

TERIFLUNOMIDE- teriflunomide tablet, film coated
Zydus Lifesciences Limited

Teriflunomide Tablets

SPL MEDGUIDE

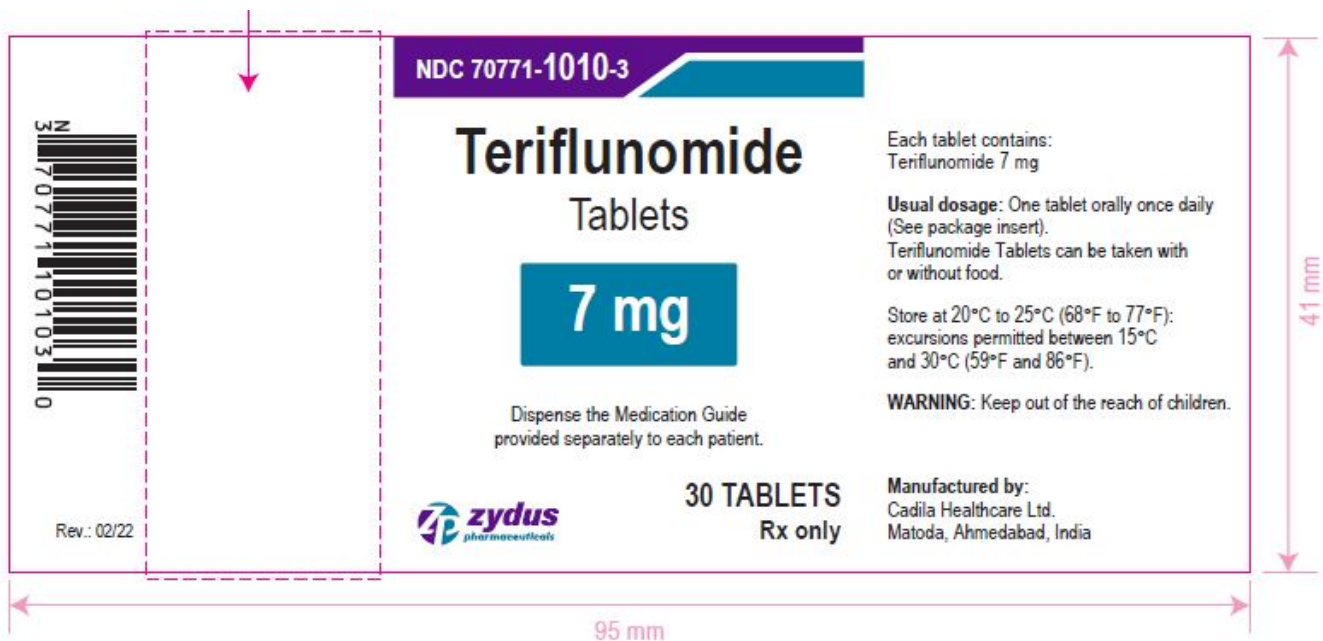
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1010-3

Teriflunomide Tablets, 7 mg

30 Tablets

Rx only



NDC 70771-1011-3

Teriflunomide Tablets, 14 mg

30 Tablets

Rx only



TERIFLUNOMIDE

teriflunomide tablet, film coated

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1010 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| TERIFLUNOMIDE (UNII: 1C058IKG3B) (TERIFLUNOMIDE - UNII:1C058IKG3B) | TERIFLUNOMIDE | 7 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|---------------|----------------------------|---------------------|----------|
| Color | WHITE (WHITE TO OFF WHITE) | Score | no score |
| Shape | ROUND (ROUND) | Size | 6mm |
| Flavor | | Imprint Code | 1114 |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1010-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2023 | |
| 2 | NDC:70771-1010-8 | 2 in 1 CARTON | 02/14/2023 | |
| 2 | NDC:70771-1010-7 | 1 in 1 CARTON | | |
| 2 | | 14 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 | ANDA209668 | 02/14/2023 | |

TERIFLUNOMIDE

teriflunomide tablet, film coated

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70771-1011 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| TERIFLUNOMIDE (UNII: 1C058IKG3B) (TERIFLUNOMIDE - UNII:1C058IKG3B) | TERIFLUNOMIDE | 14 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------------------------|---------------------|----------|
| Color | BLUE (BLUE TO LIGHT BLUE) | Score | no score |
| Shape | ROUND (ROUND) | Size | 8mm |
| Flavor | | Imprint Code | 1115 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70771-1011-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2023 | |
| 2 | NDC:70771-1011-8 | 2 in 1 CARTON | 02/14/2023 | |
| 2 | NDC:70771-1011-7 | 1 in 1 CARTON | | |
| 2 | | 14 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 | ANDA209668 | 02/14/2023 | |

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|--|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1010, 70771-1011) , MANUFACTURE(70771-1010, 70771-1011) |

Revised: 9/2023

Zydus Lifesciences Limited