

FIRST TIME GENERIC APPROVAL

Brand Name	Aubagio®
Generic Name	teriflunomide
Drug Manufacturer	Accord Healthcare Inc., Aurobindo Pharma Limited, Camber, Dr. Reddy's, Glenmark Pharmaceuticals Inc., Sandoz, Teva, Viatris, and Zydus

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

September 4, 2018

LAUNCH DATE

March 13, 2023

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): Various

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Teriflunomide is a pyrimidine synthesis inhibitor indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

MECHANISMS OF ACTION

Teriflunomide, an immunomodulatory agent with anti-inflammatory properties, inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in de novo pyrimidine synthesis. The exact mechanism by which teriflunomide exerts its therapeutic effect in multiple sclerosis is unknown but may involve a reduction in the number of activated lymphocytes in CNS.

DOSE FORM AND STRENGTH

7 mg and 14 mg film-coated tablets.

DOSE & ADMINISTRATION

7 mg or 14 mg orally once daily, with or without food.

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