

FELBAMATE- felbamate tablet
Zydus Lifesciences Limited

Felbamate Tablets, USP

SPL MEDGUIDE

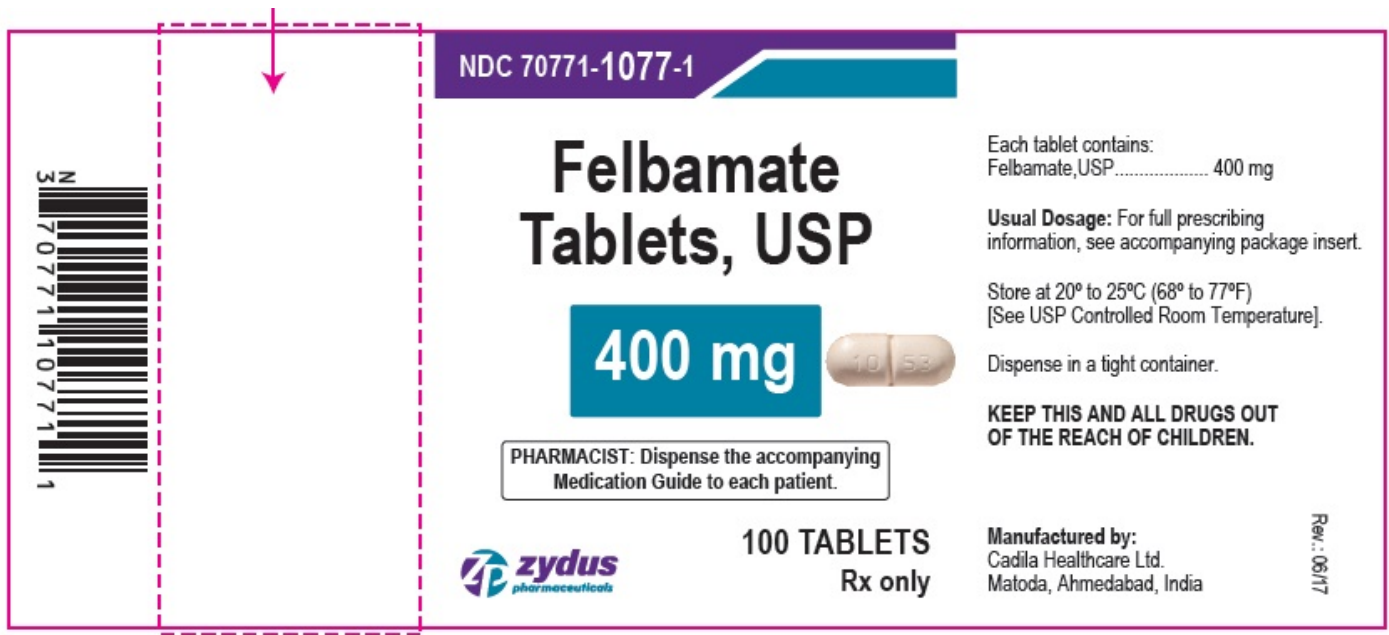
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1077-1

Felbamate tablets USP, 400 mg

100 Tablets

Rx only



NDC 70771-1078-1

Felbamate tablets USP, 600 mg

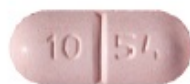
100 Tablets

Rx only

NDC 70771-1078-1

Felbamate Tablets, USP

600 mg



PHARMACIST: Dispense the accompanying Medication Guide to each patient.



100 TABLETS
Rx only

Each tablet contains:
Felbamate, USP 600 mg

Usual Dosage: For full prescribing information, see accompanying package insert.

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:
Cadila Healthcare Ltd.
Matoda, Ahmedabad, India

Rev: 09/17



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: 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 | 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) |

