

Once-Daily

MAR-TERIFLUNOMIDE 14 mg tablets (teriflunomide)



EDUCATIONAL PATIENT BROCHURE

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 (PM) for full prescribing information, which is available on the Health Canada Website: health-products.canada.ca/dpd-bdpp/index-eng.jsp or Marcan's website: www.marcanpharma.com

Patient's name:	Patient's age:
First visit date:	Patient's gender: Male <input type="checkbox"/> Female <input type="checkbox"/>
First prescription date:	Today's date:

PLEASE FILL THIS CHECKLIST AND RETURN TO THE PHARMACY OR SHARE A SCAN COPY VIA
EMAIL TO SAFETY.CANADA@MARCANPHARMA.COM.

THIS IS IN VIEW OF OVERSIGHT OF PATIENT SAFETY AND TO FULFIL THE REGULATORY
REQUIEMENT OF HEALTH CANADA

LIVER DISORDER

Teriflunomide may cause liver disorders. Severe liver injury including fatal liver failure occurred rarely in patients treated with teriflunomide. The risk for severe liver disorder may be increased if you take 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 teriflunomide and every month, for at least 6 months after you start taking teriflunomide. Call your doctor right away if you experience any symptoms of liver disorder like yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite.

BIRTH CONTROL, PREGNANCY AND RISK OF BIRTH DEFECTS

Teriflunomide is not given in women who are pregnant or women of child bearing potential not using reliable contraception. If you are a woman of childbearing age, you should have a pregnancy test done before you start taking teriflunomide.

Do not take teriflunomide if you are pregnant. If used during pregnancy, teriflunomide may cause major birth defects and even death to your baby.

Women must not become pregnant while receiving this drug. It is recommended that all women of childbearing potential on teriflunomide must use reliable contraception. Pregnancy must be avoided by using effective birth control when a man or woman is on teriflunomide. Continue birth control for two years after you stop taking teriflunomide to make sure your blood levels of teriflunomide are low enough. Your doctor can prescribe a medicine to help lower your blood levels of teriflunomide more quickly. Your doctor can inform you when it is safe to get pregnant or to father a child.

If you become pregnant, or have late starting your period or have any reason to suspect pregnancy while taking teriflunomide or within 2 years after stopping it, tell your doctor right away.

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

For details in the Canada contact: Marcan Medical Information department: 1-855-627-2261 or safety.canada@marcanpharma.com

RISK OF HAEMATOLOGICAL EFFECTS

Your doctor should do blood tests before starting treatment with teriflunomide and while you are taking it. These tests will monitor:

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

Teriflunomide may cause your test results to look abnormal. Your doctor will interpret the results. Talk to your doctor if you have any symptoms like fatigue, fever, aches, pains and flu-like symptoms, bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.

Patients with low white blood cell count should not receive certain vaccinations during teriflunomide treatment and 6 months after.

RISK OF HYPERTENSION

Teriflunomide may cause increase the blood pressure.

Your doctor will decide to monitor blood pressure before treatment initiation and periodically during treatment.

Talk to your doctor if you have any symptoms like 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.

RISK OF SERIOUS INFECTIONS

You can contact your doctor immediately if they have any symptoms or signs of an infection

You should also inform your doctor if you are prescribed or taking any other medicines that affect the immune system

Pregnancy Registry:

If you become pregnant while taking teriflunomide or after you stop taking teriflunomide, talk to your doctor about enrolling in the Teriflunomide Pregnancy Registry at 1 855 627 2261. The purpose of this registry is to collect information about the effect of teriflunomide exposure during pregnancy.

You can access the program details and educational materials at the website www.marcanpharma.com

PATIENT CARD

Please provide the patient with the Patient Card, to be used as a tool to remind the patient 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.

*Referred to as accelerated elimination procedure in the Product Monograph

The patient has been informed about and understands the benefits of and risks associated with this treatment. Female patients have been checked for pregnancy, advised of the need for reliable contraception, informed about the option of the MAR-TERIFLUNOMIDE washout process and the pregnancy registry.

Patient's name:	
Prescriber's signature:	
Prescriber's Contact details	

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

- Canada Vigilance website:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call the Canada Vigilance National Office at 1-866-234-2345 (toll-free)
- Marcan Medical Information department: 1-855-627-2261 or
safety.canada@marcanpharma.com

MARCAN

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