FIRST TIME GENERIC APPROVAL

Brand Name	fesoterodine fumarate
Generic Name	fesoterodine fumarate
Drug Manufacturer	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.