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Package Leaflet: Information for the patient

Imipramine 10 mg and 25 mg Tablets

Imipramine Hydrochloride
This medicine will be called Imipramine Tablets in this leaflet.

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

What is in this leaflet:

1. What Imipramine Tablets are and what they are used for

These tablets are available in two different strengths containing either 10 mg or 25 mg of the active ingredient, imipramine. Imipramine belongs to a group of medicines called antidepressants.

Imipramine Tablets are used to treat depressive illnesses in adults. They can also be used in children to help treat bed wetting.

2. What you need to know before you take Imipramine Tablets

Do not take Imipramine Tablets if:
- You are allergic to imipramine, or to any other similar antidepressants, or to any of the other ingredients of this medicine (these are listed in section 6)
- You have recently had a heart attack, you suffer from heart block or an irregular heartbeat
- You have periods of mania (feeling elated or over-excited)
- You have severe liver disease
- You suffer with porphyria
- You have glaucoma (increased pressure inside the eye)
- You have problems passing urine
- You are taking, or have taken, a monoamine oxidase inhibitor (also used to treat depression) in the last 3 weeks or you are taking a reversible MAO-A inhibitor, such as moclobemide.

Imipramine Tablets should not be taken by children under 6 years of age.

Warnings and precautions:
Talk to your doctor or pharmacist before taking Imipramine Tablets if:
- You suffer from epilepsy, have brain damage or are undergoing electro-convulsive therapy (ECT)
- You suffer from severe kidney disease or you have a tumour of the adrenal gland (eg phaeochromocytoma or neuroblastoma)
- You have an over active thyroid gland and/or are taking any medicine for a thyroid disorder
- You have constipation that has persisted for a long time
- You suffer from a panic disorder, as anxiety may increase during the first few days of treatment
- You have ever had glaucoma or prostate problems
- You have a mental illness such as schizophrenia
- You have low or unstable blood pressure
- You are being weaned off dependency on alcohol and some drugs
- You wear contact lenses
- You are due to have any surgery, including dental, that involves a local or general anaesthetic. Make sure the doctor or dentist knows you are taking imipramine.

The use of Buprenorphine together with imipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Imipramine Tablets")

Thoughts of suicide and worsening of your depression or anxiety disorder:
If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:
- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend** that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Other medicines and Imipramine Tablets
Imipramine Tablets can affect some other medicines you may be taking. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly any of the following:
- Medicines to control high blood pressure such as bethanidine, guanethidine, debrisoquine, methyldopa, reserpine, clonidine or diuretics ("water tablets")
- Medicines to treat some heart conditions, ie. propranolol, labetolol, diltiazem, verapamil and quinidine
- Medicines to treat angina that you spray or dissolve under your tongue (eg glyceryl trinitrate "GTN", isosorbide dinitrate)
- Sympathomimetic drugs such as adrenaline (epinephrine), noradrenaline (norepinephrine), ephedrine, isoprenaline, phenylephrine and phenylpropanolamine. These may be present in many cough and cold remedies and local anaesthetics
- Oral contraceptives or other drugs containing oestrogens such as hormone replacement therapy (HRT)
- Cimetidine, to treat stomach ulcers
- Methylphenidate (Ritalin), used to treat attention deficit hyperactivity disorder (ADHD) in children
- Medicines used to treat epilepsy such as phenytoin, carbamazepine or barbiturates e.g. phenobarbital
- Nicotine. Let your doctor know if you are a heavy smoker or are using nicotine replacement therapy to help you stop smoking
- Medicines called "benzodiazepines" such as diazepam, nitrazepam, oxazepam, alprazolam
- Medicines used to treat some psychiatric disorders such as thioridazine or chlorpromazine
- Other drugs to treat depression, including drugs called selective serotonin reuptake inhibitors (SSRIs e.g. fluoxetine or fluvoxamine)
- Anticoagulants, to prevent blood clotting e.g. warfarin
- Disulfiram, to treat alcohol dependence
- Anticholinergic drugs such as antihistamines (for allergies) and atropine to relax intestinal smooth muscle and regulate the heart rate
- Apraclonidine and brimonidine (to treat glaucoma)
- Ritonavir (to treat HIV)
- Medicines to treat Parkinson's disease such as entacapone, selegiline or biperiden
- Appetite suppressants
- Altretamine (to treat some types of cancer)
- Painkillers such as nefopam, tramadol, codeine, dihydrocodeine
- Baclofen (a muscle relaxant)
- Buprenorphine/opioids as these medicines may interact with imipramine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Imipramine Tablets and alcohol
Avoid drinking alcohol while you are taking this medicine.

Pregnancy, breastfeeding and fertility
Imipramine Tablets should not be taken during pregnancy or if breast-feeding. If Imipramine Tablets are taken in the last 3 months the baby may be born with breathing difficulties, lethargy, colic, irritability, changes in blood pressure, tremors, spasm. If the doctor considers it essential to use Imipramine treatment during pregnancy, it should be withdrawn at least 7 weeks before the expected delivery date.

Driving and using machines
Imipramine Tablets may make you feel drowsy, dizzy or confused. They might also affect your eyesight. If you are affected you should not drive or operate machinery.

Blood tests
Your doctor will carry out tests to monitor your blood cell count or your liver function while you are taking these tablets, and may want to check your blood pressure before you start taking them.

Dental check ups
If you are taking this medicine for a long time you must go to the dentist regularly for check-ups as this medicine may cause tooth decay.

Continued, please turn over.

Imipramine Tablets contain lactose, sucrose, sunset yellow (E110) and the 25 mg tablets also contain sodium benzoate (E211)
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains lactose and sucrose.
- The tablet colouring contains sunset yellow (E110) which may cause allergic reactions.
- The 25mg tablet colouring also contains 0.0011mg of sodium benzoate (E211) in each tablet.

