IMPORTANT WARNING:

A small number of children, teenagers, and young adults (up to 24 years of age) who took antidepressants ("mood elevators") such as imipramine during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant. Children younger than 18 years of age should not normally take imipramine except to prevent bedwetting, but in some cases, a doctor may decide that imipramine is the best medication to treat a child's condition.

You should know that your mental health may change in unexpected ways when you take imipramine or other antidepressants even if you are an adult over 24 years of age. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking imipramine, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

The doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with imipramine. Read the information carefully and ask your doctor or pharmacist if you have any questions. You also can obtain the Medication Guide from the FDA website: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/UCM096273.

No matter your age, before you take an antidepressant, you, your parent, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania (frenzied, abnormally excited mood) or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.
**Why is this medication prescribed?**

Imipramine tablets and capsules are used to treat depression. Imipramine tablets are also used to prevent bedwetting in children. Imipramine is in a class of medications called tricyclic antidepressants. It treats depression by increasing the amounts of certain natural substances in the brain that are needed to maintain mental balance. There is not enough information to explain how imipramine prevents bedwetting.

**How should this medicine be used?**

Imipramine comes as a tablet and a capsule to take by mouth. When imipramine tablets or capsules are used to treat depression, they are usually taken one or more times a day and may be taken with or without food. When imipramine tablets are used to prevent bedwetting in children, they are usually taken one hour before bedtime. Children who wet the bed early in the evening may be given one dose in the mid-afternoon and another dose at bedtime. Try to take imipramine at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take imipramine exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor may start you on a low dose of imipramine and gradually increase your dose.

It may take 1-3 weeks or longer for you to feel the full benefit of imipramine. Continue to take imipramine even if you feel well. Do not stop taking imipramine without talking to your doctor. Your doctor will probably want to decrease your dose gradually.

**Other uses for this medicine**

Imipramine is also used occasionally to treat eating disorders and panic disorders. Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses. Ask your doctor or pharmacist for more information.

**What special precautions should I follow?**

Before taking imipramine,

- tell your doctor and pharmacist if you are allergic to imipramine, any other medications, or any of the ingredients in imipramine tablets or capsules. Ask your doctor or pharmacist for a list of the ingredients.
- tell your doctor if you are taking a monoamine oxidase (MAO) inhibitor such as isocarboxazid (Marplan), linezolid (Zyvox), methylene blue, phenelzine (Nardil), selegiline (Eldepryl, Emsam, Zelapar), and tranylcypromine (Parnate), or if you have stopped taking an MAO inhibitor within the past 14 days. Your doctor will probably tell you not to take imipramine. If you stop taking imipramine, you should wait at least 14 days before you start to take an MAO inhibitor.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: anticoagulants (blood thinners) such as warfarin (Coumadin, Jantoven); antihistamines; cimetidine (Tagamet); flecainide (Tambocor); levodopa (Sinemet, Larodopa); lithium (Eskalith, Lithobid); medication for high blood pressure, mental illness, nausea, seizures, Parkinson's disease, asthma, colds, or allergies; methylphenidate (Ritalin); muscle relaxants; propafenone (Rhythmol); quinidine; sedatives; selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac, Sarafem), fluvoxamine (Luvox), paroxetine (Paxil), and sertraline (Zoloft); sleeping pills; thyroid medications; and tranquilizers. Your doctor may need to change the doses of your medications or monitor
you carefully for side effects. Your doctor may tell you not to take imipramine if you have taken fluoxetine in
the past 5 weeks.
• tell your doctor if you have recently had a heart attack. Your doctor may tell you not to take imipramine.
• tell your doctor if you are being treated with electroshock therapy (procedure in which small electric shocks
are administered to the brain to treat certain mental illnesses), and if you have or have ever had an
enlarged prostate (a male reproductive gland), difficulty urinating, seizures, an overactive thyroid gland, or
liver, kidney, or heart disease.
• tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become
pregnant while taking imipramine, call your doctor.
• if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking imipramine.
• you should know that this medication may make you drowsy. Do not drive a car or operate machinery until
you know how this medication affects you.
• remember that alcohol can add to the drowsiness caused by this medication.
• tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this
medication.
• plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, sunglasses,
and sunscreen. Imipramine may make your skin sensitive to sunlight.
• you should know that imipramine may cause angle-closure glaucoma (a condition where the fluid is
suddenly blocked and unable to flow out of the eye causing a quick, severe increase in eye pressure which
may lead to a loss of vision). Talk to your doctor about having an eye examination before you start taking
this medication. If you have nausea, eye pain, changes in vision, such as seeing colored rings around
lights, and swelling or redness in or around the eye, call your doctor or get emergency medical treatment
right away.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for your next dose, skip the
missed dose and continue your regular dosing schedule.

What side effects can this medication cause?

Imipramine may cause side effects. Tell your doctor if any of these symptoms are severe or do not go
away:
• nausea
• drowsiness
• weakness or tiredness
• excitement or anxiety
• nightmares
• dry mouth
• skin more sensitive to sunlight than usual
• changes in appetite or weight
• constipation
• difficulty urinating
• frequent urination
• changes in sex drive or ability
• excessive sweating

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, call your doctor immediately or get emergency medical treatment:
• jaw, neck, and back muscle spasms
• slow or difficult speech
• shuffling walk
• uncontrollable shaking of a part of the body
• fever, sore throat, or other signs of infection
• difficulty breathing or swallowing
• severe rash
• yellowing of the skin or eyes
• irregular heartbeat

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at http://www.fda.gov/Safety/MedWatch] or by phone [1-800-332-1088].

Imipramine may cause other side effects. Tell your doctor if you have any unusual problems while you are taking this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor.
Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

**Brand names**

- Tofranil®
- Tofranil® PM

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