PACKAGE LEAFLET: Information for the patient

IMIPRAMINE

Sugar-coated tablets – 25 mg

(Imipramine 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 IMIPRAMINE IS AND WHAT IT IS USED FOR

Imipramine belongs to the group of tricyclic antidepressants. These drugs change the chemical level of neurotransmitters in the brain and relieve the symptoms of depression.

Imipramine 25 mg sugar-coated tablets are used:

- in the treatment of the symptoms of depression;
- in enuresis nocturna (nightly bedwetting) in children.

2. BEFORE YOU TAKE IMIPRAMINE

Do not take Imipramine and tell your doctor if:

- you are hypersensitive (allergic) to imipramine hydrochloride, to the other tricyclic antidepressants or to any of the other excipients of Imipramine;
- you have heart diseases such as: irregular heart beats, heart block or have recently passed a heart attack;
- you suffer from periods of exaggerated behaviour (mania);
- you have severe liver disease;
- you suffer from porphyria (a genetic disorder that causes skin blisters, abdominal pain and nervous system disorders);
- have increased pressure in the eye (glaucoma);
- you are taking monoamine oxidase inhibitors (I - MAO) or you have taken I - MAO within 3 weeks before depression reappearance;
- the patient is under 6 years old.

Thoughts of suicide, worsening of depression or anxiety disorders

If you are depressed and/or have anxiety disorders you may have thoughts of harming or killing yourself many times. These thoughts may increase when you start the treatment with antidepressants, usually within the first two weeks or longer.

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

You should ask for help from your relatives or your friends when you are depressed or have anxiety disorders, and ask them to read the package leaflet. You should ask them if your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Take special care with Imipramine

Consult with your doctor or pharmacist before taking Imipramine if you:

- suffer from a psychiatric disorder (such as schizophrenia or maniacal depression);
- are dependent from alcohol or medicines used to treat fits;
- have an enlargement of the prostate gland;
- have overactive thyroid glands and you are taking medicines to treat thyroid disorders;
- are with diabetes, because blood sugar levels may be altered;

- have a history of epilepsy or brain damage;
- have low blood pressure or a poor circulation;
- have liver impairment;
- have severe kidney impairment;
- have a tumour of the adrenal glands (such as phaeochromocytoma, or neuroblastoma);
- suffer from panic attacks;
- suffer for a long time from constipation;
- wear contact lenses;
- are making an electroconvulsive therapy (ECT);
- are due to have surgery, including dental, that involve the use of anaesthetics;
- are elderly, because this age group is particularly sensible to the side effects.

Blood tests

While you are taking Imipramine sugar - coated tablets, your doctor should regularly monitor your blood cell levels and also the liver function.

Other precautions you should be aware

Imipramine sugar-coated tablets may cause problems with your teeth, thus it is advisable to make a dental check up.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Imipramine.
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 Imipramine if you have been given any other drug during treatment.
It is especially important that your doctor knows that you are being treated with:

- medicines that treat epilepsy such as: barbiturates, phenytoin, carbamazepine, phenobarbital;
- medicines called “benzodiazepines” such as: diazepam, nitrazepam, oxazepam, alprazolam;
- medicines that treat depression, such as: selective serotonin reuptake inhibitors (SSRIs) such as: fluoxetine, fluvoxamine;
- disulfiram that treats alcohol addiction;

- monoamine oxidase inhibitors (I-MAO); imipramine therapy should not be started without passing 3 weeks from I-MAO withdrawal,
- nicotine replacement therapy;
- methylphenidate (used to treat attention deficit / hyperactivity disorder (ADHD));
- medicines that stop blood coagulation (warfarin);
- antihistamines (medicines that treat allergies);
- altretamine (drug that treats some types of cancer);
- apraclonidine and brimonidine (that treat glaucoma);
- baclofen (myorelaxant drug);
- nefopam, tramadol, codeine, dihydrocodeine that treat severe pain;
- medicines that treat some heart disturbances, such as: diltiazem, verapamil, labetalol, propranolol, quinidine;
- medicines that treat angina as spray or sublingually (such as: glyceryl trinitrate "GTN", isosorbide dinitrate);
- every drug that treats high blood pressure, as: guanethidine, debrisoquine, bethanidine, methyldopa, reserpine, clonidine or diuretics;
- drugs that treat some mental illnesses such as: thioridazine, chlorpromazine;
- cimetidine (that treats ulcer);
- entacapone or selegiline (to treat Parkinson's disease);
- oral contraceptives or with hormone replacement therapy (HRT);
- appetite suppressants;
- sympathomimetic drugs such as: adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine and phenylpropanolamine (these may be present in many local anaesthetics or in many cough and cold remedies);
- ritonavir (that treats HIV).

Taking Imipramine with food and drinks

It should be taken with a glass of water (250 ml water). You are advised not to take alcoholic drinks, because it may give symptoms such as: blurred vision, drowsiness, loss of vigilance.

Pregnancy and breastfeeding

Ask for the advice of your doctor or pharmacist before taking this drug.

Imipramine should be discontinued during pregnancy and breastfeeding.

