PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TERIFLUNOMIDE 14 TEVA may cause serious side effects, including:

1. Liver problems:

TERIFLUNOMIDE 14 TEVA may cause serious liver problems that may lead to death. Your risk of liver problems may be higher if you take other medicines that also affect your liver. Your doctor should do blood tests to check your liver function:

- **within 6 months before you start taking TERIFLUNOMIDE 14 TEVA,**
- **once a month for 6 months after you start taking TERIFLUNOMIDE 14 TEVA.**

Tell your doctor right away if you have any of the following symptoms of liver problems:

- **nausea,**
- **vomiting,**
- **stomach pain,**
- **loss of appetite,**
- **tiredness,**
- **your skin or whites of your eyes turn yellow,**
- **dark urine.**

2. Harm to your unborn baby:

TERIFLUNOMIDE 14 TEVA may cause harm to your unborn baby. Do not take TERIFLUNOMIDE 14 TEVA if you are pregnant. Do not take TERIFLUNOMIDE 14 TEVA unless you are using effective birth control.

- **If you are a female, you should have a pregnancy test before you start taking TERIFLUNOMIDE 14 TEVA. Use effective birth control during your treatment with TERIFLUNOMIDE 14 TEVA.**
- **After stopping TERIFLUNOMIDE 14 TEVA, continue using effective birth control until you have blood tests to make sure your blood levels of TERIFLUNOMIDE 14 TEVA are low enough. If you become pregnant while taking TERIFLUNOMIDE 14 TEVA or within 2 years after you stop taking it, tell your doctor right away.**

- **For men taking TERIFLUNOMIDE 14 TEVA:**

  If your female partner plans to become pregnant, you should stop taking TERIFLUNOMIDE 14 TEVA and ask your doctor how to quickly lower the levels of TERIFLUNOMIDE 14 TEVA in your blood. If your female partner does not plan to become pregnant, you and your female partner should use effective birth control during your treatment with TERIFLUNOMIDE 14 TEVA. TERIFLUNOMIDE 14 TEVA remains in your blood after you stop taking it, so continue using effective birth control until TERIFLUNOMIDE 14 TEVA blood levels have been checked and they are low enough.

TERIFLUNOMIDE 14 TEVA, 14 mg film-coated tablets

Teriflunomide

TERIFLUNOMIDE 14 TEVA contains sugar, 72,25 mg lactose monohydrate

Read all of this leaflet carefully before you start taking TERIFLUNOMIDE 14 TEVA:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- TERIFLUNOMIDE 14 TEVA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. **WHAT TERIFLUNOMIDE 14 TEVA IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE TERIFLUNOMIDE 14 TEVA**
3. **HOW TO TAKE TERIFLUNOMIDE 14 TEVA**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE TERIFLUNOMIDE 14 TEVA**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT TERIFLUNOMIDE 14 TEVA IS AND WHAT IT IS USED FOR:

TERIFLUNOMIDE 14 TEVA contains the active substance teriflunomide which is an immunomodulatory

medicine and adjusts the immune system to limit its attack on the nervous system.

TERIFLUNOMIDE 14 TEVA is used for the treatment of adult patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of relapses and to delay the accumulation of physical disability.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TERIFLUNOMIDE 14 TEVA:

Do not take TERIFLUNOMIDE 14 TEVA:

- if you are hypersensitive (allergic) to teriflunomide or any of the other ingredients of TERIFLUNOMIDE 14 TEVA (listed in **section 6**)
- if you have severe liver problems
- if you are using leflunomide (used to treat rheumatoid arthritis and psoriatic arthritis)
- if you are pregnant, think you may be pregnant, or are breastfeeding
- if you suffer from a serious problem which affects your immune system e.g. acquired immunodeficiency syndrome (AIDS)
- if you have a serious problem with your bone marrow, or if you have low numbers of red or white cells in your blood or a reduced number of blood platelets
- if you are suffering from a serious infection
- if you have severe kidney problems which require dialysis
- if you have very low levels of proteins in your blood (hypoproteinaemia).

