

## 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
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### 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 pheochromocytoma 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.

#### 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.

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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.

### Important information about some of the other ingredients of Imipramine Hydrochloride Oral Solution

- **Sorbitol** – 1.5g per 5ml spoonful. This may have a mild laxative effect. Also, tell your doctor if you have an hereditary intolerance to some sugars
- **Methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216)** – may cause allergic reactions (possibly delayed)

## 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).

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.

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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](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 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 (E420), saccharin sodium (E954), hydroxyethylcellulose, propylene glycol (E1520), banana flavour, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (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 and Manufacturer

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

This leaflet was last revised in 05/2016.

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