Targeted Questionnaire for Women of Childbearing Potential (WCBP) (for counselling)

PrNAT-TERIFLUNOMIDE

Teriflunomide Tablets 14 mg

Please complete this form and save a copy in the patient's record.

Indication: NAT-TERIFLUNOMIDE (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.

Patient Details:

Age:

Gender:

Is Patient a woman of childbearing potential (WCBP)? (Yes or No)

Teriflunomide is contraindicated in women who are pregnant or women of childbearing potential not using reliable contraception. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. If pregnancy does occur during treatment, the drug should be immediately discontinued and an accelerated elimination procedure (AEP) should be initiated. Under these conditions, the patient should be referred to an obstetrician/gynecologist, preferably experienced in reproductive toxicity, for further evaluation and counseling.

If Patient is a WCBP

Please provide details on:

- Was a pregnancy test performed before initiation of treatment with NAT-TERIFLUNOMIDE? (Yes or No)
- Was the pregnancy test negative? (Yes or No)
- Is the patient currently using reliable contraception method to avoid pregnancy? (Yes or No)
- Was the patient fully counseled on the potential for serious risk to the fetus? (Yes or No)

WCBP must not be started on NAT-TERIFLUNOMIDE until pregnancy is excluded and it has been confirmed that they are using reliable contraception. Therefore, WCBP must use effective contraception

during NAT-TERIFLUNOMIDE treatment and during an accelerated drug elimination procedure after NAT-TERIFLUNOMIDE treatment.

Healthcare Professional can discuss about reliable contraception method with the patient if requested, to avoid pregnancy during NAT-TERIFLUNOMIDE treatment.

Please provide details on:

- Did the patient request advice regarding effective contraception? (Yes or No)

- If the answer to the above is Yes, which contraceptive methods were discussed with the patient?

If a woman becomes pregnant while taking NAT-TERIFLUNOMIDE, stop treatment, apprise patient of the potential risk to a fetus, and perform an AEP to achieve a teriflunomide plasma concentration of <0.02 mg/L. Upon discontinuing NAT-TERIFLUNOMIDE, it is recommended all females of reproductive potential undergo an AEP.

A TERIFLUNOMIDE Enhanced Pharmacovigilance Pregnancy Active Surveillance Program has been established to collect information about the effect of generic teriflunomide exposure during pregnancy. Physicians are encouraged to enroll pregnant women in the Enhanced Pharmacovigilance Pregnancy Active Surveillance Program, or pregnant women may enroll themselves, by calling 1-800-296-9329.

Therapy:

Start Date:

Discontinuation Date (if applicable):

Contact Details of Healthcare Professional Completing the Form

Name & position title:

Signature:

Date: