PACKAGE LEAFLET:
INFORMATION FOR THE PATIENT

Imipramine 25 mg

Tablets

Imipramine Hydrochloride

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. 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 of side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Imipramine is and what it is used for
2. What you need to know before you take Imipramine
3. How to take Imipramine
4. Possible side effects
5. How to store Imipramine
6. Contents of the pack and other information

1. What Imipramine is and what it is used for

Imipramine belongs to a group of medicines called tricyclic antidepressants. These medicines alter the levels of chemicals in the brain to relieve the symptoms of depression.

Imipramine is used to treat:

- the symptoms of depression
- the relief of bed-wetting at night by children.

2. What you need to know before you take Imipramine

Do not take Imipramine if you (or your child if they are the patient):

- are allergic to Imipramine, other tricyclic antidepressants of any of the other ingredients (listed in section 6)
- have a heart disorder, such as irregular heartbeat, heart block or have recently had a heart attack
- suffer from periods of increased and exaggerated behaviour (mania)
- have severe liver disease
- suffer with porphyria (a genetic disorder of the red blood cells haemoglobin causing skin blisters, abdominal pain and brain/nervous system disorders)
- are not able to pass urine
- have increased pressure in the eye (glaucoma)
- are taking monoamine oxidase inhibitors (MAOI) or you have taken an MAO within the last 14 days
- if the child is under 6 years old.

Warnings and precautions

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 young adults (less than 25 years old) 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.

Talk to your doctor before taking Imipramine if you (or your child if they are the patient):

- have any psychiatric disorder (e.g. schizophrenia or manic depression)
- are taking buprenorphine. The use of buprenorphine together with Imipramine can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Imipramine")
- are withdrawing from alcohol or medicines used to treat fits
- have ever had glaucoma or an enlarged prostate gland
- have an overactive thyroid gland and are taking medicines to treat a thyroid disorder
- have a history of epilepsy or brain damage
- have low blood pressure or poor circulation
- have severe kidney disease
- have a tumour of the adrenal gland (e.g. phaeochromocytoma or neuroblastoma)
- suffer from panic attacks
- suffer from long term constipation
- wear contact lenses
- are receiving electroconvulsive therapy (ECT)
- are due to have any surgery, including dental, that involves an anaesthetic.

Other medicines and Imipramine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Imipramine:

- Medicines used to treat epilepsy such as barbiturates, phenytoin, carbamazepine, phenobarbital
- Medicines called "benzodiazepines" such as diazepam, nitrazepam, oxazepam and alprazolam
- Medicines to treat depression, such as fluoxetine and fluvoxamine (Selective Serotonin Reuptake Inhibitors (SSRIs))
- Disulfiram, used to treat alcohol addiction
- Nicotine replacement therapy
- Methylphenidate, used to treat attention deficit/ hyperactivity disorder (ADHD)
- Medicines to stop your blood clotting such as warfarin
- Antihistamines (medicines to treat allergies)
- Altretamine (used to treat some types of cancer)
- Apraclonidine and brimonidine (to treat glaucoma)
- Baclofen (a muscle relaxant)
- Pain relievers such as nefopam, tramadol, codeine, dihydrocodeine
- Medicines used to treat some heart conditions such as diltiazem, verapamil, labetalol, propranolol, quinidine
- Medicines for angina that you spray or dissolve under your tongue (e.g. glyceryl trinitrate "GTN", isosorbide dinitrate)
- Any medicines to treat high blood pressure such as guanethidine, debrisoquine, bethanidine methyldopa, reserpine, clonidine or diuretics ("water" tablets)
- Medicines used to treat some mental illnesses such as thioridazine chlorpromazine
- Cimetidine (to treat ulcers)
- Entacapone or selegiline (to treat Parkinson's disease)
- Oral contraceptives ("the pill") or Hormone Replacement Therapy (HRT)
- Appetite suppressants
- Sympathomimetic medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (norepinephrine), phenylephrine and phenylpropanolamine (these may be present in many cough and cold remedies or local anaesthetics)
- Ritonavir (to treat HIV)
- Buprenorphine/opioids. You may experience symptoms of serotonin syndrome 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 if experiencing such symptoms.

Taking Imipramine with alcohol

Do not drink alcohol while you are taking this medicine. Alcohol may increase drowsiness and make you less alert.

