passing water (urine), dilation of the pupil of the eye, glaucoma and blockage of the small intestine)
Heart: feeling faint when getting up (postural hypotension), high or severely low blood pressure, fast/racing heart, palpitations, irregular heartbeats, changes in ECG readings
Stomach and intestines: feeling or being sick, loss of appetite, inflammation of the mucus 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: hair loss, ringing in the ears, small purple red spots. An increase risk of bone fractures has been observed in patients taking this type of medicine.
Withdrawal symptoms: feeling or being sick, stomach pain, diarrhoea, difficulty sleeping, nervousness, anxiety, headache, irritability
Children: changes in behaviour.

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 out of the sight and reach of children.
Store below 25°C in a dry place.
Do not take Imipramine tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.
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 (the ingredient that makes the tablets work) is imipramine hydrochloride. Each tablet contains either 10mg or 25mg of the active ingredient.
- The other ingredients are carnauba wax, colloidal silica, gelatin, lactose, magnesium stearate, maize starch, polyvidone, stearic acid, sucrose, E170, E171, E211, E414, E460, and E553. The 10mg tablets also contain E110, E123 and E127. The 25mg tablets also contain sodium hydroxide, E216 and E218 and E172.

What Imipramine tablets look like and contents of the pack
Imipramine tablets are red (10mg) or tan (25mg) circular, biconvex, sugar-coated tablets, diameter 5.9mm (10mg) or 6.4mm (25mg).

Pack sizes are 28 tablets

Marketing Authorisation holder and Manufacturer: Accord, Barnstaple, EX32 8NS, UK.

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Package leaflet: Information for the patient

Imipramine 10mg and 25mg tablets

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 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
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 tablets are and what they are used for

Imipramine belongs to a group of medicines called tricyclic antidepressant drugs. 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.
- for the relief of bed-wetting at night by children.

2 What you need to know before you take Imipramine Tablets

Do not take Imipramine tablets and **tell** your doctor if you or your child (if they are the patient):
- are **allergic** (hypersensitive) to imipramine, other tricyclic antidepressants or any of the other ingredients (see section 6).
- have **heart disease** such as irregular heart beats, 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 water**
- have increased pressure in the eye (**glaucoma**)
- are taking monoamine oxidase inhibitors **(MAOI)** or you have taken MAOIs within the previous 14 days for depression
- 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.

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Check with your doctor or pharmacist before taking Imipramine tablets if you or your child (if they are the patient):

- have any **psychiatric disorder** (eg schizophrenia or manic depression)
- are taking buprenorphine. The use of buprenorphine together with Imipramine tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Imipramine tablets")
- 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 (*eg* phaeochromocytoma or neuroblastoma)
- suffer from **panic attacks**
- suffer from long term **constipation**
- wear **contact lenses**
- are being given electroconvulsive therapy (**ECT**)
- are due to have **any surgery,** including dental, that **involves an anaesthetic**.

Other medicines and Imipramine tablets

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

- medicines to treat epilepsy such as barbiturates, phenytoin, carbamazepine, phenobarbital
- medicines called "benzodiazepines" such as diazepam, nitrazepam, oxazepam, alprazolam
- medicines to treat depression, such as selective serotonin reuptake inhibitors (SSRIs) such as fluoxetine, fluvoxamine
- disulfiram to treat alcohol addiction
- nicotine replacement therapy
- methylphenidate (used to treat attention deficit/hyperactivity disorder (ADHD))
- medicines to stop your blood clotting (*eg* warfarin)
- antihistamines (medicines to treat allergies)
- altretamine (to treat some types of cancer)
- apraclonidine and brimonidine (to treat glaucoma)
- baclofen (a muscle relaxant)
- painkillers such as nefopam, tramadol, codeine, dihydrocodeine
- medicines to treat some heart conditions such as diltiazem, verapamil, labetalol, propranolol, quinidine
- medicines to treat angina that you spray or dissolve under your tongue (eg 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 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 .These medicines may interact with Imipramine tablets and 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 when experiencing such symptoms.

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 machinery.

Blood tests

Whilst taking Imipramine tablets your doctor will regularly monitor your blood cell levels or liver function.

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Dental check ups

As Imipramine tablets can cause problems with your teeth, it is advisable to have regular dental checks ups.

Imipramine tablets contain

- **lactose and sucrose**
  If you have been told by your doctor you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- **sunset yellow (E110), amaranth (E123), propylhydroxybenzoate (E216) and methylhydroxybenzoate (E218)**
  Imipramine 10mg tablets contain sunset yellow (E110) and amaranth (E123) which may cause allergic reactions.
  Imipramine 25mg tablets contain propylhydroxybenzoate (E216) and methylhydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
- **sodium benzoate (E211)**
  This medicine contains sodium benzoate 0.0025mg in each 10mg tablet and 0.0022mg in each 25mg tablet.

3 How to take Imipramine tablets

Always take Imipramine tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with a **glass of water**. You are advised **not to drink alcohol** with this medicine.

Doses
Depression:
Adults – 25mg three times a day increasing to 150mg-200mg a day in divided doses. 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 (over 60 years) - Initially 10mg a day increasing to 30-50mg a day.

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

If you take more Imipramine tablets than you should

If you or the patient (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your 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 Imipramine tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take another as soon as you remember and then your next dose at the usual time.

If you stop taking imipramine tablets

Talk to your doctor before you stop taking the tablets and follow their advice as you may experience withdrawal symptoms (see section 4).

4 Possible side effects

Like all medicines, Imipramine tablets can cause side effects, 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, feeling sick), a skin rash, which may be itchy, sensitivity to the sun or sun lamps, puffy, swollen face or tongue, which may be severe causing shortness of breath, shock and collapse.

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, weight gain or loss, SIADH (syndrome of inappropriate antidiuretic hormone secretion)
Brain and central nervous system: disorientation, dizziness, tiredness or sleepiness, weakness, headache, difficulty concentrating, confusion, agitation, mood swings, aggressiveness, difficulty sleeping, delusions, seeing things that are not there, anxiety, restlessness, pins and needles, tremor, muscle spasm or lack of muscle control, speech problems, fits. Anticholinergic effects (dry mouth, constipation, blurred or double vision, sweating, hot flushes, difficulty

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