FLETËUDHËZUES I PAKETIMIT:
Information for the patient

AMITRIPTILINE

Sugar – coated tablets - 25 mg

(Amitriptyline hydrochloride)

Read this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT AMITRIPTILINE IS AND WHAT IT IS USED FOR
Amitriptiline is a tricyclic antidepressant that has a structure with three rings. It inhibits the neuronal reuptake of noradrenaline and of serotonine (5 - HT) in the central nervous system. The inhibition of these monoamino - neurotransmitters, which potentiate the action of amitriptyline in the brain, seems to be related with its antidepressant activity. If the sedative effect and other side effects of amitriptyline are observed at the beginning of the treatment, the antidepressant effect is noticed only after some weeks.

Amitriptiline - sugar - coated tablet is used:

- in all the depressive conditions such as: melancholy, manic - depressive psychosis, neurotic depressions, depressions during the nonmelancholic psychosis, anxiety, discontent for life, avoidance of family life and society, decreased professional performance, neurovegetative disbalance, psychosomatic disorders and hypochondriasis;
- in enuresis (when the organic pathology is excluded).

2. BEFORE YOU TAKE AMITRIPTILINE
Do not take Amitriptiline if:
- you suffer from hypersensibility to amitriptyline, to the other tricyclic antidepressants, or to any of the other excipients of Amitriptiline sugar - coated tablets;
- you concomitantly take monoamine oxidase inhibitors (except cases when absolutely necessary and under the careful supervision of the doctor);
- you suffer from heart block of any degree;
- you have passed an acute myocardial attack;
- you suffer from mania;
- you suffer from severe liver diseases;
- you suffer from porphyria;
- you are breast - feeding;
- the patient is a child under 6 years old.

In these cases consult with your doctor or go directly to the hospital.

Take special care with Amitriptiline
Consult with your doctor or pharmacist before taking Amitriptiline.
Amitriptiline should be used with special care in patients:
- with cardiovascular diseases (especially with arrhythmias);
- with epilepsy;
- during pregnancy;
- with liver impairment;
- with thyroid diseases;
- who suffer from psychoses;
- who suffer from closed angle glaucoma;
- with urinary retention;
- with chronic constipation;
- with concomitant electroconvulsive therapy;
- with prostate hypertrophy;
- with pyloric stenosis;
- with phaeocromocytoma;
- with diabetes, because blood sugar concentrations may be altered;
- who are elderly, because they are very sensitive to the side effects;
- who have suicidal attempts, who should be carefully supervised during the initial phases of the treatment.

Care should be taken also during anaesthesia, because an increased risk for arrhythmias and hypotension may happen.

Taking other medicines
Concomitant treatment with other drugs may affect or be affected by Amitriptiline.
Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Amitriptiline if you have been given any other drug during treatment.
Interactions involving tricyclic antidepressants often result from altered metabolism of one or another drug. Drugs that inhibit or induce the cytochromes P450, CYP2D6 isoenzyme, may affect tricyclic metabolism and produce marked alterations of plasmatic concentrations. Adverse effects may be enhanced by antimuscarinic drugs or by central nervous system depressants, including alcohol.
Barbiturates and other enzyme inducers such as rifampicin and some antiepileptics may increase the metabolism of tricyclic antidepressants, may lower the plasmatic concentrations and may lead to reduced antidepressant response. Cimetidine, methylphenidate, antipsychotics, and calcium - channel blockers may reduce the metabolism of tricyclics, leading to increased plasma concentrations and accompanying toxicity.
Patients taking thyroid preparations may show an accelerated response to tricyclic antidepressants and occasionally liothyronine has been used to produce this effect in patients with refractory depression. However, the use of tricyclics with thyroid hormones may precipitate cardiac arrhythmias.
The antihypertensive effects of debrisoquine, guanethidine, and clonidine may be reduced by tricyclic antidepressants.
The pressor effects of sympathomimetics, especially those of the drugs like adrenaline and noradrenaline, may be enhanced by tricyclic antidepressants; however, there is no clinical evidence of dangerous interactions between local anaesthetics that contain adrenaline and tricyclic antidepressants. Special care should, however, be taken to avoid inadvertent intravenous injection of the local anaesthetic.
Drugs that prolong the QT interval, including antiarrhythmics such as amiodarone or quinidine, the antihistamines like astemizole and terfenadine, some antipsychotics (notably pimozide, sertindole, and thioridazine), cisapride, halofantrine, and sotalol, may increase the possibility of ventricular arrhythmia when concomitantly taken with tricyclic antidepressants. This may be exacerbated when the interacting drugs (such as quinidine or some antipsychotics) also reduce the metabolism. However, during the concomitant use of different antidepressants under expert supervision in cases of refractory depression, severe undesirable effects may occur that include serotonine syndrome. For this reason, there should be a long interval during which no drug should be used while an antidepressant is discontinued and another is initiated. Tricyclic antidepressants should not generally be given to patients receiving MAO inhibitors for at least 2 weeks after their withdrawal. No treatment - free period is necessary after stopping the reversible inhibitor of monoamine oxidase type A (RIMA) and starting a tricyclic.
At least 1 to 2 weeks should pass between withdrawing a tricyclic antidepressant and starting any drug liable to provoke a serious reaction (e.g. phenelzine).

