

## Patient information leaflet

**IMIPRAMINE 25 MG TABLETS BP**

**Read all of this leaflet carefully before you start taking this medicine. It contains important information.**

- Keep this leaflet. You may want to read it again.
- If you have any other questions, or if there is something you do not understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Never give it to someone else. It may not be the right medicine for 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 is and what it is used for
2. What you need to know before you take Imipramine Tablets
3. How to take Imipramine Tablets
4. Possible side effects
5. How to store Imipramine Tablets
6. Contents of the pack and other information

**1. What Imipramine is and what it is used for**

Imipramine belongs to a class of antidepressant drugs known as the tricyclic antidepressant drugs. These medicines alter the levels of chemicals in the brain to relieve the symptoms of depression. Imipramine is used to treat depression. It can also be used to treat bed-wetting in children.

**2. What you need to know before you take Imipramine Tablets****Do not take this medicine if you:**

- have previously suffered an **allergic reaction** while taking this medicine or any other tricyclic antidepressants
- are allergic to **any of the other ingredients** in this medicine (see section 6 - further information)
- suffer from **glaucoma** (increased eye pressure)
- have **heart disease** such as irregular heartbeats, heart block or recently had a heart attack
- suffer from **severe liver disease**
- suffer from periods of increased and exaggerated behaviour (**mania**)
- suffer with **porphyria** (a genetic disorder of the red blood cells haemoglobin causing skin blisters, abdominal pain and brain/nervous system disorders)
- have **difficulty passing water**
- are **taking monoamine oxidase inhibitors** (MAOIs), such as moclobemide, or you have taken MAOIs within the previous 14 days for depression

**This medicine should not be given to children under 6 years of age.**

**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.

**Warnings and precautions**

**Talk to your doctor or pharmacist** before taking Imipramine tablets if you or your child (if the child is the patient):

- suffer from any mental illness (**psychiatric disorder**) other than depression (e.g. schizophrenia or manic depression)
- are **withdrawing** from **alcohol or medicines** used to treat fits
- have ever **had glaucoma**

- have an **enlarged prostate** gland
- have an **overactive thyroid** gland and are taking medicines to treat a thyroid disorder
- suffer from **epilepsy** (fits) or **brain damage**
- suffer from **constipation**
- have low **blood pressure** or problems with your **circulation**
- have a **tumour** of the adrenal gland (e.g. pheochromocytoma or neuroblastoma)
- suffering from severe **kidney disease**
- suffer from **panic attacks**
- wear **contact lenses** as the use of Imipramine may lead to eye problems
- are being given electroconvulsive therapy (**ECT**)
- are due to have **any surgery**, including dentistry that **involves an anaesthetic**

**Having operations and tests**

If you are to undergo surgery or medical tests tell your doctor or dentist that you are taking Imipramine.

**Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicine obtained without a prescription. **Especially:**

- medicines for epilepsy, e.g. phenytoin, barbiturates, and carbamazepine, phenobarbital
- medicines such as sleeping tablets or tranquillisers including diazepam, nitrazepam, oxazepam and alprazolam
- medicines to treat depression, such as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, fluvoxamine
- disulfiram, a drug used in the treatment of alcohol abuse
- nicotine replacement therapy
- methylphenidate, a drug used in the treatment of childhood behavioural disorders
- medicines used to thin the blood (anticoagulants, e.g. warfarin)
- medicines (antihistamines) used for colds, sinuses, hay fever or allergies
- altretamine (to treat some types of cancer)
- alpraclonidine and brimonidine (to treat glaucoma)
- baclofen (a muscle relaxant)
- painkillers such as nefopam, tramadol, codeine, dihydrocodeine
- medicines used for heart disease, such as diltiazem, verapamil, labetalol, propranolol and quinidine
- medicines to treat angina that you spray or dissolve under your tongue (e.g. glyceryl trinitrate "GTN", isosorbide dinitrate)
- medicines used for high blood pressure such as guanethidine, debrisoquine, bethanidine, methyl dopa, reserpine, clonidine or diuretics (water tablets)
- medicines to treat some mental illnesses such as phenothiazines (e.g. chlorpromazine, thioridazine) and atropine
- cimetidine, a drug used in the treatment of ulcers
- drugs used to treat Parkinson's disease (e.g. entacapone, selegiline, orphenadrine, procyclidine and biperiden)
- oral contraceptives ("the pill") or oestrogens (e.g. used for hormone replacement therapy)
- appetite suppressants
- sympathomimetic medicines such as adrenaline (epinephrine), ephedrine, isoprenaline, noradrenaline (nor epinephrine), phenylephrine, phenylpropanolamine (these may be present in many cough and cold remedies or local anaesthetics)
- ritonavir (to treat HIV)
- bronchodilators, which are used to help your breathing

**Pregnancy and breast-feeding**

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

**Driving and using machines**

Imipramine may impair your alertness or cause drowsiness or blurred vision; alcohol can make these symptoms worse. Make sure you are not affected before you drive or operate machines.

### Tests

During your treatment with Imipramine tablets, your doctor may wish to carry out a number of tests on your heart, blood and liver. This is quite usual and nothing to be concerned about.

### Dental check ups

You should have regular dental check-ups whilst taking Imipramine. Imipramine can cause dryness of the mouth, which may increase the risk of tooth decay.

### Sugar intolerance

If you have been told you have an intolerance to some sugar, contact your doctor before taking this medicine, as it contains a type of sugar called lactose or sucrose.

## 3. How to take Imipramine

Always take this medicine exactly as your doctor has told you. The pharmacist's label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist.

- The tablet should be swallowed with a glass of water.
- You are advised not to drink alcohol with this medicine.
- Keep taking your medicine until your doctor tells you to stop.
- Do not stop because you do not feel any better.
- This medicine may take up to four weeks to work.

### DOSES:

#### For Depression:

- **Adults:** Initially 25mg (one tablet) one to three times daily. If necessary, your doctor may increase this dose gradually up to 150-200mg per day. In severe cases (treated in hospital) the dose may be increased up to a maximum of 100mg three times a day. The usual maintenance dose is between 50mg and 100mg a day in divided doses.
  - **Elderly:** Lower doses may be used. Initially 10mg at night increasing gradually up to 30 - 50 mg daily in divided doses.
- For Bed wetting: Children only** (To be taken at bedtime and for no longer than 3 months):
- Under 6 years – not recommended
  - 6-7 years (body weight 20-25kg or 44-55lbs): 25mg a day.
  - 8-11 years (body weight 25-35kg or 55-77lbs): 25-50mg a day.
  - Over 11 years (body weight 35-54kg or 77-119lbs): 50-75mg a day.

#### If you take more medicine than you should

If you or anyone else has swallowed a lot of the tablets all together, contact your nearest hospital casualty department or doctor immediately.

**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 a dose

If you forget to take a tablet, do not take the missed dose until the next dose is due. Do not take two doses together. If you see another doctor or go into hospital, let the doctor or the hospital staff know what medicines you are taking.

#### If you stop taking the medicine

If you need to stop taking your medicine, your doctor will advise you about reducing the dose gradually to avoid unwanted effects. You may experience withdrawal symptoms if you stop the treatment too quickly. These may include sleeping problems, irritability and sweating.

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

## 4. Possible side effects

Like all the medicine, Imipramine tablets can cause side effects in some people, particularly the elderly, although not everybody gets them **STOP TAKING the tablets and contact a doctor at once if you** have the following **allergic reaction**: pneumonitis (fever, chills, cough, difficulty breathing, unusual weight loss, and feeling sick), skin rash or itching, sore throat, shortness of breath, shock and collapse, increased sensitivity to sunlight, swollen face, or tongue.

**Tell your doctor if you notice any of the following side effects** or notice any other effects not listed

- **Blood:** reduction in some blood cells (you may experience a sore throat, mouth ulcers and recurring infections, bleeding or bruising easily)
- **Endocrine system and metabolism:** disturbances in sexual function or sex drive, breast swelling in men and women, production or over-production of breast milk, changes in blood sugar levels, trembling and weight gain or loss, SIADH (syndrome of inappropriate

antidiuretic hormone secretion)

- **Brain and central nervous system:** disorientation, light-headedness (especially when standing up), dizziness, tiredness or sleepiness, weakness, headache, muscle spasm difficulty concentrating, agitation, mood changes, delirium (confusion), tremor, aggressiveness, difficulty in sleeping, delusions, hallucinations (seeing things that are not there), restlessness, pins and needles, or lack of muscle control, difficulty in speaking, fits. Anticholinergic effects (dry mouth, constipation, blurred or double vision, sweating, hot flushes, difficulty passing water (urine), dilation of the pupil of the eye, glaucoma and intestinal obstruction)
- **Heart:** feeling faint when getting up (postural hypotension), high or severely low blood pressure, fast/racing heart, palpitations, irregular heart-beats, changes in ECG readings
- **Stomach and intestines:** feeling or being sick, anorexia (loss of appetite), inflammation of the mucous membranes in the mouth, tongue lesions.
- **Liver:** impaired liver function, hepatitis, including changes in liver function (as seen in blood tests), jaundice (yellowing of the skin and/or whites of the eyes)
- **Other:** drowsiness; eye pain; loss of balance; muscle weakness or stiffness; brownish spots on skin; hair loss, ringing in the ears, small purple red spots. An increased risk of bone fractures has been observed in patients taking this type of medicine.
- **Withdrawal symptoms:** nausea (vomiting); feeling or being sick, stomach pain, diarrhoea, nervousness, anxiety, irritability
- **Children:** changes in behaviour.
- Imipramine may also increase your feelings of anxiety at the start of treatment.

### 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Imipramine

### Keep all the medicines out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the label, carton, and blister after 'EXP'. The expiry date refers to the last date of that month.
- Imipramine Tablets should be stored at room temperature below 25°C, in a dry place and protected from light.
- Keep the container tightly closed.
- Store in the original container.

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 Imipramine tablets contain:

- **The active substance** is 25mg of Imipramine Hydrochloride.
- **The other ingredients** are lactose monohydrate, maize starch, povidone, magnesium stearate, stearic acid, polyvinyl acetate phthalate, ethyl acetate, talc, calcium carbonate, acacia, sucrose, shellac, yellow carnauba wax and white beeswax. The tablets contain the colours titanium dioxide (E171), tartrazine aluminium lake (E102), amaranth aluminium lake (E123), erythrosine aluminium lake (E127) and indigo carmine aluminium lake (E132) and the preservative sodium benzoate (E211)

### What Imipramine tablets look like and contents of the pack:

- Imipramine tablets 25mg are red-brown, circular, sugar coated tablets.
- Pack sizes of Imipramine 25mg tablets are 7, 14, 28, 56, 84, 100, 500 and 1000 tablets in containers.

### Marketing Authorization holder and Manufacturer:

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

**Telephone:** 0208 997 5444

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To request a copy of this leaflet in large print or audio format, please contact the licence holder at the address (or telephone, fax) above.

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