PATIENT INFORMATION BROCHURE

PrNAT-TERIFLUNOMIDE

Teriflunomide Tablets 14 mg

Patient's Name:	
Healthcare Practitioner's Name:	
Healthcare Practitioner's Phone Number:	
Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program contact information	Telephone: 1-800-296-9329 OR visit www.natcopharma.ca

Talk to your healthcare provider to see if NAT-TERIFLUNOMIDE may be right for you.

INDICATION
NAT-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.

IMPORTANT SAFETY INFORMATION
Do not take NAT-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, have an infection or have low platelets, low white blood cells or an uncontrolled infection.

Please see the Patient Medication Information Leaflet/ Package Insert for more information.

Consider NAT-TERIFLUNOMIDE:

Teriflunomide is a once-daily dose product.

You can take NAT-TERIFLUNOMIDE any time of day, with or without food. Ask your healthcare provider if NAT-TERIFLUNOMIDE may help with your relapsing MS:

- The majority of people taking teriflunomide did not experience a relapse during clinical studies.[1]
- Teriflunomide 14 mg decreased the number of new brain lesions by 80% vs. placebo.[1]
- 80% of people taking teriflunomide 14 mg experienced no disability progression.[1]

Your healthcare provider will run certain tests before you start treatment. Once on NAT-TERIFLUNOMIDE, your healthcare provider will monitor your liver enzyme levels monthly for the first 6 months and conduct periodic blood pressure checks.

Do not take NAT-TERIFLUNOMIDE if you have severe liver problems. NAT-TERIFLUNOMIDE may cause serious liver problems, which can be life-threatening. Your risk may be higher if you take other medicines that affect your liver. Your healthcare provider should do blood tests to check your liver within 6 months before you start NAT-TERIFLUNOMIDE and monthly for 6 months after starting

NAT-TERIFLUNOMIDE. Tell your healthcare provider right away if you develop any of these symptoms of liver problems: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of your skin or whites of your eyes, or dark urine.

Please see the Patient Medication Information Leaflet/ Package Insert for more information.

Talk to your healthcare provider about Teriflunomide's long-term safety profile.

Do not take NAT-TERIFLUNOMIDE if you are pregnant. If used during pregnancy, NAT-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 NAT-TERIFLUNOMIDE. You should have a pregnancy test before starting NAT-TERIFLUNOMIDE. If pregnancy does occur during treatment, the drug should be immediately discontinued and an accelerated elimination procedure should be initiated. If you become pregnant while taking NAT-TERIFLUNOMIDE or within 2 years after stopping, tell your healthcare provider right away and enroll in the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program by calling 1-800-296-9329. For more information on Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program visit the manufacturer's website – www.natcopharma.ca.

Do not take NAT-TERIFLUNOMIDE if you are of childbearing potential and not using effective birth control.

It is not known if teriflunomide passes into breast milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from teriflunomide, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

If you are a man whose partner plans to become pregnant, you should stop taking NAT-TERIFLUNOMIDE and undergo an accelerated elimination procedure to decrease the plasma concentration of teriflunomide to less than 0.02 mg/L. If your partner does not plan to become pregnant, use effective birth control while taking NAT-TERIFLUNOMIDE.

Please see the Patient Medication Information Leaflet/ Package Insert for more information.

Do not take NAT-TERIFLUNOMIDE if you have had an allergic reaction to teriflunomide or a medicine called leflunomide.

Do not take NAT-TERIFLUNOMIDE if you take a medicine called leflunomide for rheumatoid arthritis.

Teriflunomide may stay in your blood for up to 2 years after you stop taking it. Your healthcare provider can conduct an accelerated elimination procedure to remove teriflunomide from your blood quickly.

Please see the Patient Medication Information Leaflet/ Package Insert for more information.

Slow the progression of disability

Disability progression can affect functions of the body, such as motor, sensory, bowel and bladder, visual and mood.[*3]

Before taking NAT-TERIFLUNOMIDE, talk with your healthcare provider if you have: liver or kidney problems; a fever or infection, or if you are unable to flight infections; diabetes; high blood pressure; blood

or bone marrow problems; tuberculosis; older than 60 years; pregnant or plan to become pregnant. Your healthcare provider will check your serum transaminases and bilirubin levels, blood cell count, screen for latent tuberculosis, blood pressure and a negative pregnancy test (for women of child bearing potential), before you start NAT-TERIFLUNOMIDE. Talk with your healthcare provider if you take or are planning to take other medicines.