Taking Amitriptiline with food and drinks
It is advised not to take Amitriptiline with alcoholic drinks.

Pregnancy and breast - feeding
Ask for the advice of your doctor or pharmacist before taking this drug.
Amitriptiline should be used during pregnancy only if the benefits for the mother outweigh the risks for the foetus.
Amitriptiline should not be used during breast - feeding.

Driving and using machinery
Amitriptiline may cause drowsiness and other effects that damage the vigilance, especially at the beginning of the treatment. For this reason, patients who are being treated with Amitriptiline, should not drive and use machinery.

Important information about some of the excipients of Amitriptiline
This drug contains lactose and sucrose. If you have an intolerance to some sugars, contact your doctor before taking this drug.

3. HOW TO TAKE AMITRIPTILINE
Always take Amitriptiline as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Amitriptiline are too strong or too weak, talk to your doctor or pharmacist.
The tablets should be taken by mouth with at least a glass of water (with 250 ml of water).
You are advised not to consume alcoholic drinks during the time you are taking this drug.

Dosage:
For the treatment of **depression**, amitriptyline hydrochloride is given by mouth initially at 50 - 75 mg in divided doses (or as a single dose at night). Doses are gradually increased up to 200 mg daily, and for hospitalized patients in severe depressive condition, the dose may also increase to 300 mg daily.
For adolescents and elderly patients who often have a reduced tolerance to the tricyclic antidepressants, doses up to 25 mg daily are recommended, given in divided doses or as a single dose at night. It is not recommended the use of amitriptyline in children less than 16 years old for the treatment of depression.
Amitriptiline is also given for the treatment of **enuresis nocturna** in children where the organic pathologies are excluded.
For children 6 - 10 years old, the dose of 10 - 20 mg daily is recommended, while for children over 11 years old, it is recommended the dose of 25 - 50 mg daily. The dose should be given 30 minutes before bedtime and the treatment, including a gradual withdrawal, should not continue for more than 3 months.
It is recommended to make a complete medical examination before a further treatment course.

If you take more Amitriptiline
If you have taken more Amitriptiline than you should, or if your children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.
Overdose from amitriptyline presents a high risk of fatality.
The symptoms from overdose include excitement and restlessness wtih marked antimuscarinic effects such as: dry mouth, dry skin, dilated pupils, tachycardia, urine retention, and constipation.
Severe symptoms include: unconsciousness, convulsions and myoclonus, hypereflexia, hypothermia, hypotension, delirium, confusion, metabolic acidosis, respiratory and cardiac depression with arrhythmias that may be fatal.

If you forget to take Amitriptiline
If you forget a dose (or more doses), take the next dose when it is time to take it usually.
Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you stop taking Amitriptiline
Amitriptiline should be gradually withdrawn to avoid the risk of relapse.
If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all other medicines, Amitriptiline may cause side effects, although not everybody manifests them. Sometimes they are serious, sometimes not. Do not get alarmed by this list of possible side effects. No one of them may appear to you.
Some side effects may appear at the beginning of the treatment and disappear spontaneously with continued treatment.
Amitriptiline may cause these side effects:
- in the cardiovascular system (orthostatic hypotension, tachycardia, palpitations, arrhythmias, ECG changes);
- in the central nervous system (confusion, hallucinations, concentration disorders, memory disorders, delusions, nervousness, agitation, panic, insomnia, scary dreams, mania, worsening of psychosis, drowsiness, dizziness, weakness, emotional instability, torpor, tremor, extrapyramidal symptoms like: pseudoparkinsonism, movement disorders, acathisia, and contractions);
- in the skin (exanthema, itching, photosensibility reactions, dry skin, acne);
- in the gastrointestinal tract (nausea, vomiting, anorexia, diarrhea, flatulence, dry mouth, constipation);
- hematological (bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia, leucopenia);
- in the respiratory system (pharingitis, rhinitis, sinusitis, cough);
- in the urogenital system (sexual function disorders, impotence, menstrual disorders, dismenorrhea, nocturia, increased micturition, vaginitis, cystitis, urinary retention);
- in the eye (blurred vision, conjunctivitis, increased intraocular pressure, mydriasis, dry eyes);
- tinnitus;
- special taste in the mouth;
- nasal congestion;
- gynecomastia.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE AMITRIPTILINE
Keep out of the reach and sight of children!
Do not use Amitriptiline after the expiry date which is stated on the package.
Store below 25°C.
Store in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION
What Amitriptiline contains
The active substance is amitriptyline hydrochloride.
Each sugar - coated tablet contains 25 mg amitriptyline hydrochloride.
The other excipients are: microcrystalline cellulose, lactose, talc, magnesium stearate, gelatin, povidone, calcium carbonate, titanium dioxide, sucrose, Opalux pink, Opaglos white 6000.

Content of the pack
Carton box with 30 sugar - coated tablets.

Explanatory of the illustration icons on the packaging:

According to medical prescription.

Content. Warning.

Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

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SPECIFICATION

CROPING AREA 15 x 25 cm

PAY ATENTION, all the layers are visible. If you have to print this document please check or uncheck the specific layers.