FOR YOUR RMS PATIENTS, INCLUDING THOSE WITH LESS AGGRESSIVE DISEASE,

HOW DO YOU PRIORITIZE THEIR DISEASE NEEDS?[1,2]

RMS=relapsing forms of multiple sclerosis.

INDICATION

AUBAGIO® (teriflunomide) is 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.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATOTOXICITY AND EMBRYOFETAL TOXICITY

- **Clinically significant and potentially life-threatening liver injury, including acute liver failure requiring transplant, has been reported in patients treated with AUBAGIO in the postmarketing setting. Concomitant use of AUBAGIO with other hepatotoxic drugs may increase the risk of severe liver injury.**
- **Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy. Monitor ALT levels at least monthly for 6 months after starting AUBAGIO. If drug-induced liver injury is suspected, discontinue AUBAGIO and start an accelerated elimination procedure with cholestyramine or activated charcoal. AUBAGIO is contraindicated in patients with severe hepatic impairment. Patients with pre-existing liver disease may be at increased risk of developing elevated serum transaminases when taking AUBAGIO.**
- **AUBAGIO is contraindicated for use in pregnant women and in women of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposure lower than that in humans. Exclude pregnancy before the start of treatment with AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure after AUBAGIO treatment. Stop AUBAGIO and use an accelerated drug elimination procedure if the patient becomes pregnant.**

Please see additional Important Safety Information throughout and **Full Prescribing Information**, including **boxed WARNING.**

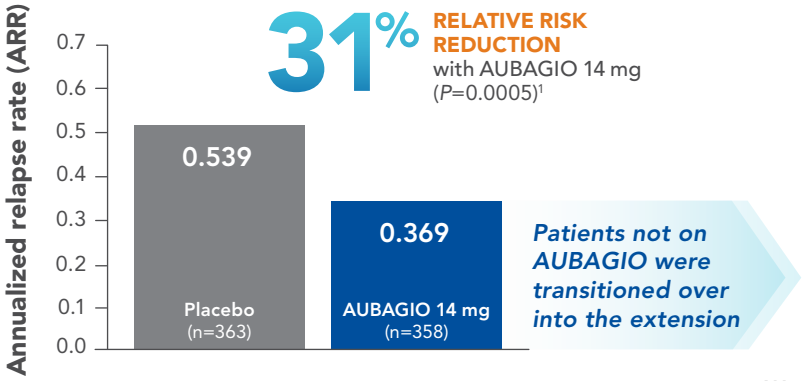
Once-daily AUBAGIO® (teriflunomide) 14 mg tablets

AUBAGIO is available in 14 mg and 7 mg tablets.

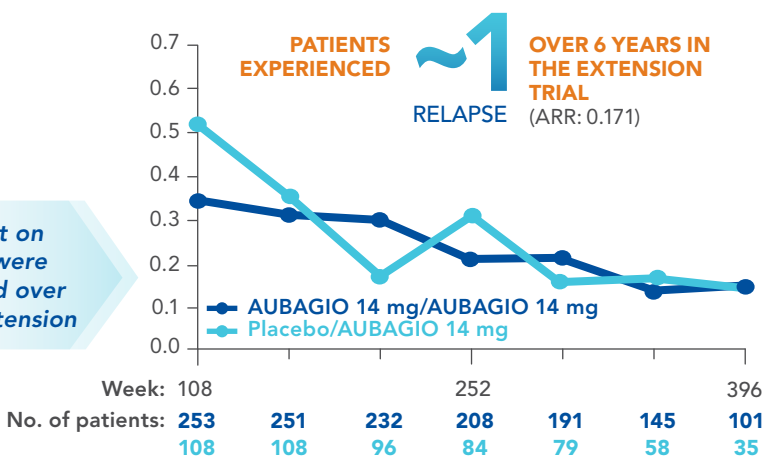
DO YOU BELIEVE DIFFERENT PATIENTS HAVE DIFFERENT RELAPSE REDUCTION NEEDS?

AUBAGIO® (teriflunomide) provided significant reduction in relapses and maintained its impact for up to 7.5 years (core plus extension trial)[1,2]

TEMSO CORE[1]



TEMSO EXTENSION[2]



- 31% relative risk reduction with AUBAGIO 7 mg (n=365) versus placebo (*P*=0.0002) in the core trial[1]
- ARR was 0.370 with AUBAGIO 7 mg in the core trial and 0.198 over the extension trial (n=252)[1,2]

In TOWER[1,3]

- ARR was 0.319 for AUBAGIO 14 mg (n=370) versus 0.501 for placebo (n=388) in the core trial; *P*=0.0001 versus placebo. Extension: Patients experienced ~1 relapse every 6 years with AUBAGIO 14 mg (ARR: 0.180; n=233)
- ARR was 0.389 for AUBAGIO 7 mg in the core trial (n=407; *P*=0.0183 versus placebo) and 0.200 over the extension trial (n=265)
  - — All patients were transitioned to AUBAGIO 14 mg in TOWER extension

How might AUBAGIO meet the relapse reduction needs of your RMS patients, including those with less aggressive disease?

