The above effects are often mild and may disappear during treatment. If they are severe or last for more than a few days, tell your doctor.

You are **unlikely** to experience any of the following side effects but if you do – **see your doctor as soon as possible.**

- drowsiness, tiredness
- dizziness
- restlessness, anxiety, irritability
- nausea (feeling sick)
- any yellowing of your skin or the whites of your eyes
- sore throat or fever
- glaucoma (increased pressure in the eye)
- difficulty in passing water
- hair loss
- swelling of the breasts and discharge of milk
- dilation of the pupils
- increased sensitivity to sunlight
- sexual difficulties
- ringing in the ears
- mood changes, aggression
- activation of psychotic symptoms
- vomiting, loss of appetite, weight loss
- paralytic ileus (no bowel movement)
- diarrhoea
- stomach pain
- any general swelling
- tingling or numbness
- poor blood circulation which makes the toes and fingers numb and pale
- skin rash or itching
- darkening of skin
- loss of balance
- muscle weakness or stiffness, muscle spasm
- difficulty in controlling movements
- changes to the electrical waves in your brain
- difficulty in speaking
- inflammation of the lungs which causes breathlessness, cough and raised temperature
- feeling your heartbeat or irregular heartbeat
- heart failure
- red or brownish spots on skin
- fits, confusion or delirium
- sleep disturbances or difficulty in sleeping
- raised blood pressure
- low blood pressure
- hallucinations
- believing in things that are not real (delusions)
- change in blood sugar levels
- a condition called 'syndrome of inappropriate anti-diuretic hormone secretion' which will cause a lowering of salt in your body
- severe reduction in number of white blood cells which makes infections more likely
- reduction in blood platelets, which increases risk of bleeding or bruising
- other blood disorders
- raised levels of enzymes in your liver
- impaired liver function
- inflammation of the mouth or sores on the tongue.

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 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 Hydrochloride Oral Solution

Keep this medicine out of the sight and reach of children.

Keep the medicine in a cool place (below 25°C).

Keep the bottle tightly closed and in its carton when not in use.

Do not use for more than 1 month after first opening.

Do not use this medicine after the expiry date which is stated on the carton as {EXP MM/YYYY}. 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 Hydrochloride Oral Solution contains

The **active** ingredient is imipramine. Each 5ml contains 25mg imipramine hydrochloride.

The **other** ingredients are betacyclodextrin (E459), sorbitol solution 70% (E420), saccharin sodium (E954), hydroxyethylcellulose, propylene glycol (E1520), banana flavour, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and water (**see end of section 2** "Important information about some of the other ingredients" for further information on sorbitol and benzoates).

What Imipramine Hydrochloride Oral Solution looks like and contents of the pack

Imipramine Hydrochloride Oral Solution is a clear, colourless, banana-flavoured solution. It comes in bottles of 150ml.

Marketing Authorisation Holder

Essential Pharma Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

Manufacturer

Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE.

This leaflet was last revised in 06/2024. Imi25mgin5mlSoln-PL-UK-3

ESSENTIAL

Patient Information Leaflet

Imipramine Hydrochloride 25mg/5ml Oral Solution

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

1. What Imipramine Hydrochloride Oral Solution is and what it is used for

Imipramine Hydrochloride Oral Solution contains the active ingredient imipramine. This belongs to a class of medicines called tricyclic antidepressants and is used to treat:

- the symptoms of depression
- night-time bed-wetting in children.

2. What you need to know before you take Imipramine Hydrochloride Oral Solution

Do not take Imipramine Hydrochloride Oral Solution if:

- you are allergic to imipramine or any other tricyclic antidepressant, or to any of the other ingredients of this medicine (listed in Section 6, and end of Section 2)
- you have serious heart or liver disease
- you have narrow angle glaucoma (increased pressure in the eye)
- you have difficulty in passing water
- you suffer from mania
- you suffer with porphyria - a genetic disorder of the red blood cells (haemoglobin) causing skin blisters, abdominal pain and brain/nervous system disorders
- you have had a heart attack in the past 3 months
- you are taking (now or recently) any other medicines for depression (particularly monoamine oxidase inhibitors [MAOIs] such as moclobemide within the last 3 weeks).

