What is in this leaflet

1. What Imipramine Hydrochloride Oral Solution is and what is it 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 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 suffer from mania
- 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 of the other ingredients of this medicine
- 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.

Continued overleaf
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 behavior.

While you are taking Imipramine Hydrochloride Oral Solution:
- 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.
- If you already suffer from a panic disorder, you may experience an increase in your anxiety disorder, and ask them to read this leaflet.
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

Children taking Imipramine Hydrochloride Oral Solution may have behavioral 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.
- medications for depression called MAOIs (monamine oxidase inhibitors) such as moclobemide – see Section "Do not take Imipramine Hydrochloride Oral Solution"
- 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 bupropion
- 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 spironolactone or amiodarone
- medications for high blood pressure such as guanethidine, diuretics, branched-chain fatty acids (water tablets)
- medication to treat angina that you spray or dissolve under your tongue such as glyceryl trinitrate or isosorbide dinitrate
- medication for colds, sinus problems, containing decongestants such as phenylephrine or pseudoephedrine
- antihistamines for hay fever or allergies
- aspirin used to treat asthma
- oral contraceptives or oestrogen (e.g. hormone replacement therapy (HRT))

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.

These may be increased when first starting antidepressants. This is because these medicines all take about two weeks but sometimes longer to work properly.

Children taking Imipramine Hydrochloride Oral Solution may have behavioral 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.
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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 you have thought of harming yourself or killing yourself at any time, contact your doctor or go to a hospital straight away.
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.
- 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.
- Contacts 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”
- 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 bupropion
- 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 spironolactone or amiodarone
- medications for high blood pressure such as guanethidine, diltiazem, bendroflumethiazide, clonidine, alpha-methyldopa or diuretics (water tablets)
- medication to treat angina that you spray or dissolve under you tongue such as glyceryl trinitrate or nitroglycerin
- medication to treat epilepsy such as carbamazepine or phenytoin
- antifungal medication such as terbinafine
- medications for depression called MAOIs (monoamine oxidase inhibitors) such as moclobemide – see Section “Do not take Imipramine Hydrochloride Oral Solution”
- medications that contain sympathomimetics such as pseudoephedrine or phenylpropanolamine
- antihistamines for hay fever or allergies
- isoxsuprine used to treat asthma
- oral contraceptives or oestrogen (e.g. hormone replacement therapy [HRT])

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 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 dizzier 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 (E219) and propyl hydroxybenzoate (E216) – may cause allergic reactions (possibly delayed)

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: 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. Overdose in children is possible and could be potentially fatal.

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

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.

Alterations – 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

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.

Continued overleaf
Imipramine Hydrochloride Oral Solution

This leaflet was last revised in 05/2016.

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 6).”

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.

Warning 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 of the other ingredients
- a withdrawal from alcohol or any antidepressant drugs
- electroconvulsive therapy (ECT) treatment and are taking Imipramine Hydrochloride Oral Solution – you will be carefully supervised.

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
- nighttime bed-wetting in children.

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

Imipramine Hydrochloride Oral Solution is used to treat:

Thoughts of suicide and worsening of your depression or anxiety disorder

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.

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
- you are taking (now or recently) any other medicines for depression (particularly monoamine oxidase inhibitors [MAOIs] such as moclobemide within the last 3 weeks).

By reporting side effects you can help provide more information on the safety of this medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

3. How to take Imipramine Hydrochloride Oral Solution

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

4. Possible side effects

An increased risk of bone fractures has been observed in patients taking this type of medicine.

5. How to store Imipramine Hydrochloride Oral Solution

Imipramine Hydrochloride Oral Solution contains:

- the symptoms of depression
- nighttime 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
- you are taking (now or recently) any other medicines for depression (particularly monoamine oxidase inhibitors [MAOIs] such as moclobemide within the last 3 weeks).

By reporting side effects you can help provide more information on the safety of this medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

3. How to take Imipramine Hydrochloride Oral Solution

Keep the 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 6).”

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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.