Information on sodium content
The 10mg tablets do not contain any sodium and the 25mg tablets contain less than 1mmol sodium (23mg) per tablet, that is to say essentially sodium free.

3. How to take Imipramine Tablets

For oral use. The tablets should be swallowed with a drink of water.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You will be given a low dose to begin with, which will be gradually increased by your doctor. The usual doses are given below.

To treat a depressive illness
Adults: Usual starting dose is 75 mg a day, in divided doses. This dose will be increased gradually to 150 – 200 mg a day. Once you start to feel better your doctor will gradually reduce the dose. If you are in hospital the doses may be higher than those given above.

Elderly: Patients over 60 years of age will start on 10 mg a day. The dose will be increased gradually to 30 – 50 mg a day, to be taken in divided doses.

To treat bed wetting
Children aged 6 or over: 25 – 75 mg a day, at bedtime. The dose depends on the child's body weight. The doctor will gradually reduce the dose and treatment should not continue for any longer than 3 months.

If you take more Imipramine Tablets than you should
You should contact your doctor or go to your nearest hospital casualty department immediately. Take your tablets or the pack with you so that the doctor knows what you have taken. Symptoms of an overdose include fast or irregular heart beat, low blood pressure, drowsiness, fits, coma, agitation, muscle rigidity, being sick or fever.

If you forget to take Imipramine Tablets
If you miss a dose don't worry. Do not take a double dose to make up for the forgotten dose, just carry on with the normal routine.

If you stop taking Imipramine Tablets
If the doctor tells you that you no longer need to take the tablets, you should carefully follow their advice about how to stop your course of treatment. If you stop taking these tablets suddenly you may get withdrawal symptoms such as stomach pain, diarrhoea, headache, difficulty sleeping, feeling or being sick, nervousness, irritability, excessive sweating and anxiety.

4. Possible side effects

Like all medicines, this medicine can cause side effects, particularly in the elderly, although not everybody gets them. These tablets can affect people in many different ways. Changes in behaviour may occur in children.

Some side effects can be serious. Stop taking Imipramine Tablets and tell your doctor straightaway if you notice the following very rare symptoms:
- Fever, chills, cough, difficulty breathing, unusual weight loss, feeling sick (signs of pneumonitis)
- A skin rash, which may be itchy, sensitivity to the sun or sun lamps, swelling of the face, lips or tongue, which may be severe causing shortness of breath, shock and collapse. These may be the symptoms of a severe allergic reaction.

The following side effects have also been reported.

Very common (may affect more than 1 in 10 people):
- Weight gain
- Shaking
- Constipation
- Dry mouth, sweating and hot flushes
- Problems with eyesight and blurred vision
- Increased heart rate, dizziness or feeling faint when getting up (postural hypotension) or severely low blood pressure, changes in ECG readings.

Common (may affect up to 1 in 10 people):
- Changes in libido (interest in sex), tiredness, drowsiness, difficulty sleeping, anxiety, hallucinations (seeing or hearing things that are not real), restlessness, confusion, mood changes, over-excitedness, headache, dizziness
- Palpitations (feeling your heart beating), fast or irregular heartbeat
- Loss of appetite, feeling or being sick
- Changes in liver function (usually only detected by blood tests)
- Skin rash or itching
- Problems passing urine
- Numbness or tingling anywhere in the body.

Rare (may affect up to 1 in 1,000 people):
- Psychosis (signs of this are personality change, loss of contact with reality, delusions, hallucinations, incoherent speech and agitation)
- Ringing in the ears
- Impaired liver function
- Fits.

Very rare (may affect up to 1 in 10,000 people):
- Blood disorders which can cause fever, sore throat, tiredness, bruising and sometimes abnormal bleeding or make infections more likely
- Swelling of, or milk flow from, the breasts
- Weight loss
- Difficulty in controlling movements, muscle weakness or stiffness, fever, muscle spasm, difficulty in speaking
- Raised blood pressure, heart problems
- Stomach problems, sore mouth or tongue
- Aggression
- Changes in blood sugar levels
- Over production of anti-diuretic hormone resulting in water retention
- Hepatitis with or without jaundice (yellowing of the skin and whites of the eyes)
- Oedema (build up of fluid under the skin)
- Skin sensitivity to sunlight and red spots on the skin, hair loss
- Increased pressure inside the eye, widening of the pupils
- Paralytic ileus (symptoms include a swollen abdomen, being sick and difficulty passing a motion).

Frequency not known (frequency cannot be estimated from the available data):
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- An increased risk of bone fractures has been observed in patients taking this type of medicine.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 Imipramine Tablets

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 carton or label after Exp:.
The expiry date refers to the last day of that month.
Do not store above 25°C. Store in the original package or container and keep the container tightly closed, in order to protect the tablets from moisture.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What this medicine contains
Each tablet contains either 10 mg or 25 mg of the active ingredient, imipramine hydrochloride. The other ingredients are lactose, talc, colloidal anhydrous silica, stearic acid, sucrose, titanium dioxide (E171), sunset yellow (E110). In addition the 10 mg tablets contain aluminium hydroxide gel and the 25 mg tablets contain sodium benzoate (E211), erythrosine (E127), indigo carmine (E132) and maize starch.

What Imipramine Tablets look like and contents of the pack
The 10 mg tablets are round, orange sugar coated.
The 25 mg tablets are round, reddish brown sugar coated.
They are supplied to your pharmacist in packs of 28, 56, 100, 250, 500 or 1000 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder is Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

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If you would like the leaflet in a different format, please contact the Marketing Authorisation holder at the above address.