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

ELETRIPTAN HYDROBROMIDE TABLETS

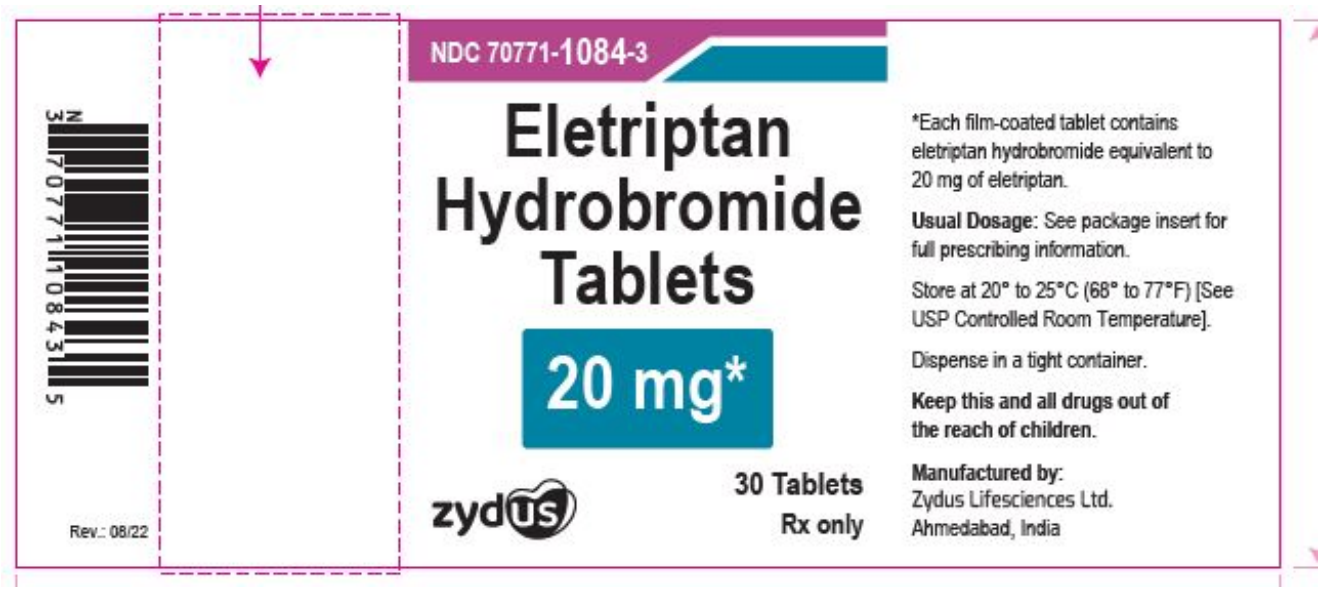
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

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: 3SY5LH9PMK)	
CROSCARMELLOSE 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)