Pregnancy and Breast Feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Imipramine tablets should not be taken during pregnancy or if breast-feeding.

If Imipramine tablets are taken in the last three months, the baby may be born with breathing difficulties, lethargy, colic, irritability, changes in blood pressure, tremors or spasm.

Imipramine tablets should be withdrawn at least 7 weeks before the expected delivery date.

Driving and using machines

Imipramine may impair alertness, cause drowsiness or blurred vision. Make sure you are not affected before you drive or operate machinery.

Imipramine contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Imipramine contains the colouring agents amaranth (E123) and tartrazine (E102)

Which may cause allergic reactions.

Imipramine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) as sodium benzoate (E211) per tablet, that is to say essentially 'sodium-free'.

3. How to take Imipramine

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

Swallow the tablets whole with a glass of water.

Recommended doses:

Depression

Adults: 25 mg three times a day increasing to 150 mg-200 mg a day in divided doses. In severe cases (treated in hospital) the dose may be increased up to a maximum of 100 mg three times a day.
The usual maintenance dose is between 50 mg and 100 mg a day in divided doses.
Elderly (over 60 years): Initially 10 mg a day increasing to 30 mg-50 mg a day.

Nightly Bed-wetting

Children only, to be taken at bedtime (for no longer than 3 months and up to a maximum of 75 mg a day):
Over 11 years (35-54 kgs) – 50 mg-75 mg a day
8-11 years (25-35 kgs) – 25 mg-50 mg a day
6-7 years (20-25 kgs) – 25 mg a day
Under 6 years – not recommended

If you take more Imipramine than you should

If you (or your child if they are the patient) accidentally takes too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.
Symptoms of an overdose include: fast or irregular heartbeat, low blood pressure, drowsiness, fits, coma, agitation, muscle rigidity, being sick or fever.

If you forget to take Imipramine

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

Product Name	Imipramine 25 mg	**Sap code :**	[TBA]	**Reference Artwork**	TW119669 (launch)
Packaging Material	Package leaflet	**Reason of change :**	TW122965 (SmPC)	Proof 1	18/08/2023
Size : Foil Width		**Country :**	UK	Proof 2	22/08/2023
Size : Foil Repeat Length		**Pack Size :**	[All]	Proof 3	29/01/2024
Size : Strip Size		**Barcode No. :**	NA	Proof 4	29/01/2024
Size : PI - Open Size	150 (L) x 500 (W) mm *	**Pharmacode :**	[TBA]		
Size : Carton/Label		**No. of colours :**	1		
PM Style/Type :	Pre-fold form	**Min. Font Size :**	9 points (Reg text)		
Remark (If any) :					

Black C

DEPARTMENT	CHECKED BY (SKPL- PKG.DEV)	REVIEWED BY (SKPL-PROD/MFG)	REVIEWED BY (SKPL-RA)	APPROVED BY (SKPL - QA)
SIGN/DATE				

If you stop taking Imipramine
Talk to your doctor before you stop taking the tablets as you may experience withdrawal symptoms (see section 4).

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

4. Possible side effects

Like all medicines, Imipramine can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:
- allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylactic reactions)
- shortness of breath or difficulty in breathing (allergic alveolitis)
- swelling of parts of the body (oedema)
- frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)

Frequent side effects:
- shakiness (tremor)
- faster heartbeat (tachycardia), changes in ECG reading
- low blood pressure when changing position (postural hypotension)
- dry mouth
- sweating, hot flushes
- constipation
- blurred vision or visual disturbance
- weight gain

Occasional side effects:
- tiredness, weakness or lack energy (fatigue), drowsiness
- restlessness, increased anxiety, agitation
- delirium, confusion, disorientation, dizziness
- seeing or hearing things that are not real (hallucinations), particularly in older patients and those suffering from Parkinson's disease
- sleep disturbances
- mood changes
- tingling or numbness in the hands or feet (paraesthesia)
- headache
- disrupted heart rhythm/irregular heartbeat (arrhythmias, conduction disorders), feeling your heartbeat (palpitations)
- difficulty passing urine
- feeling sick (nausea) or being sick (vomiting)
- loss of appetite
- raised levels of enzymes in the liver (detected in blood tests)
- skin rash
- skin rashes with the formation of wheals (urticaria)
- disturbances in sexual function or sex drive

