

## FIRST TIME GENERIC APPROVAL

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|--------------------------|-------------------------------|
| <b>Brand Name</b>        | fesoterodine fumarate         |
| <b>Generic Name</b>      | fesoterodine fumarate         |
| <b>Drug Manufacturer</b> | Dr.Reddy's Laboratories Inc., |

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First Time Generic

#### FDA APPROVAL DATE

August 13, 2019

#### LAUNCH DATE

June 17, 2022

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 204975

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION FOR USE

Fesoterodine fumarate extended-release tablets are indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency.

#### MECHANISMS OF ACTION

Fesoterodine is a competitive muscarinic receptor antagonist. After oral administration, fesoterodine is rapidly and extensively hydrolyzed by nonspecific esterases to its active metabolite, 5-hydroxymethyl tolterodine, which is responsible for the antimuscarinic activity of fesoterodine.

Muscarinic receptors play a role in contractions of urinary bladder smooth muscle. Inhibition of these receptors in the bladder is presumed to be the mechanism by which fesoterodine produces its effects.

#### DOSE FORM AND STRENGTH

Extended-release tablets: 4 mg and 8 mg.

#### DOSE & ADMINISTRATION

Overactive bladder (OAB) in Adults: The recommended starting dosage is 4 mg orally once daily. Based upon individual response and tolerability, increase to the maximum dosage of 8 mg once daily.

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