ETODOLAC- etodolac tablet, film coated, extended release
Zydus Lifesciences Limited

Etodolac Extended-release Tablets, USP

SPL MEDGUIDE

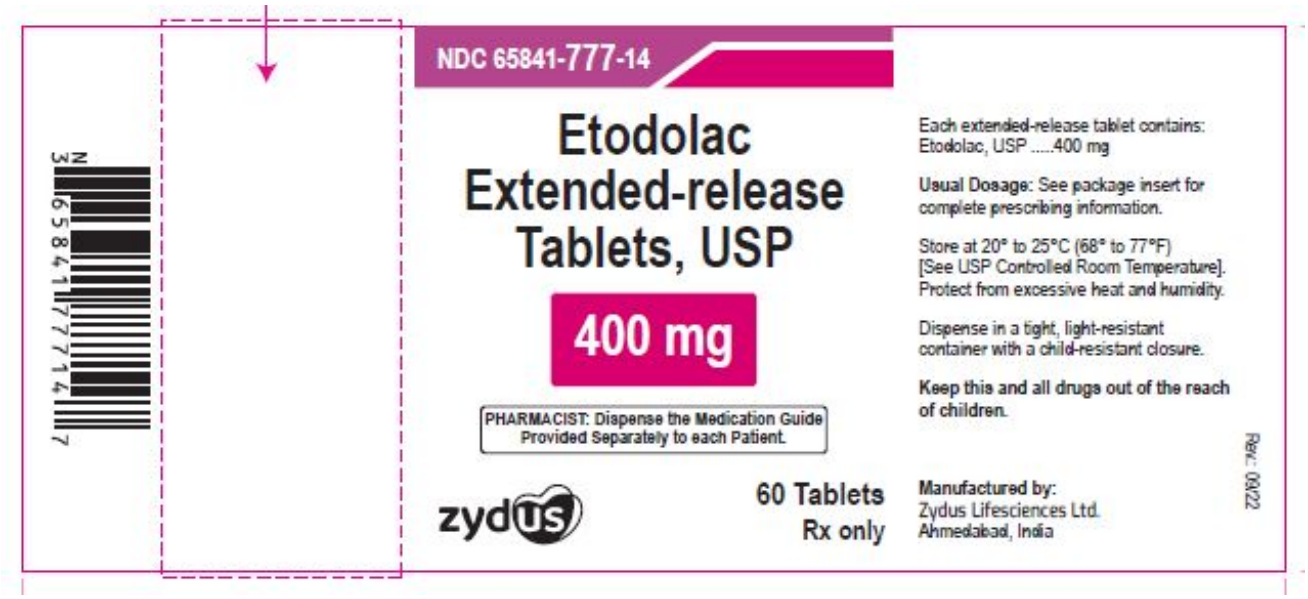
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-777-14 in bottle of 60 tablets