Warnings and precautions:

Take special care with TERIFLUNOMIDE 14 TEVA:

- if you have liver problems and/or if you drink large amounts of alcohol. Your doctor will carry out blood tests before and during treatment to check how well your liver is working. If your test results show a problem with your liver, your doctor may stop your treatment with TERIFLUNOMIDE 14 TEVA. Please read **section 4**.
- if you have high blood pressure (hypertension) whether it is controlled with medicines or not. TERIFLUNOMIDE 14 TEVA can cause an increase in blood pressure. Your doctor will check your blood pressure before the start of treatment and regularly thereafter. Please read **section 4**.

- If you have an infection. Before you take TERIFLUNOMIDE 14 TEVA, your doctor will make sure you have enough white blood cells and platelets in your blood. As TERIFLUNOMIDE 14 TEVA decreases the number of white cells in the blood this may affect your ability to fight the infection. Your doctor may do blood tests to check your white blood cells if you think you have an infection. Herpes virus infections may occur with teriflunomide treatment. In some cases, this has resulted in serious complications. You should inform your doctor immediately if you suspect you have any symptoms of herpes virus infections which include painful, recurring blisters or ulcers, fever, body aches and swollen lymph nodes. Please read **section 4**.
- if you have respiratory symptoms.
- if you have severe skin reactions.
- if you have weakness, numbness and pain in the hands and feet.
- if you are due for a vaccination.
- if you take leflunomide with TERIFLUNOMIDE 14 TEVA.
- if you are using any other immunosuppressants (often called immunomodulators) or antineoplastic medicine (usually used to treat cancer).
- if you are switching to or from TERIFLUNOMIDE 14 TEVA.
- if you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

Children and adolescents:

TERIFLUNOMIDE 14 TEVA should not be used in children and adolescents under 18 years of age. This is because the effects of the medicine in this age group are not known.

Other medicines and TERIFLUNOMIDE 14 TEVA:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Rifampicin (to treat tuberculosis)

- Carbamazepine (to treat epilepsy and neuropathic pain)
- Phenobarbitone (to treat epilepsy)
- Phenytoin (to treat epilepsy)
- St. John's Wort (to treat mild to moderate depression, nervousness, tiredness, poor appetite and trouble sleeping)
- Cholestyramine (to treat cholesterol)
- Activated charcoal (to treat medicine overdose or poisoning)
- Repaglinide and nateglinide (to treat diabetes)
- Paclitaxel (to treat cancer)
- Pioglitazone or rosiglitazone (to treat diabetes)
- Oral contraceptives, 0,03 mg ethinylestradiol and 0,15 mg levonorgestrel
- Duloxetine (to treat major depressive disorder, generalised anxiety disorder, fibromyalgia, and neuropathic pain)
- Alosetron (used for the management of severe diarrhoea-predominant irritable bowel syndrome in women only)
- Theophylline (to treat chronic obstructive pulmonary disease and asthma)
- Tizanidine (to treat muscle spasticity due to spinal cord injury or multiple sclerosis)
- Warfarin (to treat blood clots such as deep vein thrombosis and pulmonary embolism and to prevent stroke in people who have atrial fibrillation, valvular heart disease or artificial heart valves)
- Cefaclor (to treat certain bacterial infections such as pneumonia and ear infections)
- Benzylpenicillin (to treat bacterial infections)
- Ciprofloxacin (to treat bacterial infections)
- Indomethacin (a nonsteroidal anti-inflammatory drug commonly used to reduce fever, pain, stiffness, and swelling from inflammation)
- Ketoprofen (to treat pain or fever)
- Furosemide (to treat fluid build-up due to heart failure, liver scarring, or kidney disease)
- Cimetidine (to treat heartburn or peptic ulcers)
- Methotrexate (to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions)
- Zidovudine (used to prevent and treat HIV/AIDS)

- Rosuvastatin (to treat cholesterol)
- Topotecan (to treat ovarian cancer, lung cancer and other cancer types)
- Sulfasalazine (to treat rheumatoid arthritis)
- Daunorubicin (to treat acute myeloid leukaemia, acute lymphocytic leukaemia, chronic myelogenous leukaemia, and Kaposi's sarcoma)
- Doxorubicin (to treat breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukaemia)
- Simvastatin, atorvastatin and pravastatin (to treat cholesterol).