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

- Patients with severe hepatic impairment.
- Pregnant women and females of reproductive potential not using effective contraception.
- Patients with a history of hypersensitivity reaction to teriflunomide, leflunomide, or to any of the inactive ingredients in AUBAGIO.
- Co-administration with leflunomide.

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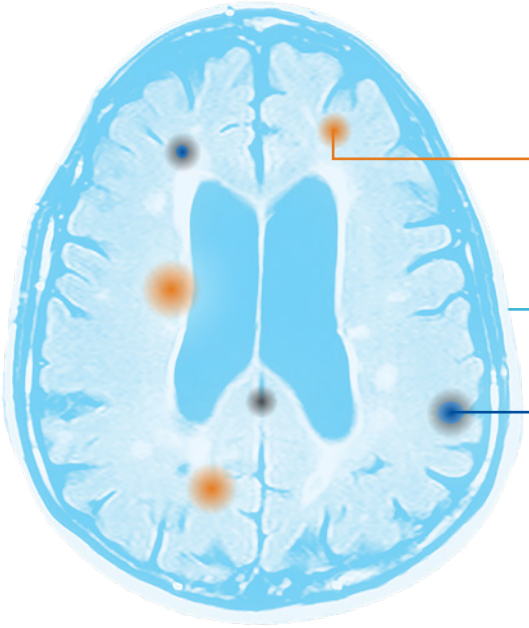
SIGNIFICANT REDUCTION IN THE NUMBER OF GD+ LESIONS AND TOTAL LESION VOLUME[1]

AUBAGIO® (teriflunomide) 14 mg significantly reduced the number of Gd+ T1 lesions and total lesion volume over 108 weeks versus placebo in TEMSO[1,4]



80%

FEWER GD+ T1 LESIONS
compared with placebo[1,4]

AUBAGIO 14 mg: 0.261, Placebo: 1.331; *P*<0.0001

- 57% fewer lesions with AUBAGIO 7 mg (0.570) versus placebo (*P*<0.0001)[1,4]

69%

REDUCTION IN TOTAL LESION VOLUME
compared with placebo[1]

AUBAGIO 14 mg: 0.345 mL, Placebo: 1.127 mL; *P*=0.0003

- AUBAGIO 7 mg demonstrated a 33% reduction versus placebo (0.755 mL versus 1.127 mL for placebo; *P*=0.0317)[1]

Mean total lesion volume at baseline was 19.3 mL

Not actual MRI.
For illustrative purposes only.

AUBAGIO 14 mg (n=358)
AUBAGIO 7 mg (n=365)
Placebo (n=363)

Learn more about the MRI data, including data on brain volume loss, for AUBAGIO here

Gd+=gadolinium enhancing.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- **Hepatotoxicity:** Clinically significant liver injury, which could be life-threatening, can occur at any time during treatment with AUBAGIO. Patients with pre-existing acute or chronic liver disease, or those with serum ALT >2 times the upper limit of normal (ULN) before initiating treatment, should not normally be treated with AUBAGIO. In clinical trials, if ALT elevation was >3 times the ULN on 2 consecutive tests, patients discontinued AUBAGIO and underwent accelerated elimination. Consider additional monitoring if co-administering AUBAGIO with other potentially hepatotoxic drugs; monitor patients who develop symptoms suggestive of hepatic dysfunction (eg, unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine).

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HOW IMPORTANT IS DELAYING DISABILITY PROGRESSION IN RECENTLY DIAGNOSED RMS PATIENTS?

