ESCITALOPRAM- escitalopram tablet, film coated
Cadila Healthcare Limited

ESCITALOPRAM TABLETS

SPL MEDGUIDE

Manufactured by:

Cadila Healthcare Ltd.

India.

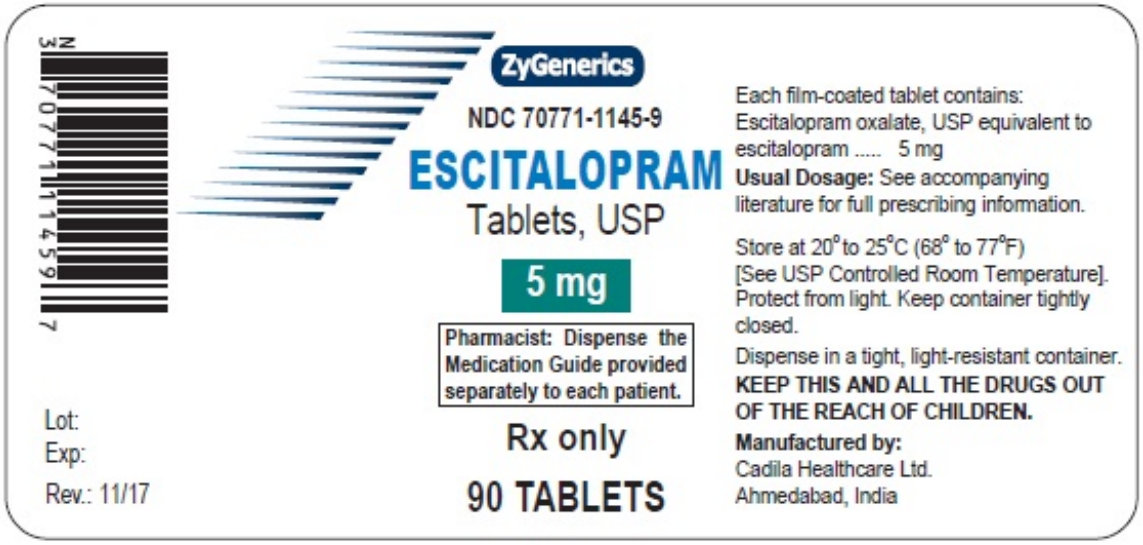
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1145-9 in bottle of 90 tablets

