Pr MINT-TERIFLUNOMIDE

IMPORTANT SAFETY INFORMATION FOR PATIENTS & CAREGIVERS

Teriflunomide Tablets
14 mg Teriflunomide
Immunomodulator Agent

INDICATION

Mint-Teriflunomide is indicated for 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.

IMPORTANT INFORMATION ABOUT MINT-TERIFLUNOMIDE

WARNINGS and PRECAUTIONS

LIVER DISORDER:

Mint-Teriflunomide may cause liver disorders. Severe liver injury including fatal liver failure occurred rarely in patients treated with Mint-Teriflunomide. The risk for severe liver disorder may be increased if you take Mint-Teriflunomide when you already have liver disease or if you are taking other drugs that affect the liver.

Your doctor should do blood tests to check your liver function:

- within 6 months before you start taking Mint-Teriflunomide.
- every month, for at least 6 months after you start taking Mint-Teriflunomide.

Call your doctor right away if you experience any symptoms of liver disorder (Yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite).

Hypertension: Mint-Teriflunomide may cause hypertension (high blood pressure).

Serious Infections: Mint-Teriflunomide may cause serious infections.

Hematologic Effects: Mint-Teriflunomide may cause decreased white blood cells.

BIRTH CONTROL, PREGNANCY and RISK OF BIRTH DEFECTS:

Do not take Mint-Teriflunomide if you are pregnant. If used during pregnancy, Mint-Teriflunomide may cause major birth defects and even death to your baby. Pregnancy must be avoided by using effective birth control when a man or woman is on Mint-Teriflunomide. Continue birth control for two years after you stop taking Mint-Teriflunomide to make sure your blood levels of Mint-Teriflunomide are low enough. Your doctor can prescribe a medicine to help lower your blood levels of Mint-Teriflunomide more quickly. Your doctor can inform you when it is safe to get pregnant or to father a child.

If you are a **woman of childbearing age,** you should have a pregnancy test before you start taking Mint-Teriflunomide. If you become pregnant, are late starting your period or have any reason to suspect pregnancy while taking Mint-Teriflunomide or within 2 years after stopping it, tell your doctor right away.

Before taking Mint-Teriflunomide, tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

OTHER WARNINGS YOU SHOULD KNOW ABOUT:

Pregnancy: Mint-Teriflunomide may harm your unborn baby. Before you start treatment with Mint-Teriflunomide, your doctor should administer a pregnancy test before you start taking MINT-Teriflunomide to make sure you are not pregnant. You must use a reliable form of birth control while taking Mint-Teriflunomide. Do not become pregnant during treatment.

Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program: If you become pregnant while taking Mint-Teriflunomide or after you stop taking Mint-Teriflunomide, talk to your doctor about enrolling in the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program by calling Mint Pharmaceuticals at 1-877-398-9696 or email us at drugsafety@mintpharma.com. The purpose of this enhanced surveillance program is to collect information about the effect of Mint-Teriflunomide exposure during pregnancy.

Use in Males: If your partner can get pregnant, make sure to use a reliable form of birth control when you are taking Mint-Teriflunomide. If you wish to father a child or donate sperm, talk to your doctor about stopping your treatment.

Blood Tests: Your doctor should do blood tests before starting treatment with Mint-Teriflunomide and while you are taking it. These tests will monitor:

- blood pressure
- complete blood cell count
- liver enzyme levels

Mint-Teriflunomide may cause your test results to look abnormal. Your doctor will interpret the results.

Tuberculosis: Patients should be screened for latent tuberculosis infection.

Interstitial Lung Disease (ILD): A condition called ILD has been reported with teriflunomide. If you have a history of ILD, you are at higher risk of developing ILD again. If you already have ILD, Mint-Teriflunomide may worsen the symptoms. ILD can be a fatal disorder and can happen at any time during your treatment. Talk to your healthcare professional right away if you experience:

- persistent cough
- shortness of breath with or without fever

Accelerated Elimination Procedure:

It can take 8 months to 2 years to fully remove teriflunomide from your system. If you need to stop taking Mint-Teriflunomide, your doctor may talk to you about undergoing an accelerated elimination procedure to remove teriflunomide from your body faster.

What are possible side effects from using Mint-Teriflunomide:

These are not all the possible side effects you may have when taking Mint-Teriflunomide. If you experience any side effects not listed here, tell your healthcare professional. Including: diarrhea, nausea, flue or sinus infection, upset stomach, abdominal pain, rash, hair thinning or loss, cold sores, toothache, shortness of breath, frequent urination, having your period for longer than 7 days, sore muscles, weight loss.

Mint-Teriflunomide can cause serious side effects, including: Pancreatitis (inflammation of the pancreas), Peripheral Neuropathy (damage to nerves), Severe skin reactions such as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

See the **Serious side effects and what to do about them list** and in the Patient Medication Information Insert in your product's packaging of Mint-Teriflunomide for more information on these and other serious side effects.

SERIOUS SIDE EFFECTS & WHAT TO DO ABOUT THEM:

Talk to your healthcare professional if you experience the following:

- Infections, fatigue, fever, aches, pains and flu-like symptoms (signs of decreased white blood cells).
- Shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations (signs of hypertension or high blood pressure).
- Bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness (signs of decreased platelets).
- Numbness or tingling of hands or feet (signs of peripheral neuropathy/carpal tunnel syndrome).
- Shortness of breath when resting that gets worse with exertion, trouble breathing, lasting cough (a condition called Interstitial Lung Disease, which is a disease that inflames or scars lung tissue).
- Diarrhea with blood or pus, abdominal pain, cramping, rectal pain or bleeding, weight loss, fatigue (signs of colitis or chronic digestive disease).
- Red patches of skin covered with thick, silvery scales, dry cracked skin that may bleed, itching, burning or soreness, swollen and stiff joints (signs of psoriasis or chronic skin disease on the skin or nails).

Stop taking Mint-Teriflunomide and get immediate medical help if you experience the following:

- Yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite (signs of a liver disorder).
- Pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, lightheadedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat (signs of severe heart problems).
- Difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue, or throat (signs of an allergic reaction).
- Upper abdominal pain, fast heartbeat, nausea, vomiting, tenderness when touching the abdomen (signs of pancreatitis or an inflammation of the pancreas).
- Fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes or genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine (signs of severe skin reactions).

Deaths due to heart-related issues have occurred in patients treated with teriflunomide.

Patient Card
Your healthcare provider will give you a wallet-size card that includes your contact information, and important safety information on Mint-Teriflunomide. Keep it with you so that you can show this card to any doctor or healthcare professional in case of an emergency.

Reporting side effects:

You can report any suspected adverse reactions associated with the use of Mint-Teriflunomide to:

- **Mint Pharmaceuticals** at 1-877-398-9696 or
- You can report any suspected side effects associated with the use of health products to Health Canada by:
  - Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/ adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
  - Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

FOR MORE INFORMATION ABOUT MINT-TERIFLUNOMIDE

If you want more information about Mint-Teriflunomide:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for health professionals and includes this Consumer Information by calling 1-877-398-9696; or email drugsafety@mintpharma.com.