens-Johnson syndrome), purpura and an autoimmune disease with inflammation of blood vessels (disseminated lupus erythematosus).
Loss of hair, excessive sweating, changes in skin pigmentation, acne, hirsutism (increased male-type growth of hair in women) and inflammation of blood vessels (vasculitis) occurred in isolated cases or were occasionally reported.

**Disorders of the gastrointestinal tract:**
Loss of appetite, dryness of the mouth, nausea and vomiting occur frequently, diarrhoea and constipation rarely. Isolated cases of abdominal pain and inflammation of mucous membranes in the mouth and throat region (stomatitis, gingivitis, glossitis) have been reported.

**Hepatobiliary disorders:**
Changes in liver function parameters are common, jaundice is rare, and there are isolated cases of various forms of hepatitis (cholestatic, hepatocellular, granulomatous, mixed).

An acute life-threatening hepatitis with liver failure occurs in rare cases on the basis of an allergy, particularly in the first few months of treatment (cf. "Hypersensitivity reactions").

**Metabolic and nutritional disorders, endocrine disorders:**
A common side effect is hyponatraemia (a reduced sodium content in the serum), which occasionally causes reduced fluid elimination, accumulation of fluid in the tissue (oedema), gains in weight and reduced plasma osmolality. In rare cases it leads to water intoxication with vomiting, headache, confusion, lethargy and other neurological anomalies.
As a result of the antidiuretic effect (the inhibition of urine excretion) caused by Finlepsin 400 retard, it has occasionally reduced the serum sodium content (hyponatraemia), causing vomiting, headache and – in isolated cases – states of confusion. Isolated cases of fluid accumulation (oedemata) and gains in weight have been reported.

An overdevelopment of the breasts (gynaecomastia) and the flow of milk in men (galactorrhoea) have been reported in very rare cases.

Finlepsin 400 retard may lower the serum calcium level by speeding up the breakdown of 25-OH cholecalciferol, which in very rare cases leads to osteomalacia (softening of the bones).

The thyroid function parameters T₃, T₄, TSH and FT₄ may be affected, in particular in a combination therapy with other anticonvulsants.

In very rare cases the cholesterol levels, including the HDL cholesterol and triglyceride levels and the free cortisol in the serum, may be increased.

Carbamazepine may lower the folic acid level in the serum. There are indications that under carbamazepine the vitamin B₁₂ levels have been reduced and the homocysteine levels in the serum raised. An acute intermittent porphyria (a metabolic disorder with a liver dysfunction, colics, neurological disorders) has been triggered in two cases.

Respiratory, thoracic and mediastinal disorders:
Isolated cases of hypersensitivity reactions of the lungs with fever, shortness of breath, pneumonia and pulmonary fibrosis have been described in the literature.

Renal and urinary disorder, reproductive system disorders:
Occasional functional impairments of the kidneys may be due, in part, to the antidiuretic effect of carbamazepine. Examples are the presence of protein in the urine (proteinuria), of blood in the urine (haematuria), a reduced volume of urine (oliguria). Very rare occurrences are interstitial nephritis (inflammation of renal tissue), renal failure and other urinary disorders (dysuria, pollakisuria, retention of urine).

Isolated cases of sexual dysfunction, such as impotence, diminished libido, reduced male fertility and / or abnormal sperm formation have also occurred.

Cardiac disorders, vascular disorders:
There has been the odd case ("uncommon" to "rare") of elderly patients and patients with a known cardiac dysfunction complaining of an abnormally slow rate of heartbeat (bradycardia), a disordered rhythm of the heart and deterioration of an existing coronary heart disease.

Conduction disorders of the heart (AV blocks) may occasionally occur ("uncommon"), in isolated cases with loss of consciousness and an abnormally high or low blood pressure. Large doses in particular may result in a drop in blood pressure. Inflammation of veins (thrombophlebitis) and blood clotting (thrombo-embolism) have also been observed.

Hypersensitivity reactions:
Delayed hypersensitivity reactions affecting several organ systems have been occasionally reported. They included fever, rashes, inflammation of blood vessels, lymph node enlargement, joint pain, changes in the number of white blood cells, enlargement of the liver and spleen, and changed liver function parameters. These symptoms may occur in various combinations and may also affect other organs, such as the lungs, kidneys, pancreas, heart muscle (myocardium) and the large intestine (colon).

Acute general allergic reactions and an aseptic meningitis (i.e. a meningitis not caused by bacteria or viruses) with muscle twitching (myoclonia) and an increase in the number of certain white blood cells (eosinophilia), anaphylactic (shock) reactions and swelling of the skin and mucous membranes (angioedemata) have been observed in very rare cases.

Please inform your doctor or pharmacist if any of these side effects hampers you seriously or if you notice any side effects in yourself that are not mentioned in this leaflet.
5. HOW TO STORE FINLEPSIN 400 RETARD
Keep drugs out of reach of children.

Do not use this drug after the expiry date indicated on the container and the folding box. The expiry date refers to the last day of the month indicated.

Storage instructions
Do not store above 30° C.

The drug should not be disposed of in sewage or domestic waste. Ask your pharmacist how to dispose of drugs no longer required. In this way you will help to protect the environment.

6. FURTHER INFORMATION

What Finlepsin 400 retard contains
Its active substance is carbamacepine.
One prolonged release tablet contains 400 mg of carbamacepine.
Further ingredients are poly[ethylacrylate-co-methylmethacrylate-co-(2-trimethylammonioethyl)methacrylate chloride] (1:2:0.1), triacetine, talc, poly[acrylic acid-co-methacrylic acid]-co-(ethyl, methyl/acrylate, methacrylate] (1:1), microcrystalline cellulose, crospovidone, colloidal anhydrous silica, magnesium stearate (Ph.Eur.).

What Finlepsin 400 retard looks like and how many prolonged release tablets are contained in a pack
White to yellowish, round, cloverleaf-shaped prolonged release tablets.
Finlepsin 400 retard is available in packs of 50 prolonged release tablets (N1), 100 prolonged release tablets (N2) and 200 prolonged release tablets (N3).

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This leaflet was last updated in
February 2009

Finlepsin 400 retard is supplied in child-proof packs with reinforced covering foils. If you have difficulty taking out the prolonged release tablets, we suggest that you slightly pierce the covering foil before pressing the tablets out.