

FELBAMATE- felbamate tablet
Zydus Lifesciences Limited

Felbamate Tablets, USP

SPL MEDGUIDE

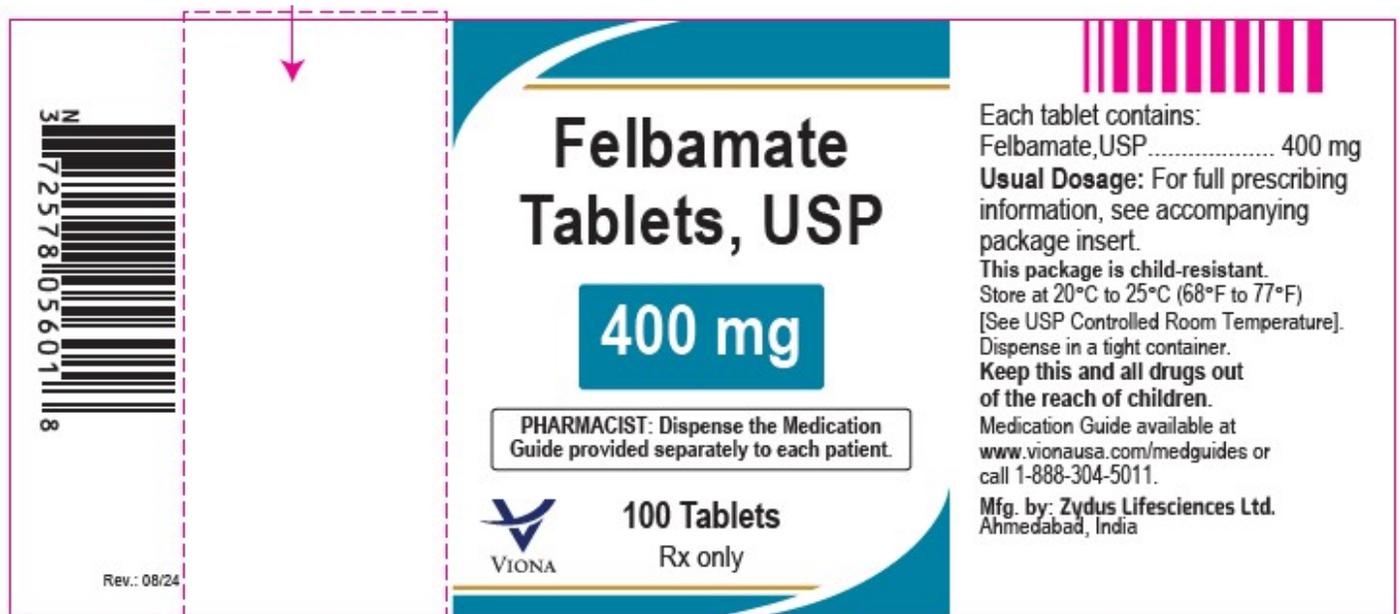
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1077-1

Felbamate tablets USP, 400 mg

100 Tablets

Rx only



NDC 70771-1078-1

Felbamate tablets USP, 600 mg

100 Tablets

Rx only



FELBAMATE

felbamate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1077
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FELBAMATE (UNII: X72RBB02N8) (FELBAMATE - UNII:X72RBB02N8)	FELBAMATE	400 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3S)	

Product Characteristics

Color	WHITE (OFF-WHITE TO PALE YELLOW COLOR)	Score	2 pieces
Shape	CAPSULE (CAPSULE)	Size	16mm
Flavor		Imprint Code	10;53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1077-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
2	NDC:70771-1077-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
3	NDC:70771-1077-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
4	NDC:70771-1077-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
5	NDC:70771-1077-4	10 in 1 CARTON	08/15/2017	
5		10 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	ANDA208970	08/15/2017	

FELBAMATE

felbamate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1078
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FELBAMATE (UNII: X72RBB02N8) (FELBAMATE - UNII:X72RBB02N8)	FELBAMATE	600 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (LIGHT PINK TO PINK)	Score	2 pieces
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	10;54
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1078-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
2	NDC:70771-1078-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
3	NDC:70771-1078-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
4	NDC:70771-1078-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	
5	NDC:70771-1078-4	10 in 1 CARTON	08/15/2017	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:70771-1078-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208970	08/15/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1077, 70771-1078) , MANUFACTURE(70771-1077, 70771-1078)