

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

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**Etodolac Extended-release Tablets, USP**

**SPL MEDGUIDE**

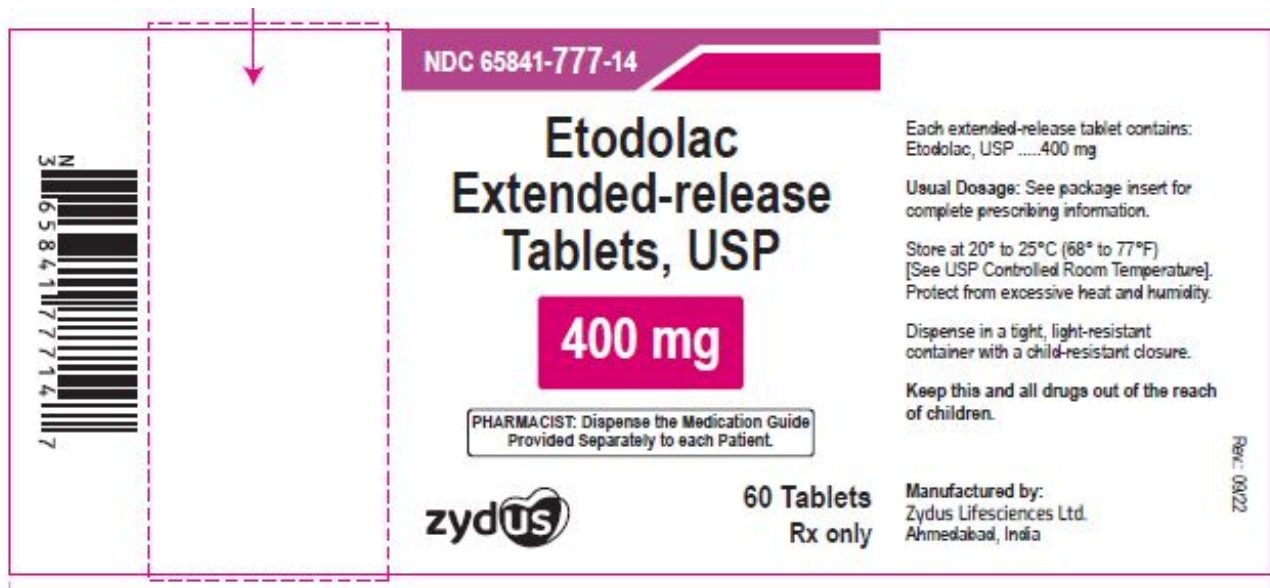
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-777-14 in bottle of 60 tablets

Etodolac Extended-release Tablets USP, 400 mg

R<sub>x</sub> only

60 tablets



NDC 65841-778-14 in bottle of 60 tablets

Etodolac Extended-release Tablets USP, 500 mg

R<sub>x</sub> 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, USP .....500 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, USP .....600 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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-777
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ETODOLAC</b> (UNII: 2M36281008) (ETODOLAC - UNII:2M36281008)	ETODOLAC	400 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>ETHYLCELLULOSE (100 MPA.S)</b> (UNII: 47MLB0F1MV)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	

**Product Characteristics**

<b>Color</b>	ORANGE (ORANGE)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	271
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-779
<b>Route of Administration</b>	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

<b>Color</b>	BLUE (BLUE)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	273
<b>Contains</b>			

### 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	
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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: 9/2023

Zydus Lifesciences Limited