PrM-TERIFLUNOMIDE

PATIENT INFORMATION BROCHURE

PLEASE ENSURE TO READ THIS PATIENT INFORMATION BROCHURE

MANTRA PHARMA®

We help provide better care.

INDICATION

M-TERIFLUNOMIDE IS A PRESCRIPTION MEDICATION USED TO TREAT ADULT PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS).

IMPORTANT SAFETY INFORMATION

Do not take M-TERIFLUNOMIDE if you have severe liver problems, are pregnant or of childbearing potential and not using effective birth control, have had an allergic reaction to teriflunomide or leflunomide or are taking a medicine called leflunomide for rheumatoid arthritis.

If you suspect that you are pregnant while taking M-TERIFLUNOMIDE or in the two years after you have stopped treatment, you must contact your doctor immediately for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to speed up the removal of teriflunomide from your body, as this may decrease the risk to your baby.

Please see important safety information on the next pages. Patient medication information and Patient information brochure are available on Mantra's web site at **www.groupemantra.ca/m-teriflunomide/.**

M-TERIFLUNOMIDE PREGNANCY ACTIVE SURVEILLANCE PROGRAM:

If you become pregnant or suspect you may be pregnant while taking M-TERIFLUNOMIDE, or become pregnant within two years after you stop taking M-TERIFLUNOMIDE, contact your doctor right away for a pregnancy test. If the test confirms you are pregnant, your doctor may suggest treatment with certain medicines to speed up the removal of teriflunomide from your body as this may decrease the risk to your baby. The M-Teriflunomide Pregnancy Active Surveillance Program has been established to collect information about the effect of teriflunomide exposure during pregnancy.

Your doctor will encourage enrolment in the M-TERIFLUNOMIDE Pregnancy Active Surveillance Program. Enrolment can be performed either by your doctor or by yourself by calling **1-833-651-1661.**

The educational materials along with the product monograph, leaflet can be found at **www.groupemantra.ca/m-teriflunomide/.**

BEGINNING TREATMEMT WITH M-TERIFLUNOMIDE

BEFORE YOU START

Your healthcare provider will need to run a few tests before beginning treatment, including:

- Blood tests to check your liver within 6 months of starting treatment
- TB (tuberculosis) skin test or blood test for tuberculosis infection
- Pregnancy test, if you are a woman of childbearing potential
- Complete blood count within 6 months of starting treatment
- Periodic blood pressure checks

AFTER YOU START

Your healthcare provider will need to:

- Monitor your liver enzymes for the first 6 months
- Check your blood pressure periodically after starting treatment

SERIOUS SIDE EFFECTS YOU SHOULD KNOW ABOUT:

In addition to the risk of liver problems, including liver failure that can be life-threatening and may require a liver transplant, and the risk of harm to an unborn baby, other possible serious side effects include:

- Decreases in white blood cell count — this may cause you to have more infections
- Certain vaccinations should be avoided during treatment with M-TERIFLUNOMIDE and for at least 6 months after discontinuation
- Allergic reactions
- Serious skin reactions that may lead to death
- Other allergies that may affect different parts of the body such as your liver, kidneys, heart, or blood cells
- Numbness or tingling in your hands or feet that is different from your RRMS symptoms
- High blood pressure
- Breathing problems (new or worsening) that may be serious and lead to death

Tell your healthcare professional of any side effect that bothers you or does not go away.

The most common side effects associated with M-TERIFLUNOMIDE:

- Headache
- Abnormal liver test results
- Diarrhea
- Hair thinning or loss
- Nausea

PREPARE FOR THE "SIDE-EFFECTS CONVERSATION" WITH YOUR HEALTHCARE PROFESSIONAL

IF YOU HAVE ALREADY STARTED YOUR TREATMENT:

1. Has your experience with side effects changed or gotten worse since you first began your treatment?
2. Are side effects getting in the way of your everyday activities and responsibilities?
3. Do you sometimes wish you could skip your treatment because of side effects?
4. Which potential side effects do you feel you can manage and which are deal-breakers?

IF YOU ARE NEW TO TREATMENT:

1. Which possible side effects are deal-breakers for you?
2. Have you weighed the benefits and possible risks of options you're considering?
3. Could possible side effects keep you from taking your treatment as prescribed?

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

M-TERIFLUNOMIDE IS A PRESCRIPTION MEDICATION USED TO TREAT ADULT PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS).

IMPORTANT SAFETY INFORMATION

M-TERIFLUNOMIDE can alter the way the body's immune system works. M-TERIFLUNOMIDE does not cure RRMS, but it can help decrease the number of attacks (relapses) that occur. M-TERIFLUNOMIDE can help slow the build-up of physical problems (disability progression) that RRMS causes.

