PATIENT CARD:
Bauda®(Teriflunomide) 14 mg film-coated tablets

This patient card provides important information on the risks of Bauda® (Teriflunomide). Please show this card to any doctor or healthcare professional involved in your medical care (e.g., in case of emergency). You should also read the patient information leaflet for further information.

Patient's name: _____
Date teriflunomide first prescribed: _____

Hospital: _____
Name of neurologist:_____
Emergency phone number for neurologist: _____

Important side effects:

Teriflunomide reduces the activity of the immune system (immunomodulator). In some people, teriflunomide can cause hepatic complications (hepatitis) and it may also decreased white blood cells and reduced platelet count (neutrophils) . Your liver function tests and blood pressure should be checked regularly during teriflunomide treatment, and your full blood count should be checked if necessary. These tests should also be checked before starting treatment.

If you have any of the following side effects, please contact your doctor immediately:

- Yellow skin or yellowing of the whites of your eyes (jaundice), unexplained nausea or vomiting, abdominal pain, or darker urine than normal. These are the symptoms of a liver problem.
- Signs of infection include pain in passing urine, confusion, high temperature (fever), cough, and swollen glands.

Monitoring:

Before treatment:

• Blood pressure

• Complete blood cell count including differential white blood cell and platelet count.

During treatment:

• Blood pressure

- o Check periodically
- Liver enzymes should be assessed every two weeks during the first 6 months of treatment, and at least every 8 weeks thereafter for at least 2 years from initiation of treatment.
- • Complete blood cell counts should be performed based on clinical signs and symptoms (e.g.infections) during treatment.

For women of childbearing potential including girls and their parents/caregivers

- Do not take BAUDA if you are, or think you may be pregnant. Reliable contraceptive measures is needed.
- If your daughter reaches menses while taking BAUDA, you should inform the doctor, who will provide specialist counselling regarding contraception and the potential risks in case of pregnancy.
- Tell your doctor if you plan to become pregnant after stopping treatment with BAUDA, as you need to ensure that the medicine has left your body before trying to become pregnant. The elimination of the active substance may take up to 2 years to occur naturally. The time can be reduced by taking certain medicines.
- A confirmation from your treating physician that the blood level of BAUDA is low enough to allow you to become pregnant is needed.

Contraception

- Teriflunomide remains in your blood for a long time after you stop taking it. Continue to use effective contraception after you stop treatment.
- Do not take BAUDA when you are breast-feeding, as teriflunomide passes into the breast milk.

Accelerated elimination procedure

- Following of the accelerated elimination procedures, verification by 2 separate tests at an interval of at least 14 days and a waiting period of one-and-a-half months between the first occurrence of a plasma concentration below 0.02 mg/l and fertilisation is required.

- Reliable contraception with oral contraceptives during the accelerated elimination procedure may be influenced. Use of alternative contraceptive methods is recommended.

Reporting of side effects:

Report suspected adverse drug reactions associated with Bauda (Teriflunomide) by contacting:

Pharmacovigilance Department at Alpha Pharma:

Email: pv@alphapharma.com.sa

Phone No: :+966 11 293 1773 Ext: 111

Mobile: :+966 53 040 8553

The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)

- Email: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/
- Call Center: 19999