PrM-TERIFLUNOMIDE

(Teriflunomide 14 mg tablets)

Prescriber Checklist

This treatment checklist will help you and your patients manage the potential risks associated with teriflunomide treatment.

M-TERIFLUNOMIDE is indicated as monotherapy for the treatment of patients with relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Severe liver injury including fatal liver failure occurred rarely in the post marketing setting.

Based on animal data, teriflunomide may cause major birth defects if used during pregnancy.

If your patient becomes pregnant or suspects she is pregnant while taking M-TERIFLUNOMIDE or up to two years after discontinuing M-TERIFLUNOMIDE, enroll your pregnant patient in the Teriflunomide Active Surveillance Program by calling 1-833-651-1661.

Teriflunomide is also associated with risks of hypertension, hematologic effects, infections, and interstitial lung disease. To minimize these risks, follow the checklist on the next pages when prescribing M-TERIFLUNOMIDE.

Should your patient experience any of the above-mentioned adverse events, please contact Mantra's Medical Information team to receive the targeted questionnaires at either **medinfo@mantrapharma.ca** or by calling **1-833-248-7326**.

IMPORTANT:

M-TERIFLUNOMIDE SHOULD NOT BE PRESCRIBED TO THE FOLLOWING PATIENTS:

- with known hypersensitivity to teriflunomide, leflunomide (the parent compound) or to any of the nonmedicinal ingredients (corn starch, FD&C blue no.1 aluminum lake, hydroxypropylcellulose, hypromellose, iron oxide yellow, lactose monohydrate, magnesium stearate, silica colloidal anhydrous, sodium starch glycolate, titanium dioxide, polyethylene glycol)
- who are currently treated with leflunomide
- with severe hepatic impairment
- who are pregnant or women of childbearing potential not using reliable contraception. M-TERIFLUNOMIDE may cause fetal harm when administered to a pregnant woman. Pregnancy must be excluded before start of treatment.
- with immunodeficiency states (e.g. AIDS)
- with impaired bone marrow function or significant anemias, leukopenia, neutropenia or thrombocytopenia
- with serious active infections

NOT RECOMMENDED IN PATIENTS:

- with severe hypoproteinemia
- with co-administration of antineoplastic or immunosuppressive therapies
- who require vaccination with live vaccines
- with severe renal impairment undergoing dialysis

CONSIDERATIONS FOR MALE PATIENTS TAKING M-TERIFLUNOMIDE:

Instruct patients and their female partners to use effective contraception to minimize any possible risk.

- M-TERIFLUNOMIDE is detected in human semen. Animal studies to specifically evaluate the risk of male-mediated fetal toxicity have not been conducted.
- To minimize any possible risk, men not wishing to father a child and their female partners should use reliable contraception.
- If patients wish to father a child, discontinue M-TERIFLUNOMIDE therapy and either administer the accelerated elimination procedure or wait until plasma concentrations of teriflunomide are <0.02 mg/mL.

The following checklist is a useful reminder of the safe use conditions and monitoring requirements for prescribing M-TERIFLUNOMIDE tablets.

ROUTINE MONITORING RECOMMENDED:

Before starting M-TERIFLUNOMIDE therapy

Check	Assessment to ensure appropriate use	Notes (e.g., date)
☐	Check transaminase and bilirubin levels (within 6 months before starting therapy) to rule out the hepatics effects.	
☐	Exclude pregnancy by pregnancy test and confirm use of effective contraception to rule out the risk of teratogenicity.	
☐	Counsel patients on the potential for serious risk to the fetus and use of effective contraception in females of reproductive potential to rule out the teratogenicity effect.	
☐	Obtain a complete blood count (CBC) within 6 months before starting therapy to rule out the hematologic effects.	
☐	Screen for latent tuberculosis infection to rule out interstitial lung disease.	
☐	Check baseline blood pressure and manage hypertension appropriately.	

During M-TERIFLUNOMIDE therapy

Check	Assessment to ensure appropriate use	Notes (e.g., date)
☐	Monitor alanine aminotransferase (ALT) levels monthly (for at least 6 months).	
☐	Check blood pressure periodically and manage hypertension appropriately.	
☐	Obtain a complete blood count (CBC) periodically. Further monitoring should be based on signs and symptoms suggestive of infection.	
☐	Remind patients to continue use of effective contraception during therapy.	
☐	Remind women of childbearing potential that if there is any reason to suspect pregnancy, patients must inform their physician immediately.	
☐	Instruct patients to reports symptoms of hepatic dysfunction and infections.	
☐	Discontinue teriflunomide and implement accelerated elimination procedure for patients: • who become or wish to become pregnant (males and females) • with increased hematological disorders • suspected drug induced acute pancreatitis • with serious infection • who develop peripheral neuropathy symptoms • with new onset or worsening of pulmonary symptoms • with severe generalized major skin reactions	

If discontinuation of the drug is necessary (in case of adverse event or pregnancy), consider initiation of an accelerated elimination procedure by administration of cholestyramine or activated charcoal. Please refer to the Product Monograph at **www.groupemantra.ca/m-teriflunomide/** or call **1-833-248-7326** for further information.

M-TERIFLUNOMIDE should be prescribed one tablet, once daily.

Encourage your patient to read the Educational Patient Card and to contact you if they need further information.

Please refer to **www.groupemantra.ca/m-teriflunomide/** website for access to the Product Monograph, to request copies of the targeted questionnaire through the Mantra's Medical Information department, to enroll in the Pregnancy Active Surveillance Program and for more information on risks associated with M-TERIFLUNOMIDE.

IMPORTANT CONTACT INFORMATION:

- **M-TERIFLUNOMIDE Pregnancy Active Surveillance Program: by calling 1-833-651-1661**
- **Mantra Pharma Inc. Medical information:**
  by calling 1-833-248-7326
  by email at medinfo@mantrapharma.ca