Rare side effects:
- activation of symptoms of mental illness
- epileptic fits
- impaired liver function

Isolated cases:
- aggressiveness
- changes in brain activity (EEG changes)
- involuntary muscle twitching (myoclonus)
- weakness
- medicine-induced movement disorders (extrapyramidal symptoms)
- lack of voluntary co-ordination of muscle movements (unsteadiness or clumsiness) (ataxia)
- speech disorders
- fever
- increase or decrease in blood pressure
- the failure of the heart to maintain adequate blood circulation (cardiac decompensation), sudden narrowing of an artery causing the blood supply to be drastically reduced (peripheral vasospasm)
- dilation of the pupil of the eye (mydriasis)
- increased pressure in the eye (glaucoma)
- blockage in the digestive tract (paralytic ileus)
- inflammation of the mouth (stomatitis)
- sores on the tongue
- stomach problems
- inflammation of the liver (hepatitis), with or without jaundice (yellowing of the skin or whites of the eyes)
- abnormal sensitivity of the skin to sunlight (photosensitivity)
- severe itching (pruritus)
- broken blood vessels that form tiny pin-point red/purple spots on the skin (petechiae)
- hair loss
- enlarged breasts (mammary glands)
- milky secretion from the breasts not due to breast-feeding (galactorrhoea)
- SIADH (Syndrome of Inappropriate Anti-Diuretic Hormone secretion). Anti-Diuretic Hormone (ADH) is produced by the brain and is stored in & released by the pituitary gland. ADH controls how your body releases and conserves water. SIADH occurs when ADH is produced somewhere other than the brain, which makes it difficult for your body to get rid of excess water. This causes a build-up of fluids as well as abnormally low sodium levels
- increase or decrease in blood sugar
- weight loss
- inflammation of the lungs (pneumonitis)
- more prone to infections due to a severe reduction in number of white blood cells (agranulocytosis, leucopenia)
- a reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- abnormal condition of the bone marrow in which it is unable to produce normal amounts of red blood cells, white blood cells, and platelets leaving the immune system in a weakened state and vulnerable to infection (bone marrow depression)
- skin rash caused by small blood vessels bleeding into the skin (purpura)

Other side effects:
- exacerbation of paranoid delusions
- suicidal ideation and suicidal behaviours (see section 2 "Warnings and precautions")
- disrupted heart rhythm/irregular heartbeat (cardiac arrhythmias) and severely low blood pressure (hypotension) may occur if Imipramine is taken in a high dose or in patients with pre-existing heart disease
- abnormally low levels of salt (sodium) in blood (hyponatraemia), usually in the elderly
- ringing in the ears (tinnitus)
- withdrawal symptoms (feeling sick [nausea], being sick [vomiting], abdominal pain, diarrhoea, difficulty sleeping [insomnia], headache, nervousness, anxiety, irritability and excessive sweating [perspiration])
- patients over 50 years of age may have an increased risk of bone fractures

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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

- 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 after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original container. Keep the container tightly closed.
- Medicines should not be disposed of 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 Imipramine contains:
Each sugar-coated tablet contains 25 mg of Imipramine.

The other ingredients are: Lactose Monohydrate, Maize Starch, Povidone, Industrial Methylated Spirits, Purified Water, Magnesium Stearate, Stearic Acid. *Sugar-coating:* Purified Talc, Calcium Carbonate, Acacia, Titanium Dioxide (E171), Sucrose, Purified Water, Industrial Methylated Spirits, Polyvinyl Acetate Phthalate, Ethyl Acetate, Stearic Acid, Tartrazine Aluminium Lake (E102), Amaranth Aluminium Lake (E123), Erythrosine Aluminium Lake (E127), Indigo Carmine Aluminium Lake (E132), Povidone, Sodium Benzoate (E211), Shellac, Yellow Carnauba Wax, White Beeswax.

What Imipramine looks like and contents of the pack:
Imipramine 25 mg tablets are red-brown, circular, sugar-coated tablets with a diameter of approximately 5.5mm.

Imipramine is available in:
Imipramine tablets are available in packs of 84, 100, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Product Licence Number:
Imipramine 25 mg Tablets: PL 11311/0709

Marketing Authorisation Holder:
Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

Manufacturer:
Clonmel Healthcare Limited
3 Waterford Road, Gurtnafleur, Clonmel
County Tipperary, IE-E91 D768, Ireland

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