

ELETRIPTAN HYDROBROMIDE- eletriptan hydrobromide tablet, film coated
Zydus Lifesciences Limited

ELETRIPTAN HYDROBROMIDE TABLETS

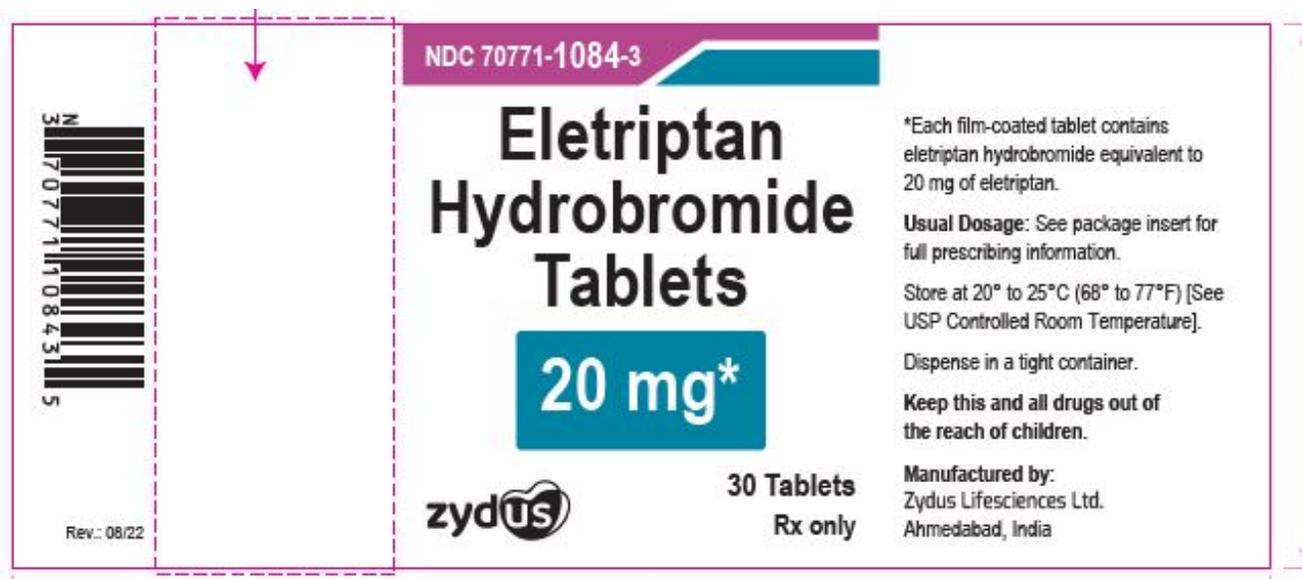
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Eletriptan hydrobromide Tablets, 20 mg

NDC 70771-1107-3

Rx only

30 Tablets



Eletriptan hydrobromide Tablets, 40 mg

NDC 70771-1108-3

Rx only

30 Tablets

NDC 70771-1085-3

Rev.: 08/22

Eletriptan Hydrobromide Tablets

40 mg*

zydus

*Each film-coated tablet contains eletriptan hydrobromide equivalent to 40 mg of eletriptan.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight container.

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

Manufactured by:
Zydus Lifesciences Ltd.
Ahmedabad, India

30 Tablets
Rx only

ELETRIPTAN HYDROBROMIDE

eletriptan hydrobromide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1107
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ELETRIPTAN HYDROBROMIDE (UNII: M41W832TA3) (ELETRIPTAN - UNII:22QOO9B8KI)	ELETRIPTAN	20 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 112 (UNII: X7XJ6RM9Q2)	
POVIDONE K30 (UNII: U725QWY32X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	ORANGE (ORANGE TO MOTTLED ORANGE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	922
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1107-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2017	
2	NDC:70771-1107-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2017	
3	NDC:70771-1107-4	10 in 1 CARTON	07/12/2017	
3	NDC:70771-1107-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1107-6	1 in 1 CARTON	07/12/2017	
4		6 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	ANDA206409	07/12/2017	

ELETRIPTAN HYDROBROMIDE

eletriptan hydrobromide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1108
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ELETRIPTAN HYDROBROMIDE (UNII: M41W832TA3) (ELETRIPTAN - UNII:22QOO9B8KI)	ELETRIPTAN	40 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3S5Y5LH9PMK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 112 (UNII: X7XJ6RM9Q2)	
POVIDONE K30 (UNII: U725QWY32X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BROWN (BROWN)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	923
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1108-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2017	
2	NDC:70771-1108-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2017	
3	NDC:70771-1108-4	10 in 1 CARTON	07/12/2017	
3	NDC:70771-1108-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1108-6	1 in 1 CARTON	07/12/2017	
4		6 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	ANDA206409	07/12/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1107, 70771-1108) , MANUFACTURE(70771-1107, 70771-1108)

