

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

Etodolac Extended-release Tablets, USP

SPL MEDGUIDE

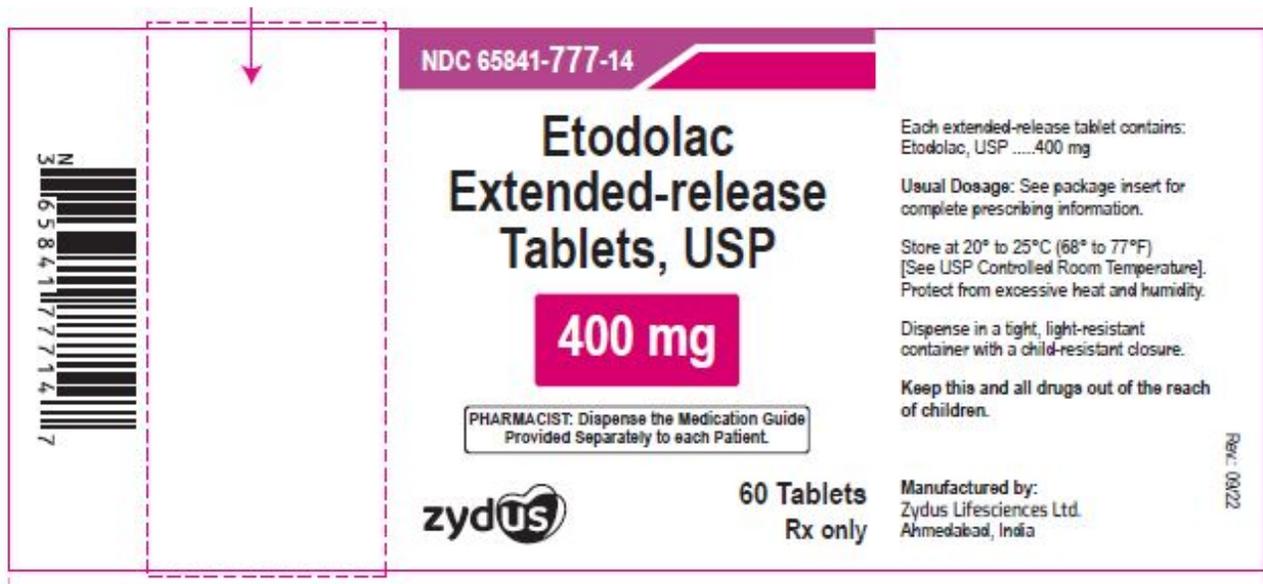
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 65841-778-14

**Etodolac
Extended-release
Tablets, USP**

500 mg

PHARMACIST: Dispense the Medication Guide
Provided Separately to each Patient.

zydus 60 Tablets
Rx only

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

Rev: 0A/22

Each extended-release tablet contains:
Etodolac, USP500 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Protect from excessive heat and humidity.

Dispense in a tight, light-resistant container with a child-resistant closure.

Keep this and all drugs out of the reach of children.

3 N
6 5 8 4 1 7 7 8 1 4
4

NDC 65841-779-14 in bottle of 60 tablets
Etodolac Extended-release Tablets USP, 600 mg
Rx only
60 tablets

NDC 65841-779-14

**Etodolac
Extended-release
Tablets, USP**

600 mg

PHARMACIST: Dispense the Medication Guide
Provided Separately to each Patient.

zydus 60 Tablets
Rx only

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

Rev: 0A/22

Each extended-release tablet contains:
Etodolac, USP600 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Protect from excessive heat and humidity.

Dispense in a tight, light-resistant container with a child-resistant closure.

Keep this and all drugs out of the reach of children.

3 N
6 5 8 4 1 7 7 9 1 4
1

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: 3WJQ0SDW1A)	
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)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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: 3WJQ0SDW1A)	
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	
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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	
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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: 11/2024

Zydus Lifesciences Limited