Children under 6 years old should **not** take this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Imipramine Hydrochloride if you have:

- epilepsy (fits) or brain damage
- severe kidney disease
- a history of low blood pressure or poor circulation
- a tumour of the adrenal gland (called phaeochromocytoma or neuroblastoma)
- an overactive thyroid and are taking medicines to treat a thyroid disorder
- constipation, especially if you are elderly or bedridden
- an intolerance to some sugars
- a withdrawal from alcohol or any anticonvulsive drugs
- electroconvulsive therapy (ECT) treatment and are taking Imipramine Hydrochloride Oral Solution – you will be carefully supervised.

If you think that any of the above apply to you then tell your doctor before taking Imipramine Hydrochloride Oral Solution.

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

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. This is because these medicines all take about two weeks but sometimes longer to work properly.

You may be more likely to think like this if:

- you have previously had thoughts about killing or harming yourself.

Continued overleaf

- you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults 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.

While you are taking Imipramine Hydrochloride Oral Solution:

- you will need routine tests (blood, heart and liver tests) from time to time. These will be carried out by your doctor
- you will be closely monitored as improvement may not occur for the first 2 – 4 weeks of treatment
- if you already suffer from a panic disorder, you may experience an increase in your feeling of anxiety when you start treatment with Imipramine Hydrochloride Oral Solution. This is usually worse in the first few days and should go away in the first 2 weeks
- have regular dental check-ups as long term treatment may increase the risk of tooth decay
- if you need an operation tell your doctor that you are taking the solution
- contact lens wearers may notice reduced production of tears.

Children taking Imipramine Hydrochloride Oral Solution may have behavioural changes.

Other medicines and Imipramine Hydrochloride

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

In particular, tell your doctor if you are taking any of the following medicines, because they may interact with Imipramine Hydrochloride Oral Solution:

- medications for depression called MAOIs (monoamine oxidase inhibitors) such as moclobemide – see Section **"Do not take Imipramine Hydrochloride Oral Solution"**
- buprenorphine/opioids (naloxone, tramadol, codeine or dihydrocodeine) - 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
- medication for depression called SSRIs (Selective serotonin reuptake inhibitors) such as fluoxetine and fluvoxamine
- a medication used to treat depression and to help stop smoking called amfebutamone
- medication for heart problems such as calcium channel blockers (e.g. diltiazem, verapamil) or beta blockers (e.g. labetalol, propranolol)
- medication for irregular heartbeat such as those containing quinidine disopyramide or amiodarone
- medications for high blood pressure such as guanethidine, debrisoquine, betanidine, reserpine, clonidine, alpha-methyldopa or diuretics (water tablets)
- medication to treat angina that you spray or dissolve under you tongue such as glyceryl trinitrate or isosorbide dinitrate
- medication for colds, sinus problems, containing decongestants such as phenylephrine or phenylpropanolamine
- antihistamines for hay fever or allergies
- isoprenaline used to treat asthma
- oral contraceptives or oestrogens (e.g. hormone replacement therapy [HRT])
- cimetidine an anti-ulcer drug
- methylphenidate used to treat behavioural disorders in children
- disulfiram or alprazolam for alcohol abuse
- barbiturates, tranquillizers (such as phenothiazines, thioridazine or benzodiazepines), general or local anaesthetics
- treatments for Parkinson's disease such as biperiden, selegiline or entacapone
- medication to treat epilepsy such as carbamazepine or phenytoin
- antifungal medication such as terbinafine
- noradrenaline, adrenaline and ephedrine, mainly used to treat low blood pressure in emergencies
- nicotine found in cigarettes or in medications used to help stop smoking
- blood-thinning tablets (anticoagulants) e.g. warfarin
- apraclonidine or brimonidine to treat glaucoma
- ritonavir to treat HIV
- medication to decrease your appetite such as sibutramine
- altretamine normally used to treat ovarian cancer
- nefopam, a painkiller
- baclofen a muscle relaxant.