If Imipramine is taken during the last trimester, the baby may be born with breathing difficulties, lethargy, colics, nervousness, changes in blood pressure, tremors, and spasms.

Driving and using machinery

Imipramine sugar-coated tablets may worsen your vigilance, and cause drowsiness or blurred vision. You should be sure that you are not under their effect before driving and using machinery.

Important information about some of the excipients of Imipramine

This drug contains lactose and sucrose. If you have an intolerance to some sugars, contact your doctor before taking this drug.

This drug also contains the azodyes Yellow sunset FCF (E110) and Ponceau 4R (E124), which may cause allergic reactions.

Imipramine also contains sodium benzoate.

3. HOW TO TAKE IMIPRAMINE

Always take Imipramine 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 Imipramine are too strong or too weak, talk to your doctor or pharmacist.

The sugar-coated tablets should be taken by mouth with at least a glass of water (with 250 ml of water).

The dosage is as follows:

<u>For depression:</u>

Adults: 25 mg, three times daily, increasing the dose up to 150 - 200 mg daily in divided doses if it is necessary. In severe cases (hospital treatments) the dosage may be increased up to 100 mg, three times daily. Usually the maintenance dose is between 50 mg and 100 mg daily, in divided doses.

Elderly (over 60 years old): initially 10 mg daily and increases up to 30 - 50 mg daily.

Children: not recommended.

For nightly bedwetting (Enuresis nocturna):

Children should take it before bedtime (but not for a longer period than 3 months and up to a maximum of 75 mg daily).

Over 11 years old (35 - 54 kg): 50 - 75 mg daily.

8 - 11 years old (25 - 35 kg): 25 - 50 mg daily.

6 - 7 years old (20 - 25 kg): 25 mg daily.

Under 6 years old - not recommended.

If you have taken more Imipramine

If you have taken more Imipramine than you should, or if your child has taken this medicine incorrectly, please contact your doctor, the hospital, or call the emergency to get an opinion for the risk and advices for the actions to be taken.

Symptoms of overdose include:

- fast or irregular heartbeats;
- low blood pressure;
- drowsiness;
- fits;
- coma;
- agitation;
- muscle rigidity;
- chills.

If you forget to take Impramine

If you forget a dose (or more doses) of Imipramine, 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 Imipramine

It should not be stopped immediately after a long-term use.

Abrupt withdrawal of Imipramine from physically dependent patients, causes the withdrawal syndrome.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, imipramine 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. None of them may appear to you.

Some side effects may appear at the beginning of the treatment and disappear spontaneously during treatment continuance.

Stop taking Imipramine sugar-coated tablets and contact with your doctor if you develop: allergic reactions, pneumonia (chills, tremor, cough, difficulty in breathing, unusual weight loss, fatigue), skin reactions, which may appear with itching, sensitivity to sunlight, oedema, oedema of the face or tongue, which may be severe and may cause shortness of breath, shock and collapse.

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

Blood: reduction of the blood cells (you may experience sore throat, mouth ulcers and periodic infections, bleeding or bruising).

Endocrine system and metabolism: sexual function disorder, breast swelling in men and women, production or overproduction of breast milk, change in the level of the sugar in the blood, weight loss or weight gain, SIADH (syndrome of inappropriate antidiuretic hormone secretion).

Central nervous system: disorientation, dizziness, tiredness, sleepiness, weakness, headache, difficulty in concentrating, confusion, agitation, mood swings, aggressiveness, difficulty on sleeping, delusion, seeing things and/or people that are not there, anxiety, nervousness, needles in the head, tremor, muscle spasms and loss of muscle control, speech problems, fits.

Antimuscarinic effects: (dry mouth, constipation, blurred or double vision, sweating, hot flushes, difficulty in urination, dilation of the pupil of the eye, glaucoma and blockage of the small intestine).

Cardiovascular system: feeling faint when getting up (postural hypotension), high or severely low blood pressure, tachycardia, palpitations, irregular heart-beats, changes in ECG reading.
Gastrointestinal tract: loss of appetite, inflammation of the mucus membranes of the mouth, tongue lesions, impaired liver function, hepatitis, including changes in liver function (that are seen in the blood test), jaundice (yellowing of the skin and whites of the eye).
Other: hair loss, tinnitus, small, red spots, sudden death.
Withdrawal symptoms: feeling tired, stomach pain, diarrhoea, difficulty on sleeping, nervousness, anxiety, headache, irritability.
Children: changes in behaviour.

5. HOW TO STORE IMIPRAMINE

Keep out of the reach and sight of children!
Do not use Imipramine 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 Imipramine contains

The active substance is imipramine hydrochloride.
Each sugar-coated tablet contains 25 mg of imipramine hydrochloride.
The excipients are: starch, lactose, gelatin, magnesium stearate, povidone, calcium carbonate, titanium dioxide, sucrose, talc, Ponceau 4R (E124), Sunset yellow FCF (E110), sodium benzoate, brilliant blue FCF, shellac, carnauba wax, white beeswax.

Content of the pack:

Carton box with 30 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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