HEALTHCARE PROFESSIONAL PRESCRIBER CHECKLIST

This material was developed by JAMP Pharma, as part of the risk minimization plan for JAMP Teriflunomide. This material is not intended for promotional use.

Discuss the following risks with the patient/carer, explain the monitoring requirements and tell them what they should do if patients experience specific signs or symptoms

Please read the Product Monograph (PM) for full prescribing information, which is available on JAMP Pharma Corporation's website: www.jampinfo.com

Patient's name:	**Patient's age:**
Date of first visit:	**Patient's gender: Male ☐ Female ☐**
Date first prescribed:	**Today's date:**

Risk of hematological effects

- ☐ Discuss the risk of decreased blood cells (affecting mainly white blood cells)
- ☐ Discuss the need for full blood count before treatment initiation and periodically thereafter, if necessary, based on clinical signs or symptoms during treatment

Risk of hypertension

- ☐ Check blood pressure before treatment initiation and periodically during treatment
- ☐ Blood pressure elevation should be appropriately managed during treatment

Risk of liver effects

- ☐ Check liver function before treatment initiation and periodically during treatment
- ☐ Patients should be counselled on the signs and symptoms of liver effects and told to contact their doctor/HCP immediately if any develop

Risk of serious infections

- ☐ Screen patients for latent tuberculosis infection before treatment initiation
- ☐ Patients should be told to contact their doctor/HCP immediately if they have any signs or symptoms of an infection
- ☐ Patients should also inform their doctor/HCP if they are prescribed or taking any other medicines that affect the immune system
- ☐ Consider an accelerated elimination procedure in case of a serious infection

Risk of teratogenicity

- ☐ Inform women of childbearing potential (WOCBP) that teriflunomide can cause serious birth defects so it is contraindicated in pregnancy, and they must use effective contraception during and after treatment until their teriflunomide blood levels are low. Women should contact their doctor/HCP immediately if they plan to conceive, stop or change contraception during this time
- ☐ Check the potential for pregnancy in all female patients before and during treatment
- ☐ Women should contact their doctor/HCP immediately and stop JAMP Teriflunomide if they become pregnant. Doctors/HCPs will: discuss and consider the accelerated elimination procedure and encourage enrolment in the JAMP Teriflunomide Enhanced Pharmacovigilance Pregnancy Active Surveillance Program conducted by JAMP Pharma: Phone: 1 866 399 9091. Email: **medinfo@jamppharma.com**; Program Website: **www.jampinfo.com**
- ☐ In men wishing to father a child, discuss that teriflunomide is detected in human semen and the possible risks this could pose to a fetus
- ☐ Advise male subjects that teriflunomide is detected in human semen. To minimize any possible riskto a fetus, men not wishing to father a child and their female partners should use reliable contraception. Men wishing to father a child should discontinue use of JAMP Teriflunomide and undergo an accelerated elimination procedure to decrease the plasma concentration of teriflunomide to less than 0.02 mg/L.

Risk of interstitial lung disease

- ☐ Discuss risk of interstitial lung disease, including the need to contact their doctor/HCP in case of signs of new onset or worsening of pulmonary symptoms, such as persistent cough and dyspnea, with or without associated fever. These may be a reason for discontinuation of the therapy and for further investigation, as appropriate. If discontinuation of the drug is necessary, consider initiation of the accelerated elimination procedure.

Patient Card

- ☐ Provide the patient with the patient card and discuss the content regularly during each consultation and **at least annually during treatment**
- ☐ Complete your contact details on the patient card and replace it as necessary
- ☐ Educate the patient to show this card to any doctor/HCP involved in medical care (e.g.in case of an emergency)
- ☐ Advise the patient to contact their doctor/HCP if they develop any signs or symptoms of the risks discussed in the patient card
- ☐ Counsel and inform before treatment and regularly thereafter WOCBP about potential risk for the fetus
- ☐ Ensure adequate monitoring of patients when new prescriptions are issued including adverse reaction checks, and risk assessments and prevention

☐ **The patient has been informed about and understands the above mentioned risks and benefits associated with this treatment.**

Prescriber's name:	**Prescriber's signature:**