AUBAGIO® (teriflunomide) 14 mg is the only oral DMT to delay disability progression in 2 Phase III trials[1,5-12]

TEMSO CORE (MEAN EDSS: 2.7)

AN ESTIMATED **80%** **REMAINED FREE FROM DISABILITY PROGRESSION** with AUBAGIO 14 mg over 108 weeks (P=0.03)[1*]

TOWER CORE (MEAN EDSS: 2.7)

AN ESTIMATED **84%** **REMAINED FREE FROM DISABILITY PROGRESSION** with AUBAGIO 14 mg over 108 weeks (P<0.05)[1*]

- The estimated proportion of patients with sustained disability progression[1]:
  - TEMSO: 20.2%, 21.7%, and 27.3% with AUBAGIO 14 mg, AUBAGIO 7 mg, and placebo, respectively
  - TOWER: 15.8%, 21.1%, and 19.7% with AUBAGIO 14 mg, AUBAGIO 7 mg, and placebo, respectively
- AUBAGIO 7 mg did not achieve a statistically significant reduction in risk of sustained disability progression versus placebo in either trial[1]
- Sustained disability progression was defined as at least a 1-point increase from baseline EDSS score ≤5.5 (or at least a 0.5-point increase for those with a baseline EDSS score of >5.5) sustained for at least 12 weeks[1]

The results were maintained in the TEMSO extension trial[2]

61% OF PATIENTS **FREE FROM DISABILITY PROGRESSION** with AUBAGIO 14 mg for up to 7.5 years in the core and extension trial[2*]

- For up to 7.5 years in the core and extension trial, 61.5% of patients remained free from disability progression with AUBAGIO 7 mg[2]

*Based on Kaplan-Meier estimates.[1]
DMT= disease-modifying therapy; EDSS=Expanded Disability Status Scale.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Embryofetal Toxicity:** AUBAGIO may cause fetal harm when administered in pregnant women. Teratogenicity and embryofetal lethality occurred in animal reproduction studies in multiple animal species at plasma teriflunomide exposures similar to or lower than that in humans at the maximum human recommended dose of 14 mg/day. AUBAGIO is contraindicated for use in pregnant women and females of reproductive potential not using effective contraception.

  Exclude pregnancy before starting AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure (AEP) after AUBAGIO treatment. If a woman becomes pregnant while taking AUBAGIO, stop treatment, apprise patient of the potential risk to a fetus, and perform an AEP to achieve an AUBAGIO plasma concentration of <0.02 mg/L. Upon discontinuing AUBAGIO, it is recommended all females of reproductive potential undergo an AEP.

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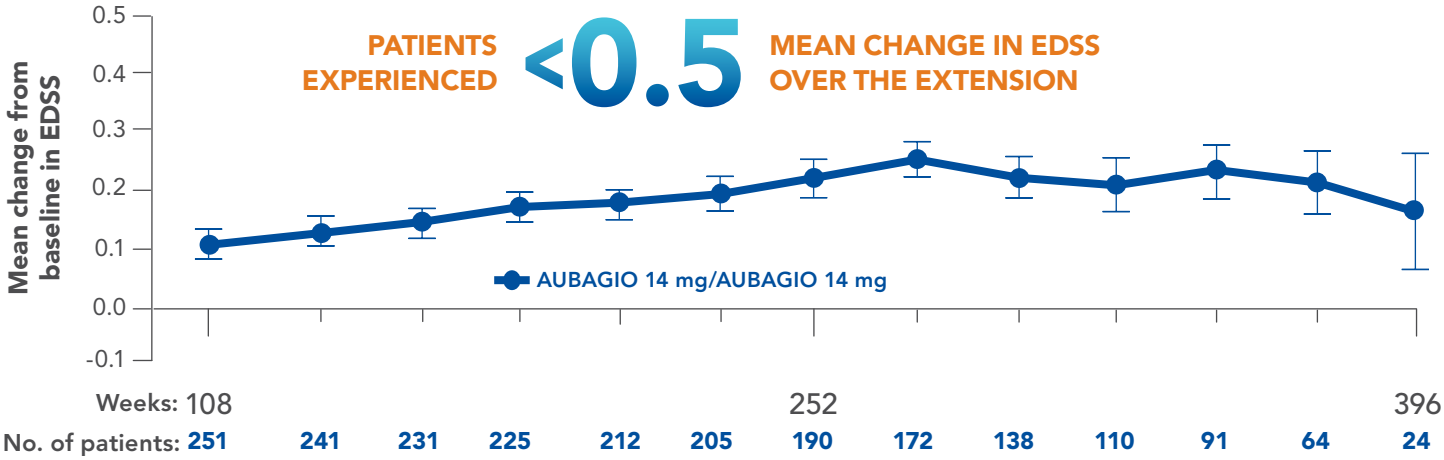
OVER TIME, DISABILITY PROGRESSION REMAINED STABLE WITH AUBAGIO 14 MG[2]

Once on AUBAGIO® (teriflunomide) 14 mg, the majority of patients had a <0.5 change in EDSS for up to 7.5 years (core plus extension trial)[1,2]