Escitalopram Oxalate Tablets USP, 5 mg

R_x only

90 tablets

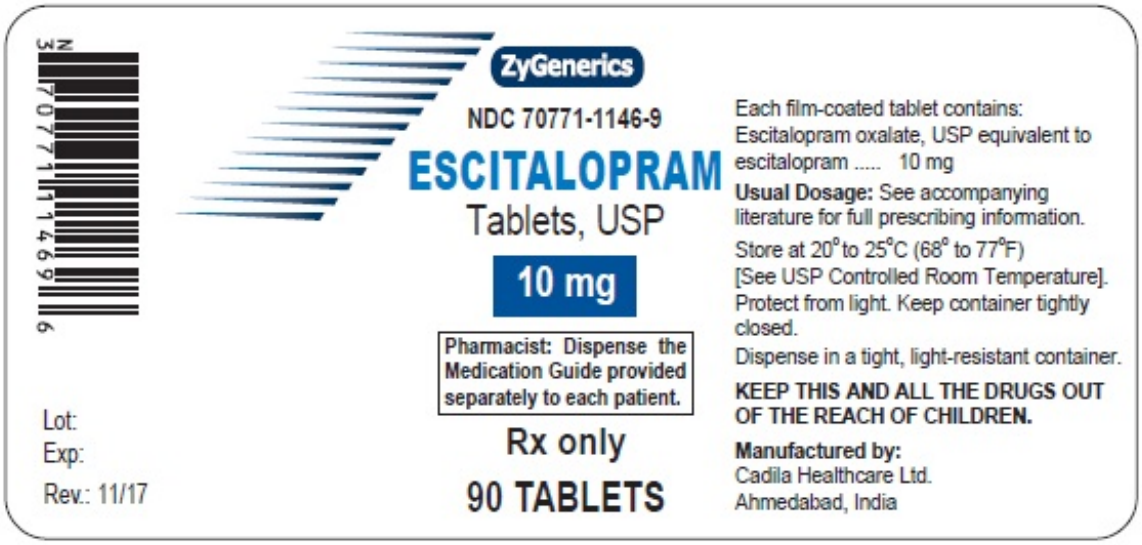


NDC 70771-1146-9 in bottle of 90 tablets

Escitalopram Oxalate Tablets USP, 10 mg

R_x only

90 tablets

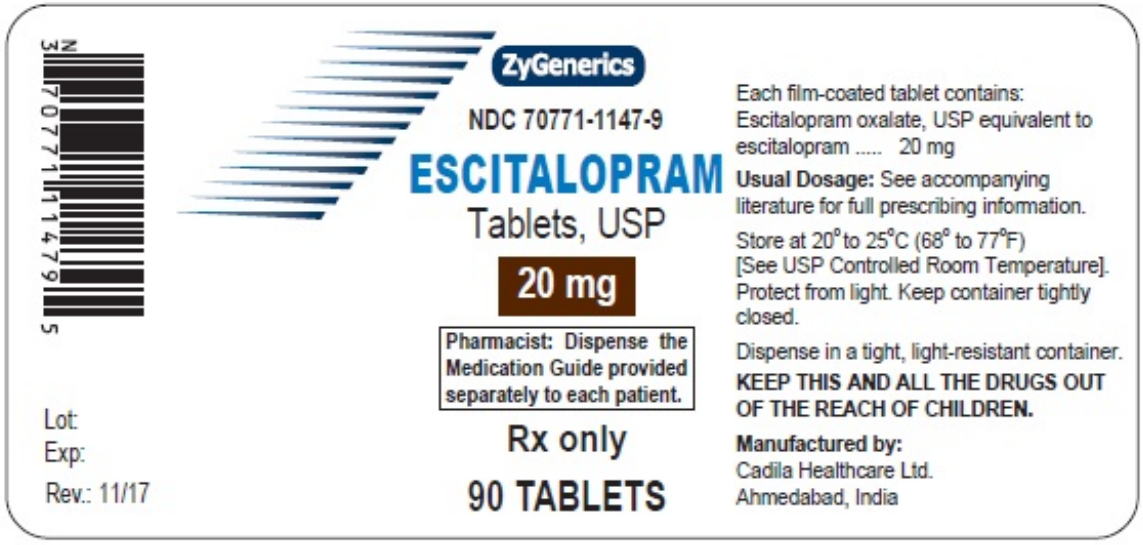


NDC 70771-1147-9 in bottle of 90 tablets

Escitalopram Oxalate Tablets USP, 20 mg

R_x only

90 tablets



ESCITALOPRAM

escitalopram tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1145
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ESCITALOPRAM OXALATE (UNII: 5U85DBW7LO) (ESCITALOPRAM - UNII:4O4S742ANY)	ESCITALOPRAM	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	ZC;37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1145-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
2	NDC:70771-1145-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
3	NDC:70771-1145-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
4	NDC:70771-1145-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
5	NDC:70771-1145-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077734	12/07/2017	

ESCITALOPRAM

escitalopram tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1146
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESCITALOPRAM OXALATE (UNII: 5U85DBW7LO) (ESCITALOPRAM - UNII:4O4S742ANY)	ESCITALOPRAM	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	ZC;23
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1146-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
2	NDC:70771-1146-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
3	NDC:70771-1146-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
4	NDC:70771-1146-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
5	NDC:70771-1146-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077734	12/07/2017	

ESCITALOPRAM

escitalopram tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1147
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESCITALOPRAM OXALATE (UNII: 5U85DBW7LO) (ESCITALOPRAM - UNII:4O4S742ANY)	ESCITALOPRAM	20 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	ZC;24
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1147-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
2	NDC:70771-1147-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
3	NDC:70771-1147-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
4	NDC:70771-1147-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	
5	NDC:70771-1147-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077734	12/07/2017	

Labeler - Cadila Healthcare Limited (918596198)

Revised: 8/2020 Cadila Healthcare Limited