

MEDICATION GUIDE
DESYREL® (DEZ ur el)
(trazodone hydrochloride)
tablets, for oral use

What is the most important information I should know about DESYREL?

Antidepressant medicines, depression or other serious mental illnesses, and suicidal thoughts or actions: Talk to your healthcare provider about:

- All risks and benefits of treatment with antidepressant medicines
- All treatment choices for depression or other serious mental illnesses
- 1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
- 2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions.**
Some people may have a higher risk of having suicidal thoughts or actions. These include people who have or have a family history of bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
- 3. **How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Call a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to your healthcare provider about the side effects of your medicines.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you take. Keep a list of all medicines to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.

It is not known if DESYREL is safe and effective in children.

What is DESYREL?

DESYREL is a prescription medicine used in adults to treat major depressive disorder (MDD). DESYREL belongs to a class of medicines known as SSRIs (or selective serotonin reuptake inhibitors).

Do not take DESYREL:

- If you take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid, and intravenous methylene blue.
- Do not take an MAOI within 2 weeks of stopping DESYREL unless directed to do so by your healthcare provider.

- Do not start DESYREL if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

Before you take DESYREL tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems, including QT prolongation or a family history of it
- have ever had a heart attack
- have bipolar disorder
- have liver or kidney problems
- have other serious medical conditions
- are pregnant or plan to become pregnant. It is not known if DESYREL will harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take DESYREL.
 - If you become pregnant during treatment with DESYREL, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185.
- are breastfeeding or plan to breastfeed. DESYREL passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take DESYREL.
- have taken a Monoamine Oxidase Inhibitor (MAOI) or if you have stopped taking an MAOI in the last 2 weeks.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using DESYREL with certain other medicines can affect each other causing serious side effects.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, buspirone, or antipsychotics
- tramadol
- over-the-counter supplements such as tryptophan or St. John's Wort
- nonsteroidal anti-inflammatory drugs (NSAIDs)
- aspirin
- warfarin (Coumadin, Jantoven)
- phenytoin (Mesantoin)
- diuretics

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take DESYREL?

- Take DESYREL exactly as your healthcare provider tells you.
- DESYREL should be taken shortly after a meal or light snack.
- If you feel drowsy after taking DESYREL, talk to your healthcare provider. Your healthcare provider may change your dose or the time of day you take your DESYREL.
- Do not stop taking DESYREL without talking to your healthcare provider.
- DESYREL should be swallowed whole or broken in half along the score line. Do not chew or crush DESYREL. Tell your healthcare provider if you cannot swallow trazodone either whole or as a half tablet.
- If you take too much DESYREL, call your healthcare provider, your Poison Control Center at 1-800-222-1222, or go to the nearest emergency room right away.

What should I avoid while taking DESYREL?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how DESYREL affects you. DESYREL can slow your thinking and motor skills.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking DESYREL until you talk with your healthcare provider. DESYREL may make your sleepiness or dizziness worse if you take it with alcohol or other medicines that cause sleepiness or dizziness.

What are the possible side effects of DESYREL?**DESYREL can cause serious side effects or death, including:**

- **See “What is the most important information I should know about DESYREL?”**
- **Serotonin syndrome.** Symptoms of serotonin syndrome include: agitation, hallucinations, problems with coordination, fast heartbeat, tight muscles, trouble walking, sweating, fever, nausea, vomiting, and diarrhea.
- **Irregular or fast heartbeat or faint (QT prolongation)**
- **Low blood pressure.** You feel dizzy or faint when you change positions (go from sitting to standing)
- **Unusual bruising or bleeding**
- **Erection lasting for more than 6 hours (priapism)**
- **Feeling high or in a very good mood, then becoming irritable, or having too much energy, feeling like you have to keep talking or do not sleep (mania).**
- **Withdrawal symptoms.** Symptoms of withdrawal can include anxiety, agitation, and sleep problems. Do not stop taking DESYREL without talking to your healthcare provider.
- **Visual problems.**
 - eye pain
 - changes in vision
 - swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- **Low sodium in your blood (hyponatremia).** Symptoms of hyponatremia include: headache, feeling weak, feeling confused, trouble concentrating, memory problems and feeling unsteady when you walk.

Get medical help right away, if you have any of the symptoms listed above.

The most common side effects of DESYREL include:

- swelling
- blurred vision
- dizziness
- sleepiness
- tiredness
- diarrhea
- stuffy nose
- weight loss

These are not all the possible side effects of DESYREL. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DESYREL?

- Store DESYREL at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep in tight container
- Keep out of the light
- Safely throw away medicine that is out of date or no longer needed.

Keep DESYREL and all medicines out of the reach of children.**General information about the safe and effective use of DESYREL.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DESYREL for a condition for which it was not prescribed. Do not give DESYREL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DESYREL that is written for health professionals.

What are the ingredients in DESYREL?

Active ingredient: trazodone hydrochloride, USP

Inactive ingredients: 50 mg and 100 mg: Corn starch, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, and triacetin 150 mg: magnesium stearate, microcrystalline cellulose, pregelatinized starch, and stearic acid 300 mg: magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, and stearic acid

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