TERIFLUNOMIDE 14 TEVA with food and drink:

TERIFLUNOMIDE 14 TEVA can be taken with or without food.

Pregnancy, breastfeeding and fertility:

Do not take TERIFLUNOMIDE 14 TEVA if you are or think you may be pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TERIFLUNOMIDE 14 TEVA.

Tell your doctor if you plan to become pregnant after stopping treatment with TERIFLUNOMIDE 14 TEVA, as you need to ensure that most of this 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 to a few weeks by taking certain medicines which speed up removal of TERIFLUNOMIDE 14 TEVA from your body. In either case it should be confirmed by a blood test that the active substance has been sufficiently removed from your body and you need confirmation from your treating doctor that the blood level of TERIFLUNOMIDE 14 TEVA is low enough to allow you to become pregnant.

If you suspect that you are pregnant or become pregnant while taking TERIFLUNOMIDE 14 TEVA or in the two years after you have stopped treatment and have not taken certain medicines to remove

TERIFLUNOMIDE 14 TEVA from your blood, you must contact your doctor immediately for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to speed up the removal of TERIFLUNOMIDE 14 TEVA from the body, as this may decrease the risk to your baby.

Contraception:

You must use an effective method of contraception during and after treatment with TERIFLUNOMIDE 14 TEVA. Teriflunomide remains in your blood for a long time after you stop taking it. Continue to use effective contraception after you stop treatment.

- Do this until the levels of TERIFLUNOMIDE 14 TEVA in your blood are low enough - your doctor will check this.
- Talk with your doctor about the best method of contraception for you and any potential need for contraception change.

Do not take TERIFLUNOMIDE 14 TEVA when you are breastfeeding, as TERIFLUNOMIDE 14 TEVA passes into the breastmilk.

Fertility:

Results of studies in animals have not shown an effect on fertility. Although human data are lacking, no effect on male and female fertility is anticipated.

Driving and using machines:

TERIFLUNOMIDE 14 TEVA might make you feel dizzy which may impair your ability to concentrate and react.

It is not always possible to predict to what extent TERIFLUNOMIDE 14 TEVA may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which TERIFLUNOMIDE 14 TEVA affects you.

TERIFLUNOMIDE 14 TEVA contains lactose monohydrate:

TERIFLUNOMIDE 14 TEVA contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE TERIFLUNOMIDE 14 TEVA:

Do not share medicines prescribed for you with any other person.

Always take TERIFLUNOMIDE 14 TEVA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on your starting dose. The recommended dose of TERIFLUNOMIDE 14 TEVA is 14 mg orally once daily.

The film-coated tablet should be swallowed whole with some water.

Use in children and adolescents:

TERIFLUNOMIDE 14 TEVA is not intended to be used in children and adolescents below 18 years old as it has not been studied in MS patients below 18 years old.

Your doctor will tell you how long your treatment with TERIFLUNOMIDE 14 TEVA will last. Do not stop treatment early. If you have the impression that the effect of TERIFLUNOMIDE 14 TEVA is too strong or too weak, tell your doctor or pharmacist.

If you take more TERIFLUNOMIDE 14 TEVA than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of TERIFLUNOMIDE 14 TEVA:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TERIFLUNOMIDE 14 TEVA:

Do not stop taking TERIFLUNOMIDE 14 TEVA or change your dose without talking to your doctor first.

4. POSSIBLE SIDE EFFECTS:

TERIFLUNOMIDE 14 TEVA can have side effects.

