FESOTERODINE FUMARATE - fesoterodine fumarate tablet, film coated, extended release
Zydus Lifesciences Limited

FESOTERODINE FUMARATE EXTENDED-RELEASE TABLETS

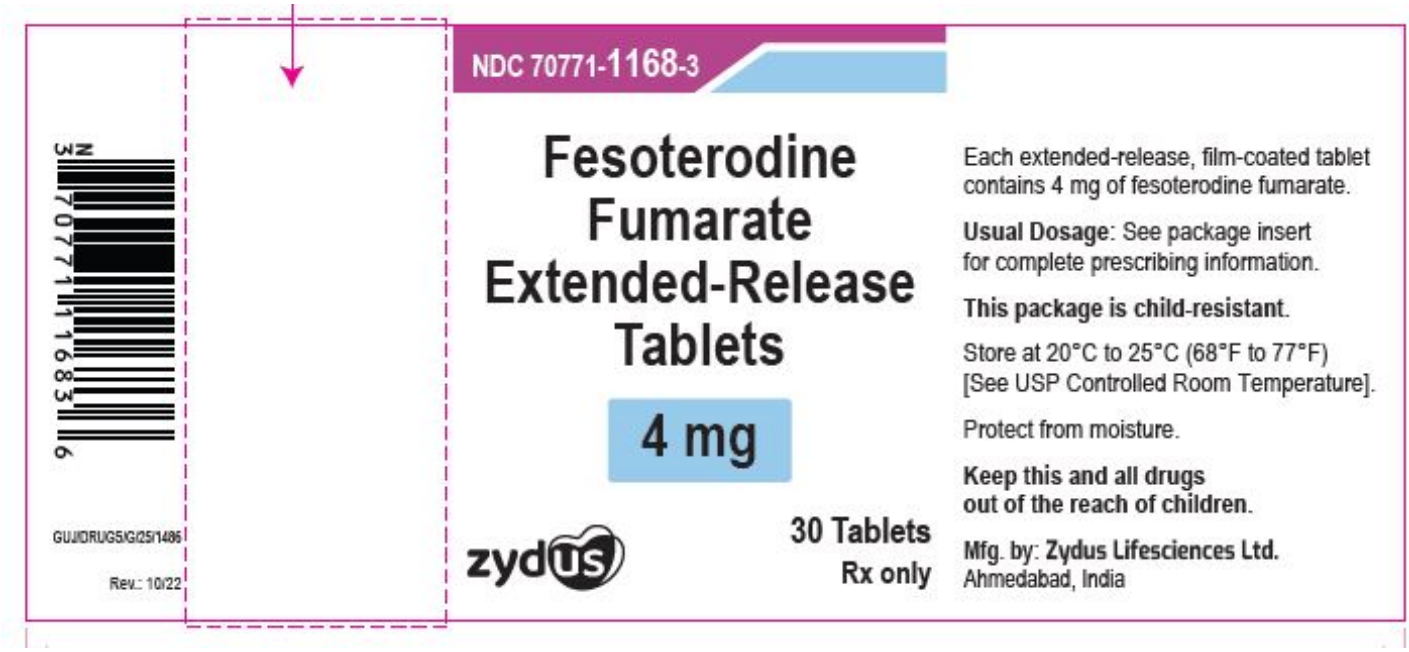
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1168-9 in bottle of 90 tablets

Fesoterodine Fumarate Extended-release Tablets, 4 mg

Rx only

90 tablets



NDC 70771-1169-9 in bottle of 90 tablets

Fesoterodine Fumarate Extended-release Tablets, 8 mg

Rx only

90 tablets

FESOTERODINE FUMARATE

fesoterodine fumarate tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1168
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FESOTERODINE FUMARATE (UNII: EOS72165S7) (FESOTERODINE - UNII:621G617227)	FESOTERODINE FUMARATE	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics			
Color	YELLOW (Light Yellow)	**Score**	no score
Shape	OVAL (Oval)	**Size**	13mm
Flavor		**Imprint Code**	479
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1168-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
2	NDC:70771-1168-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
3	NDC:70771-1168-4	10 in 1 CARTON	12/07/2017	
3	NDC:70771-1168-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204946	12/07/2017	

FESOTERODINE FUMARATE

fesoterodine fumarate tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1169
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FESOTERODINE FUMARATE (UNII: EOS72165S7) (FESOTERODINE - UNII:621G617227)	FESOTERODINE FUMARATE	8 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (White to Off-White)	**Score**	no score
Shape	OVAL (Oval)	**Size**	13mm
Flavor		**Imprint Code**	480
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1169-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
2	NDC:70771-1169-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
3	NDC:70771-1169-4	10 in 1 CARTON	12/07/2017	
3	NDC:70771-1169-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204946	12/07/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1168, 70771-1169) , MANUFACTURE(70771-1168, 70771-1169)

Revised: 8/2022 Zydus Lifesciences Limited