Imipramine Hydrochloride Oral Solution with food and drink

DO NOT DRINK alcohol while you are taking this medicine.

Pregnancy and Breast-feeding

Ask your doctor for advice before taking any medicine.

Treatment with Imipramine Hydrochloride Oral Solution should be avoided during pregnancy unless your doctor considers it necessary.

If Imipramine is taken in the last 3 months of pregnancy, your baby may be born with withdrawal symptoms. These may be shortness of breath, tiredness, uncontrollable crying and irritability.

If you are breastfeeding, you may be advised to stop taking Imipramine Hydrochloride Oral Solution gradually, or to stop breastfeeding, because imipramine passes into breast milk.

Driving and using machines

You may feel dizzy or sleepy or have blurred vision when you take this medicine.

DO NOT drive or operate machinery without advice from your doctor or pharmacist.

Imipramine Hydrochloride Oral Solution contains methyl and propyl hydroxybenzoates, sorbitol and propylene glycol:

- **methyl hydroxybenzoate** (E218) and **propyl hydroxybenzoate** (E216) – may cause allergic reactions (possibly delayed)
- **sorbitol** (E420). This medicine contains 1.05g in each 5ml spoonful. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **propylene glycol** (E1520). This medicine contains 510.4mg propylene glycol in each 5ml spoonful. If you are pregnant, breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium free'.

3. How to take Imipramine Hydrochloride Oral Solution

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

Depression:

Adults: At first, one 5ml spoonful (25mg) one to three times a day. Your doctor may increase your dose gradually as needed. However, the dose is usually not more than 6 to 8 spoonfuls (150-200mg) a day unless you are in hospital.

Elderly: Your doctor may prescribe lower doses of Imipramine Hydrochloride Oral Solution, particularly when you first start taking this medicine.

Night-time Bed-wetting

Children over 6 years: 1 to 3 spoonfuls (25mg-75mg) a day at bedtime depending on the age and weight of the child. Treatment with Imipramine Hydrochloride Oral Solution must be checked after 3 months.

Keep taking your medicine until your doctor tells you to stop. **Do not stop suddenly because you do not feel any better** – the solution may take up to 4 weeks to work.

If you take more Imipramine Hydrochloride Oral Solution than you should

If you (or a child) accidentally take too much Imipramine Hydrochloride Oral Solution, tell your doctor at once or contact your hospital casualty department. Overdosage in children is serious and could be potentially fatal.

If you forget to take Imipramine Hydrochloride Oral Solution

It is important to take your medicine at the right times. If you forget to take a dose, take the next dose at the usual time

DO NOT take a double dose to make up for the forgotten dose.

If you stop taking Imipramine Hydrochloride Oral Solution

Keep taking your medicine until your doctor tells you to stop. Do not stop suddenly because you do not feel any better. If you need to stop treatment, your doctor will tell you how to reduce the dose gradually. This is to help prevent unwanted effects such as headache, sickness, stomach upset, diarrhoea, sleeplessness, nervousness and anxiety.

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

4. Possible side effects

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

Allergic reactions – skin rash or itching, swelling of the face, lips, tongue or throat, or difficulty in breathing may be signs of an allergic reaction. If this happens, STOP taking Imipramine Hydrochloride Oral Solution and seek medical advice.

Serious side effects: tell a doctor straight away

- if you feel more depressed, including thinking about suicide

The **most common** side effects are:

- dry mouth
- blurred vision
- headache
- hot flushes, sweating
- constipation
- trembling
- weight gain
- fast heartbeat
- light headedness (especially when getting up from lying or sitting position).

Continued overleaf