Not all side effects reported for TERIFLUNOMIDE 14 TEVA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERIFLUNOMIDE 14 TEVA, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking TERIFLUNOMIDE 14 TEVA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to TERIFLUNOMIDE 14 TEVA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- influenza (a common viral infection that includes fever and muscle aches)
- upper respiratory tract infection
- urinary tract infection
- bronchitis (inflammation of the lining of the bronchial tubes)
- sinusitis (a condition where the cavities around the nasal passages become inflamed)
- pharyngitis (a sore throat)
- cystitis (inflammation of the bladder)
- viral gastroenteritis (intestinal infection)
- Herpes virus infections, including oral herpes and herpes zoster
- tooth infection
- laryngitis (inflammation of your voice box)

- tinea pedis (fungal infection that begins between the toes)
- neutropenia (an abnormally low count of a type of white blood cells)
- a decrease in the number of red blood cells (anaemia)
- paraesthesia (pins-and-needles in the arms, hands, legs or feet)
- palpitations (sensation that the heart is racing, pounding, fluttering or skipping a beat)
- increase in ALT (increase in blood levels of certain hepatic enzymes)
- increased gamma glutamyl transferase (GGT) increase (liver enzyme)
- aspartate aminotransferase increase (liver enzyme)
- decrease in neutrophil count (type of white blood cell)
- white blood cell count decrease
- blood creatine phosphokinase increased (indication of kidney function)
- high blood pressure.

Less frequent side effects:

- decrease in the number of blood platelets (mild thrombocytopenia)
- increased feeling or sensitivity, especially in the skin; stabbing or throbbing pain along one or more nerves, problems in the nerves of the arms or legs (peripheral neuropathy)
- post-traumatic pain.
- neuralgia (pain that travels along the length of a nerve)
- inflammation of the colon characterised by discomfort and pain in the abdomen
- severe skin reactions which might include symptoms of skin rash, blistering, or ulcers in your mouth.

Frequency not known:

- severe infections or sepsis (a potentially life-threatening type of infection) which might include symptoms of high fever, shaking, chills, reduced urine flow, or confusion
- inflammation of the lungs which might include symptoms of shortness of breath or persistent cough
- high blood pressure in the arteries of the lungs

- inflammation of the pancreas which might include symptoms of severe pain in the upper abdominal area that may also be felt in your back, nausea, or vomiting
- painful swelling and sores inside the mouth (stomatitis)
- serious liver disease which might include symptoms of yellowing of your skin or the whites of your eyes, darker urine than normal, unexplained nausea and vomiting, or abdominal pain

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- mild allergic reactions
- seasonal allergy
- anxiety
- headache
- pins and needles, feeling weak, numb, tingling or pain in the lower back or leg (sciatica)
- feeling numb, burning, tingling or pain in the hands and fingers (carpal tunnel syndrome)
- diarrhoea
- nausea
- upper abdominal pain
- vomiting
- toothache
- hair loss from the scalp or elsewhere on the body (alopecia)
- acne
- musculoskeletal pain (pain of the bones, muscles, ligaments, tendons and nerves)
- pain in a muscle or group of muscles
- joint pain
- needing to urinate more often than usual
- heavy or prolonged vaginal bleedings
- pain
- asthenia (decrease muscle strength)

- weight loss.

Less frequent side effects:

- nail disorders

Frequency not known:

- abnormal levels cholesterol or fats (lipids) in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TERIFLUNOMIDE 14 TEVA:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TERIFLUNOMIDE 14 TEVA contains:

The active substance(s) is teriflunomide.

The other ingredient(s) are:

Tablet core: Colloidal silicon dioxide, hydroxypropyl cellulose, lactose monohydrate, microcrystalline

cellulose, sodium starch glycolate, sodium stearyl fumarate, starc

Tablet coating: Opadry 03F205013 Blue: Hypromellose 2910, indigo carmine aluminium lake/FD&C blue #2, macrogol/PEG, talc, titanium dioxide.

What TERIFLUNOMIDE 14 TEVA looks like and contents of the pack:

TERIFLUNOMIDE 14 TEVA is presented as blue, round shaped tablet, debossed with "TV" on one side of the tablet and with "Y12" on the other side of the tablet.

Packaging:

7 film-coated tablets per blister.

Silver alu-alu blisters inserted in wallets and packed in cartons containing 14, 28, 84 (3 wallets of 28) and 98 (7 wallets of 14) film-coated tablets.

Each wallet is placed in a protective sleeve.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

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