*Healthcare providers measure disability progression using a test called the Expanded Disability Status Scale, or EDSS. Your first score—or your "baseline"—will determine how your disability is gauged moving forward. If your baseline score is ≤5.5, you're considered to have sustained disability progression if that score goes up by one point (lasting at least 12 weeks). If your baseline score is >5.5, you're considered to have sustained disability progression if that score goes up by at least 0.5 point (lasting at least 12 weeks).[3]

Teriflunomide slows disability progression[1]

Teriflunomide 14 mg was shown to help slow the build-up of physical problems (disability progression) that RRMS causes. A key goal of relapsing MS treatment is to slow disability progression.

See how teriflunomide works[1,2]

MS is thought to occur when immune cells become overactive and begin to attack the central nervous system, specifically targeting the outer covering of the nerves known as the myelin sheath. While we don't fully understand how teriflunomide works in relapsing MS, we do know that it works differently from other relapsing MS medicines.[1,2]

→ When you have relapsing MS, certain immune cells in your body become overactive and multiply.

→ Teriflunomide blocks an enzyme called dihydroorotate dehydrogenase (DHO-DH) that these overactive cells need to keep multiplying at their overactive rate.

→ Taken daily, teriflunomide reduces the number of overactive immune cells thought to cause /MS flare-ups, while still allowing normal immune cell activity to occur.

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

Possible serious side effects of NAT-TERIFLUNOMIDE[1]

If you experience any of the following side effects while taking NAT-TERIFLUNOMIDE, speak with your healthcare provider right away. In addition to the risk of liver problems and the risk of harm to an unborn baby, other serious side effects include:

- Reduced white blood cell count – this may cause you to have more infections
- Numbness or tingling in your hands or feet that different from your MS symptoms
- Allergic reactions, including serious skin problems
- Breathing problems (new or worsening)
- High blood pressure
- Certain vaccinations should be avoided during treatment with NAT-TERIFLUNOMIDE and for at least 6 months after discontinuation

Please the Patient Medication Information Leaflet/ Package Insert for more information.

The most common side effects associated with teriflunomide[1]

The following are some of the most common side effects reported in clinical trials. (These are not all the side effects.)

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

Tell your HCP if you have any side effect that bothers you or does not go away.

Please see the Package Insert for more information.

Beginning treatment with NAT-TERIFLUNOMIDE

Before you start[1]

Your healthcare provider will need to run a few tests within 6 months before beginning treatment, including:

- Blood tests to check your liver
- TB (tuberculosis) screening test
- Pregnancy test, if you are a woman of childbearing potential
- Complete blood count
- Blood pressure check

These tests are often done at the same time.

After you start[1]
Your healthcare provider will need to:

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

Please see the Package Insert for more information.

If you have any of the following symptoms, please contact your Healthcare Practitioner immediately.

- Unexplained nausea
- Vomiting
- Stomach pain
- Shortness of breath, trouble breathing, lasting cough
- Your skin or the whites of your eyes turn yellow
- Dark urine
- Any sign or symptoms of an infection (e.g. feeling unusually tired, fever, aches, pains and flu-like symptoms)
- Headaches, vision disorders

If there is any possibility you may be pregnant, please contact your Healthcare Practitioner immediately.

In case of a side effect or pregnancy, your Healthcare Practitioner may recommend an Accelerated Elimination Procedure in order to speed up the removal of NAT-TERIFLUNOMIDE from your body.

This procedure consists of administration of 8 g cholestyramine every 8 hours (or 4 g if 8 g is not well tolerated), or 50 g activated charcoal every 12 hours for 11 days. The efficacy of this procedure is to be confirmed with blood tests prescribed by your Healthcare Practitioner.

You can report any suspected side effects 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 1-866-234-2345

Please see provided Patient Medication Information Leaflet/ Package Insert for more information.

References: 1. NAT-TERIFLUNOMIDE (teriflunomide) Product Monograph. Natco Pharma (Canada) Inc. Control No.: 231073, Date of Revision November 14, 2019; 2. Bar-Or A, Pachner A, Menguy-Vacheron F, Kaplan J, Wiendl H. Teriflunomide and its mechanism of action in multiple sclerosis. Drugs. 2014;74:659-674. doi:10.1007/s40265-014-0212-x; 3. Healy BC, Engler D, Glanz B, Musallam A, Chitnis T. Assessment of definitions of sustained disease progression in relapsing-remitting multiple sclerosis. Mult Scler Int. 2013;2013(189624):1-9.