DO NOT USE M-TERIFLUNOMIDE IF:

- You are allergic to teriflunomide, leflunomide or to any of the other ingredients in the formulation
- You are taking a drug for rheumatoid arthritis with the medicinal ingredient leflunomide
- You have severe liver problems
- You are suffering from a serious infection
- You are pregnant, suspect you may be pregnant or plan to get pregnant
- You are a woman of childbearing age and not using effective birth control methods
- You are of childbearing age, until it is confirmed with a pregnancy test that you are not pregnant
- You have low platelets, low white blood cell counts, or uncontrolled infection. Low white blood cell counts may be caused by other things that affect the immune system, such as:
    - immunodeficiency syndrome or AIDS
    - weakened bone marrow function or transplantation
    - treatments that can suppress the immune system, such as:
        - drugs used to treat cancer
        - other drugs used to treat MS

BEFORE TAKING M-TERIFLUNOMIDE, TALK TO YOUR HEALTHCARE PROFESSIONAL IF YOU:

- have liver problems
- have high blood pressure
- have a fever or infection, or you are unable to fight infections
- have low protein levels in your blood
- had or have ever had blood or bone marrow problems
- have kidney problems
- had or have ever had tuberculosis
- have diabetes
- are older than 60 years
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. You and your doctor should decide if you should take M-TERIFLUNOMIDE or breastfeed. You should not do both at the same time.
- have a condition that affects the skin or nails called psoriasis
- have an allergy to lactose or a rare hereditary problem of galactose intolerance, total lactose deficiency or glucose-galactose malabsorption. M-TERIFLUNOMIDE contains lactose.
- are going to receive a vaccine. You should not receive a 'live attenuated vaccine' during treatment with M-TERIFLUNOMIDE. Talk to your doctor before receiving any vaccinations during or after treatment.

WHAT TO KNOW ABOUT TAKING M-TERIFLUNOMIDE

The recommended dose of M-TERIFLUNOMIDE is one tablet (14 mg) a day. You can take M-TERIFLUNOMIDE orally (by mouth) any time of day, with or without food. Your doctor will run certain tests before you start treatment. Once on M-TERIFLUNOMIDE, your doctor will monitor your liver enzymes monthly for the first 6 months and conduct periodic blood pressure checks.

Do not stop taking M-TERIFLUNOMIDE without talking with your doctor first.

If you miss a dose, just take your next dose as planned. Do not take a double dose to make up for a forgotten tablet.

If you think you have taken too many M-TERIFLUNOMIDE tablets (overdose), contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

M-TERIFLUNOMIDE may stay in your blood for up to 2 years after you stop taking it. If necessary, your doctor can prescribe a medicine that can remove M-TERIFLUNOMIDE from your blood quickly.

M-TERIFLUNOMIDE MAY CAUSE SERIOUS SIDE EFFECTS; TELL YOUR HEALTHCARE PROFESSIONAL IF YOU HAVE ANY OF THE FOLLOWING:

- **Decreased white blood cells** – this may cause you to have more infections; symptoms include fatigue, fever, aches, pain and flu-like symptoms.
- **High blood pressure**
- **Numbness or tingling of hands or feet that is different from your RRMS symptoms**
- **Psoriaris**
- **Colitis**
- **Breathing problems (new or worsening)** – these may be serious and lead to death.
- **Severe skin reactions** – This may lead to death. Stop taking M-TERIFLUNOMIDE if you have severe rash, blisters and peeling skin, shortness of breath and get immediate medical help.
- **Allergic reactions** such as difficulty breathing or swallowing, or swelling of your face, lips, tongue or throat. Stop taking M-TERIFLUNOMIDE and get immediate help.

THE MOST COMMON SIDE EFFECTS WHEN TAKING M-TERIFLUNOMIDE INCLUDE:

- **diarrhea, nausea, hair thinning or loss, abnormal liver test results.**

These are not all the possible side effects while taking M-TERIFLUNOMIDE. Tell your healthcare professional about any side effect that bothers you.

STORAGE OF M-TERIFLUNOMIDE

M-TERIFLUNOMIDE tablets should be stored between 15° and 30°C. Remove tablet from blister card only when ready to use. Keep the medicine out of reach and sight of children.

MORE INFORMATION

Please consult your healthcare professional with any questions or concerns you may have regarding your condition. This Patient Information Brochure along with the Patient Medication Information can be found at **www.groupemantra.ca/m-teriflunomide/.**