

<p>Patient Information</p> <p>Fesoterodine Fumarate (FES oh TER oh deen)</p> <p>Extended-Release Tablets, for oral use</p>	<p>healthcare provider or go to an emergency department right away.</p> <p>What should I avoid while taking fesoterodine fumarate extended-release tablets?</p>								
<p>Read the Patient Information that comes with fesoterodine fumarate extended-release tablets before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.</p>	<ul style="list-style-type: none"> • Fesoterodine fumarate extended-release tablets can cause blurred vision, dizziness, and drowsiness. Do not drive, operate machinery, or do other dangerous activities until you know how fesoterodine fumarate affects you. 								
<p>What are fesoterodine fumarate extended-release tablets?</p>	<p>Fesoterodine fumarate extended-release tablets are a prescription medicine used:</p>								
<ul style="list-style-type: none"> • in adults to treat symptoms of a condition called overactive bladder (OAB), including urge urinary incontinence (leaking or wetting accidents due to a strong need to urinate), urinary urgency (having a strong need to urinate right away), or urinary frequency (having to urinate too often). • in children 6 years of age and older with a body weight greater than 55 pounds (25 kg) to treat neurogenic detrusor overactivity (NDO). TOVIAZ is used to increase the amount of urine your bladder can hold and reduce urine leakage. 	<p>It is not known if fesoterodine fumarate is safe and effective in children younger than 6 years of age or with a body weight 55 pounds (25 kg) or less.</p>								
<p>Who should not take fesoterodine fumarate extended-release tablets?</p>	<p>Do not take fesoterodine fumarate extended-release tablets if you:</p>								
<ul style="list-style-type: none"> • are allergic to fesoterodine fumarate extended-release tablets or any of its ingredients. See the end of this leaflet for a complete list of ingredients. • are allergic to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. • are not able to empty your bladder (urinary retention). • have delayed or slow emptying of your stomach (gastric retention). • have an eye problem called uncontrolled narrow-angle glaucoma. 	<p>The most common side effects of fesoterodine fumarate extended-release tablets in adults include:</p> <ul style="list-style-type: none"> • dry mouth • constipation 								
<p>Before you take fesoterodine fumarate extended-release tablets, tell your healthcare provider about all your medical conditions, including if you:</p>	<p>The most common side effects of fesoterodine fumarate extended-release tablets in children 6 years of age and older include</p>								
<ul style="list-style-type: none"> • have problems emptying your bladder or you have a weak urine stream. • have any stomach or intestinal problems, or problems with constipation. • are receiving treatment for an eye problem called narrow-angle glaucoma. • have a condition called Myasthenia Gravis. • have kidney problems • have liver problems • are pregnant or plan to become pregnant. It is not known if fesoterodine fumarate extended-release tablets will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant. • are breastfeeding or plan to breastfeed. It is not known if fesoterodine fumarate passes into your breast milk. You should talk to your healthcare provider about the best way to feed your baby while taking fesoterodine fumarate extended-release tablets. 	<table border="1"> <tr> <td>• diarrhea</td> <td>• dry mouth</td> <td>• stomach pain</td> <td>• weight gain</td> </tr> <tr> <td>• urinary tract infection</td> <td>• constipation</td> <td>• nausea</td> <td>• headache</td> </tr> </table>	• diarrhea	• dry mouth	• stomach pain	• weight gain	• urinary tract infection	• constipation	• nausea	• headache
• diarrhea	• dry mouth	• stomach pain	• weight gain						
• urinary tract infection	• constipation	• nausea	• headache						
<p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal products. Fesoterodine fumarate extended-release tablets may affect the way other medicines work, and other medicines may affect how fesoterodine fumarate extended-release tablets work. Especially tell your healthcare provider if you are taking antimuscarinic, antibiotics, or antifungal medicines.</p>	<p>Talk to your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of fesoterodine fumarate extended-release tablets. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>								
<p>Know all the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine.</p>	<p>How should I store fesoterodine fumarate extended-release tablets?</p>								
<ul style="list-style-type: none"> • Take fesoterodine fumarate extended-release tablets exactly as your healthcare provider tells you to take it. • Your healthcare provider may lower your dose of fesoterodine fumarate extended-release tablets if you are an adult with severe kidney problems. • Your healthcare provider may lower or stop your dose of fesoterodine fumarate extended-release tablets if you are a child 6 years of age and older with a body weight greater than 77 pounds (35 kg) and have severe kidney problems or are taking certain medicines. • Take fesoterodine fumarate extended-release tablets with liquid and swallow the tablet whole. Do not chew, divide, or crush the tablet. • Take fesoterodine fumarate extended-release tablets with or without food. • If you miss a dose of fesoterodine fumarate extended-release tablets, begin taking fesoterodine fumarate extended-release tablets again the next day. Do not take 2 doses of fesoterodine fumarate extended-release tablets in the same day. • If you take too much fesoterodine fumarate extended-release tablets, call your 	<ul style="list-style-type: none"> • Store fesoterodine extended-release tablets between 68°F to 77°F (20°C to 25°C). • Protect the medicine from moisture by keeping the bottle closed tightly. • Keep fesoterodine fumarate extended-release tablets and all medicines out of the reach of children. 								
<p>General information about the safe and effective use of fesoterodine fumarate extended-release tablets</p>	<p>Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use fesoterodine fumarate extended-release tablets for a condition for which it was not prescribed. Do not give fesoterodine fumarate extended-release tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about fesoterodine fumarate extended-release tablets that is written for health professionals.</p>								
<p>What are the ingredients in fesoterodine fumarate extended-release tablets?</p>	<p>Active ingredient: fesoterodine fumarate</p>								
<ul style="list-style-type: none"> • FD&C Blue #2, fructose, glyceryl behenate, hypromellose, lactose anhydrous, lecithin soya, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide. 	<p>Inactive ingredients: FD&C Blue #2, fructose, glyceryl behenate, hypromellose, lactose anhydrous, lecithin soya, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.</p>								
<p>Rx only</p>	<p>Distributor:</p>								
<p>Dr. Reddy's Laboratories Inc.,</p>	<p>Princeton, NJ 08540</p>								
<p>Product of Italy</p>	<p>Dr. Reddy's </p>								
<p>This Patient Information has been approved by the U.S. Food and Drug Administration.</p>	<p>Revised: 09/2025</p>								
<p>To reorder additional Patient Information Leaflets, please contact Dr. Reddy's Customer Service at 1-866-733-3952.</p>	<p>150104121</p>								