Etodolac Extended-release Tablets USP, 400 mg

R_x only

60 tablets

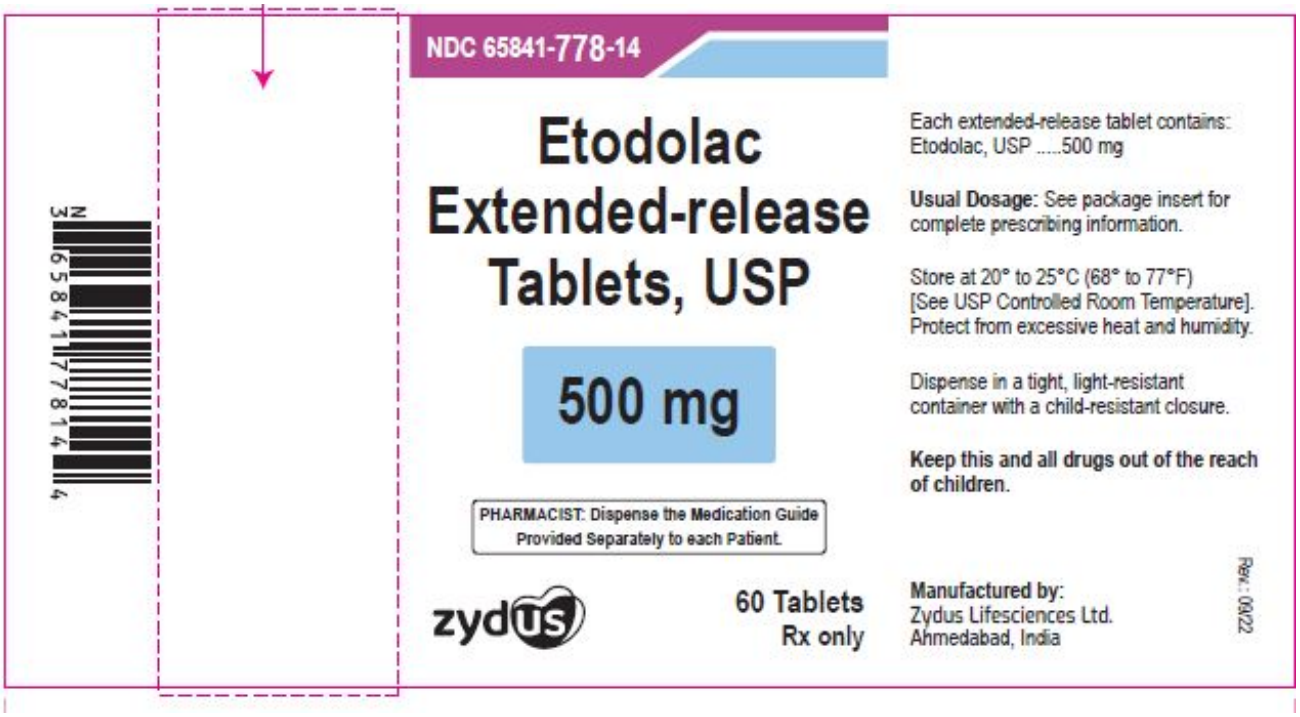


NDC 65841-778-14 in bottle of 60 tablets

Etodolac Extended-release Tablets USP, 500 mg

R_x only

60 tablets

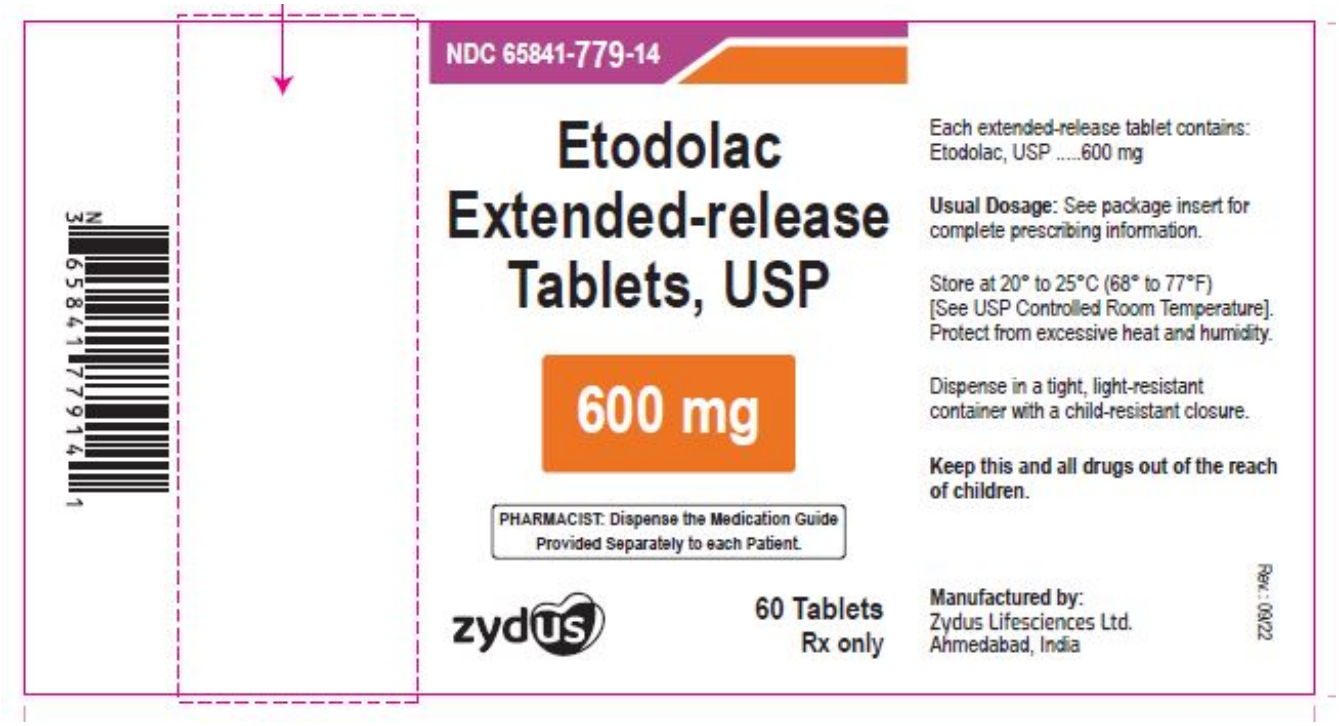


NDC 65841-779-14 in bottle of 60 tablets

Etodolac Extended-release Tablets USP, 600 mg

R_x only

60 tablets



ETODOLAC

etodolac tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-777
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ETODOLAC (UNII: 2M36281008) (ETODOLAC - UNII:2M36281008)	ETODOLAC	400 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYLCELLULOSE (100 MPA.S) (UNII: 47MLB0F1MV)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color	ORANGE (ORANGE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	17mm
Flavor		**Imprint Code**	271
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-777-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
2	NDC:65841-777-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
3	NDC:65841-777-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
4	NDC:65841-777-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
5	NDC:65841-777-77	100 in 1 CARTON	02/15/2014	
5	NDC:65841-777-30	1 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	ANDA091134	02/15/2014	

ETODOLAC

etodolac tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-778
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ETODOLAC (UNII: 2M36281008) (ETODOLAC - UNII:2M36281008)	ETODOLAC	500 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (100 MPA.S) (UNII: 47MLB0F1MV)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color	GRAY (GRAY)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	18mm
Flavor		**Imprint Code**	272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-778-	60 in 1 BOTTLE; Type 0: Not a Combination	02/15/2014	

1	14	Product	02/15/2014	
2	NDC:65841-778-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
3	NDC:65841-778-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
4	NDC:65841-778-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
5	NDC:65841-778-77	100 in 1 CARTON	02/15/2014	
5	NDC:65841-778-30	1 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	ANDA091134	02/15/2014	

ETODOLAC

etodolac tablet, film coated, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-779
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ETODOLAC (UNII: 2M36281008) (ETODOLAC - UNII:2M36281008)	ETODOLAC	600 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (100 MPA.S) (UNII: 47MLB0F1MV)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color	BLUE (BLUE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	19mm
Flavor		**Imprint Code**	273
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-779-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
2	NDC:65841-779-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
3	NDC:65841-779-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
4	NDC:65841-779-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2014	
5	NDC:65841-779-77	100 in 1 CARTON	02/15/2014	
5	NDC:65841-779-30	1 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	ANDA091134	02/15/2014	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-777, 65841-778, 65841-779) , MANUFACTURE(65841-777, 65841-778, 65841-779)

Revised: 9/2023 Zydus Lifesciences Limited