PRESCRIBER CHECKLIST

PrNAT-TERIFLUNOMIDE

Teriflunomide Tablets 14 mg

At first prescription, the Prescriber/Healthcare Professional (HCP) should discuss with the patient the risks described below and provide the Patient Card. Please see the Product Monograph for full prescribing information, which is available on the Health Canada website https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.

Patient's Name:	**Patient's Age:**
First Visit Date:	**Patient's Gender:** ☐ Male ☐ Female
First Prescription Date:	**Today's Date:**

Laboratory Tests (prior to initiation and during treatment)

☐ Check blood pressure before initiation of treatment with NAT-TERIFLUNOMIDE and periodically throughout treatment. Blood pressure should be appropriately managed during treatment with NAT-TERIFLUNOMIDE.
☐ Obtain a complete blood cell (CBC) count before initiation of treatment with NAT-TERIFLUNOMIDE and periodically during treatment. Further monitoring should be based on signs and symptoms suggestive of infection.
☐ Prior to initiating NAT-TERIFLUNOMIDE, screen patients for latent tuberculosis infection.
☐ Obtain serum transaminases and bilirubin levels within 6 months before initiation of treatment with NAT-TERIFLUNOMIDE. Monitor ALT levels at least monthly for at least six months after starting NAT-TERIFLUNOMIDE.
☐ Obtain a negative pregnancy test before initiation of treatment with NAT-TERIFLUNOMIDE

HEPATIC EFFECTS:

Teriflunomide 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 teriflunomide.

☐ Discuss the risk of liver effects, and the need to conduct liver function tests before treatment and periodically during treatment as per Product Monograph.
Blood tests required to check patient's liver function:

- within 6 months before starting NAT-TERIFLUNOMIDE.
- every month, for 6 months after starting NAT-TERIFLUNOMIDE.

Obtain serum transaminases and bilirubin levels within 6 months before initiation of treatment with NAT-TERIFLUNOMIDE. Monitor alanine aminotransferase (ALT) levels at least monthly for six months after starting NAT-TERIFLUNOMIDE.
Educate the patient about signs and symptoms of liver disease, and about the need to contact their doctor/HCP if these develop.
The common symptoms of liver disorder as per product monograph are: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, weight loss, unusual tiredness.

TERATOGENICITY:

Teriflunomide may cause major birth defects if used during pregnancy. Teriflunomide is contraindicated in women who are pregnant or in women of childbearing potential not using reliable contraception. Before

starting treatment with NAT-TERIFLUNOMIDE in women of childbearing potential, counsel patients fully on the potential for serious risk to the fetus and discuss reliable contraception methods.

In women of childbearing potential, exclude pregnancy and emphasise the need for effective contraception before starting and during their treatment with NAT-TERIFLUNOMIDE because of potential serious risks to the fetus:

☐ Check the pregnancy status before starting NAT-TERIFLUNOMIDE treatment. Obtain a negative pregnancy test before initiation of treatment with NAT-TERIFLUNOMIDE.
☐ Advise the patient that she should contact the doctor/HCP immediately if she stops contraception, before changing contraceptive measures, if there is a delay in onset of menses or any other reason to suspect pregnancy.
☐ Advise the patient that if she becomes pregnant despite using contraceptive measures, she should stop using NAT-TERIFLUNOMIDE and contact her doctor/HCP immediately who should:

- consider and discuss with the patient an Accelerated Elimination Procedure
- encourage the patient to enrol in the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program

☐ For male patients:

- whose partner plans to become pregnant: patient should stop taking NAT-TERIFLUNOMIDE and undergo an Accelerated Elimination Procedure.
- Whose partner does not plan to become pregnant: patient and partner should use a reliable and effective method of birth control.

Healthcare Professionals are encouraged to enroll pregnant women in the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program, or pregnant women may enroll themselves in the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program by calling 1-800-296-9329.Refer to the manufacturer's website – www.natcopharma.ca for more information.

HEMATOLOGICAL EFFECTS:

In patients with pre-existing anemia, leucopenia, and/or thrombocytopenia as well as in patients with impaired bone marrow function or those at risk of bone marrow suppression, the risk of hematological disorders is increased.

☐ Discuss the risk of decreased blood cell counts (affecting mainly white blood cells). Discuss the need for full blood counts before treatment and during treatment, and when signs and symptoms show/present.

Obtain a complete blood cell (CBC) count before initiation of treatment with NAT-TERIFLUNOMIDE. Further monitoring should be based on signs and symptoms suggestive of infection.

HYPERTENSION:

☐ Discuss the risk of blood pressure increase. Educate the patient to tell their doctor/HCP if they have hypertension and discuss the need for blood pressure checks and appropriate management, before and periodically during treatment.

Check blood pressure before initiation of treatment with NAT-TERIFLUNOMIDE and periodically thereafter. Elevated blood pressure should be appropriately managed during treatment with NAT-TERIFLUNOMIDE.

INFECTIONS/SERIOUS OPPORTUNISTIC INFECTIONS INCLUDING PML:

☐ Discuss risk of infections/serious infections, including the need to contact their doctor/HCP in case of signs or symptoms of infection, or if the patient takes other medicines that affect the immune system.

Teriflunomide is contraindicated in patients with severe immunodeficiency, bone marrow disease or severe, uncontrolled infections. Patients with active acute or chronic infections should not start treatment until the infection(s) is resolved. If serious infection occurs, an Accelerated Elimination Procedure may be considered.

Prior to initiating NAT-TERIFLUNOMIDE, screen patients for latent tuberculosis infection. Treat patients testing positive in tuberculosis screening, prior to initiating treatment with NAT-TERIFLUNOMIDE.

INTERSTITIAL LUNG DISEASE

☐ Discuss the risk of interstitial lung disease.
Educate patients about potential symptoms of interstitial lung disease including new onset or worsening of pulmonary symptoms, such as persistent cough and dyspnea, with or without associated fever.

Check if patient has a history of interstitial lung disease.

If discontinuation of the drug is necessary, an Accelerated Elimination Procedure may be considered

PATIENT CARD
☐ Please provide the patient with the Patient Card, to be used as a tool to remind the patient of signs to be aware of and to relay information to other doctors/HCPs involved with their incidental medical care (especially in case of medical emergencies and/or if new doctors/HCPs are involved). Please remind the patient to contact their doctor/HCP in case of signs or symptoms discussed in the Patient Card.

The patient has been informed about and understands the benefits of and risks associated with this treatment. Female patients have been checked for pregnancy, all patients (male and female) have been advised of the need for reliable contraception, informed about the option of the NAT-TERIFLUNOMIDE Accelerated Elimination Procedure and the Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program.

At prescription renewal, adverse events are checked, ongoing risks and their prevention are discussed, and checks are made to ensure adequate monitoring is taking place.

Prescriber's Name:	**Prescriber's Signature:**

Reporting suspected side effects after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the drug product. Healthcare Professionals are asked to report any suspected side affects.