TEMSO EXTENSION[2,13]



- The mean change in EDSS from baseline in the AUBAGIO 7 mg/AUBAGIO 7 mg group was 0.22 after 348 weeks in the extension trial (n=108)[2]

In TOWER extension[3]

- All patients were transitioned to AUBAGIO 14 mg in the TOWER extension trial
  - Mean change in EDSS—AUBAGIO 14 mg/14 mg: 0.10; AUBAGIO 7 mg/14 mg: 0.20

If delaying disability progression is your goal, why delay prescribing AUBAGIO?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Embryofetal Toxicity:** Women receiving AUBAGIO who wish to become pregnant must discontinue AUBAGIO and undergo an AEP, until plasma concentrations of AUBAGIO are <0.02 mg/L. Men wishing to father a child should also stop AUBAGIO and either undergo an AEP or wait until plasma concentration of AUBAGIO is <0.02 mg/L.

  Women who become pregnant while taking AUBAGIO may enroll in the AUBAGIO pregnancy registry by calling 1-800-745-4447, option 2.

- **Procedure for Accelerated Elimination of Teriflunomide:** Teriflunomide is eliminated slowly from the plasma—it takes an average of 8 months, or up to 2 years, to reach plasma concentrations <0.02 mcg /mL. Elimination may be accelerated by administration of cholestyramine or activated charcoal, but this may cause disease activity to return in patients who were responding to AUBAGIO.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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- **Bone Marrow Effects/Immunosuppression Potential/Infections:** Decreases in white blood cell counts, mainly of neutrophils and lymphocytes, and platelets have been reported with AUBAGIO. Thrombocytopenia, including rare cases with platelet counts less than 50,000/mm^3, has been reported in the postmarketing setting. Obtain a complete blood cell count within 6 months before starting treatment, with further monitoring based on signs and symptoms of bone marrow suppression. AUBAGIO is not recommended for patients with severe immunodeficiency, bone marrow disease, or severe uncontrolled infections. Tuberculosis (TB) has been observed in clinical studies of AUBAGIO. Before starting treatment, screen patients for latent TB infection with a tuberculin test. Treatment in patients with acute or chronic infections should not be started until the infection(s) is resolved. Administration of live vaccines is not recommended. The risk of malignancy, particularly lymphoproliferative disorders, or infection may be increased with the use of some medications with immunosuppressive potential, including teriflunomide.
- **Hypersensitivity Reactions:** AUBAGIO can cause anaphylaxis and severe allergic reactions. Signs and symptoms have included dyspnea, urticaria, and angioedema including lips, eyes, throat, and tongue. Inform patients of the signs and symptoms of anaphylaxis and angioedema.
- **Serious Skin Reactions:** Cases of serious skin reactions, sometimes fatal, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with AUBAGIO. Fatal outcomes were reported in one case of TEN and one case of DRESS. Inform patients of the signs and symptoms of a serious skin reaction and instruct them to discontinue AUBAGIO and seek immediate medical care. Unless the reaction is clearly not drug-related, discontinue AUBAGIO and begin accelerated elimination immediately. In such cases, patients should not be re-exposed to teriflunomide.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** DRESS, also known as multiorgan hypersensitivity, has occurred with AUBAGIO. One fatal case of DRESS that occurred within 34 days of initiation of AUBAGIO treatment has been reported in the postmarketing setting. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematologic abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. This disorder is variable in its expression, and other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity (eg, fever, lymphadenopathy) may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately.

  Discontinue AUBAGIO, unless an alternative etiology for the signs or symptoms is established, and begin an accelerated elimination procedure immediately. In such cases, patients should not be re-exposed to teriflunomide.
- **Peripheral Neuropathy:** Peripheral neuropathy, including polyneuropathy and mononeuropathy, has been reported with AUBAGIO. Age >60 years, concomitant neurotoxic medications, and diabetes may increase the risk. If peripheral neuropathy is suspected, consider discontinuing treatment and performing accelerated elimination.
- **Increased Blood Pressure:** Blood pressure increases and hypertension have occurred with AUBAGIO. Measure blood pressure at treatment initiation and manage any elevations during treatment.
- **Respiratory Effects:** Interstitial lung disease (ILD), including acute interstitial pneumonitis, has been reported with AUBAGIO. ILD may be fatal and may occur acutely at any time during therapy with a variable clinical presentation. If discontinuation of the drug is necessary, consider initiation of an accelerated elimination procedure.
- **Pancreatitis in Pediatric Patients:** AUBAGIO is not approved for use in pediatric patients. In a pediatric clinical trial, cases of pancreatitis were observed in patients receiving AUBAGIO. If pancreatitis is suspected, discontinue teriflunomide and start an accelerated elimination procedure.

