Teriflunomide Torrent

TORRENT PHARMA

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE: UK

- **Discuss the following risks with the patient/parent/carer, explain the monitoring requirements and tell them what they should do if patients experience specific signs or symptoms**
- **Please read the SPC for full prescribing information**

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

DISCUSS

Risk of haematological effects

- Risk of decreased blood cells (affecting mainly white blood cells)
- Full blood count before treatment initiation and 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 before and 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 immediately if any develop

Risk of serious infections

- Patients should be told to contact their doctor immediately if they have any signs or symptoms of an infection
- Patients should also inform their doctor 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 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
- Tell the parents/carers of girls that they should contact their doctor for counselling on the risk of teratogenicity and contraceptive advice when she starts to menstruate
- Women should contact their physician immediately and stop teriflunomide if they become pregnant. Physicians will discuss and consider the accelerated elimination procedure.

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COUNSEL & HAND-OVER

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 or healthcare professional involved in medical care (e.g. in case of an emergency)
- Advise the patient to contact their prescriber or general practitioner if they develop any signs or symptoms of the risks discussed in the patient card
- Counsel and inform before treatment and regularly thereafter WOCBP including adolescents/their parents/caregivers about potential risk for the foetus
- Ensure adequate monitoring of patients when new prescriptions are issued including adverse reaction checks, and risk assessments and prevention

Please report suspected adverse drug reactions (ADRs) to the MHRA through the YellowCard scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the *Apple App Store* or *Google Play Store*
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine. Suspected adverse reactions should also be reported to Torrent Pharma UK Ltd:
Telephone: 0800 088 5366 · Email: Medinfo.Torrent@apcerls.com

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

Prescriber's name: ----------

Prescriber's signature: ----------

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