Adverse Reactions: The most frequent adverse reactions (≥10% and ≥2% greater than placebo) with AUBAGIO 7 mg and 14 mg and placebo, respectively, were headache (18% and 16% vs 15%), ALT increased (13% and 15% vs 9%), diarrhea (13% and 14% vs 8%), alopecia (10% and 13% vs 5%), and nausea (8% and 11% vs 7%).

Drug Interactions: Monitor patients when teriflunomide is coadministered with warfarin, or with drugs metabolized by CYP1A2, CYP2C8, substrates of OAT3 transporters, substrates of BCRP, or OATP1B1/1B3 transporters.

Use in Specific Populations: Women should not breastfeed during treatment with AUBAGIO.

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Once-daily AUBAGIO® (teriflunomide) 14 mg tablets

AUBAGIO is available in 14 mg and 7 mg tablets.

One pill, once a day[1]

Actual size

MEET YOUR RMS PATIENTS' NEEDS TODAY AND TOMORROW[1,2]

17+ YEARS OF CLINICAL TRIAL AND REAL-WORLD EXPERIENCE.[1-4,13-17]

Download the Start Form

INDICATION

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BOXED WARNING: HEPATOTOXICITY AND EMBRYOFETAL TOXICITY

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References: 1. AUBAGIO (teriflunomide) [package insert]. Cambridge, MA: Genzyme Corporation. **2.** O'Connor P, Comi G, Freedman MS, et al; for the Teriflunomide Multiple Sclerosis Oral (TEMSO) Trial Group and the MRI-AC in Houston, Texas. Long-term safety and efficacy of teriflunomide: nine-year follow-up of the randomized TEMSO study. *Neurology.* 2016;86(10):920-930. **3.** Miller AE, Olsson TP, Wolinsky JS, et al; on behalf of the TOWER investigators. Long-term safety and efficacy of teriflunomide in patients with relapsing multiple sclerosis: results from the TOWER extension study. *Mult Scler Relat Disord.* 2020;46:102438. https://doi.org/10.1016/j.msard.2020.102438. **4.** O'Connor P, Wolinsky JS, Confavreux C, et al; for the TEMSO Trial Group. Randomized trial of oral teriflunomide for relapsing multiple sclerosis. *N Engl J Med.* 2011;365(14):1293-1303. **5.** Mavenclad (cladribine) [package insert]. Rockland, MA: EMD Serono, Inc; April 2019. **6.** Tecfidera (dimethyl fumarate) [package insert]. Cambridge, MA: Biogen Idec Inc.; January 2021. **7.** Gilenya (fingolimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2019. **8.** Mayzent (siponimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2021. **9.** Vumerity (diroximel fumarate) [package insert]. Cambridge,MA: Biogen Idec Inc.; January 2021. **10.** Zeposia (ozanimod) [package insert]. Summit, NJ: Celgene Corporation; September 2020. **11.** Bafiertam (monomethyl fumarate) [package insert]. High Point, NC. Banner Life Sciences LLC; May 2021. **12.** Ponvory (ponesimod) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2021. **13.** Data on file, Sanofi Genzyme. **14.** Confavreux C, O'Connor P, Comi G, et al; for the TOWER Trial Group. Oral teriflunomide for patients with relapsing multiple sclerosis (TOWER): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2014;13(3):247-256. **15.** O'Connor PW, Li D, Freedman MS, et al; on behalf of the Teriflunomide Multiple Sclerosis Trial Group University of British Columbia MS/MRI Research Group. A phase II study of the safety and efficacy of teriflunomide in multiple sclerosis with relapses. *Neurology.* 2006;66(6):894-900. **16.** Miller AE, Wolinsky JS, Kappos L, et al; for the TOPIC Study Group. Oral teriflunomide for patients with a first clinical episode suggestive of multiple sclerosis (TOPIC): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2014;13(10):977-986. **17.** Miller AE, Vermersch P, Kappos L, et al; on behalf of the TOPIC study group. Long-term outcomes with teriflunomide in patients with clinically isolated syndrome: results of the TOPIC extension study. *Mult Scler Relat Disord.* 2019;33:131-138.

Colorado Prescribers may click here for Wholesale Acquisition Cost Price Disclosure.

Vermont Prescribers may click here for Average Wholesale Price Disclosure.

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