SCHEDULING STATUS

S4

TERIFLUNOMIDE ADCO may cause serious side effects, including:
1. Liver problems: TERIFLUNOMIDE ADCO 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 ADCO,**
- **once a month for 6 months after you start taking TERIFLUNOMIDE ADCO.**

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

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

- **For men taking TERIFLUNOMIDE ADCO:**
  If your female partner plans to become pregnant, you should stop taking TERIFLUNOMIDE ADCO and ask your doctor how to quickly lower the levels of TERIFLUNOMIDE ADCO 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 ADCO. TERIFLUNOMIDE ADCO remains in your blood after you stop taking it, so continue using effective birth control until TERIFLUNOMIDE ADCO blood levels have been checked and they are low enough.

TERIFLUNOMIDE ADCO 14 mg (film-coated tablets)

Teriflunomide

TERIFLUNOMIDE ADCO contains sugar, 83,4 mg lactose monohydrate

Read all of this leaflet carefully before you start taking TERIFLUNOMIDE ADCO

- 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 ADCO 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.

1. What is in this leafletWhat TERIFLUNOMIDE ADCO is and what it is used for
2. What you need to know before you take TERIFLUNOMIDE ADCO
3. How to take TERIFLUNOMIDE ADCO
4. Possible side effects
5. How to store TERIFLUNOMIDE ADCO
6. Contents of the pack and other information

1. What TERIFLUNOMIDE ADCO is and what it is used for

TERIFLUNOMIDE ADCO contains the active substance teriflunomide which is an immunomodulatory medicine and adjusts the immune system to limit its attack on the nervous system.

TERIFLUNOMIDE ADCO 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 ADCO

Do not take TERIFLUNOMIDE ADCO:

- if you are hypersensitive (allergic) to teriflunomide or any of the other ingredients of TERIFLUNOMIDE ADCO (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 a woman of childbearing potential and you are not on reliable contraception.
- if you are pregnant, think you may be pregnant, or if you are breastfeeding your baby.
- 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 ADCO:

- 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 ADCO. Please read section 4.
- if you have hypoproteinaemia, e.g. in nephrotic syndrome (a kidney disorder that causes your body to pass too much protein in your urine).
- if you have high blood pressure (hypertension) whether it is controlled with medicines or not. TERIFLUNOMIDE ADCO can cause an increase in blood pressure. Your doctor will checkyour blood pressure before the start of treatment and regularly thereafter. Please read section 4.
- if you have an infection before you start treatment or when you developed an infection during treatment. Before you take TERIFLUNOMIDE ADCO, your doctor will make sure you have enough white blood cells and platelets in your blood. As TERIFLUNOMIDE ADCO 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. Please read section 4.
- if you have respiratory symptoms.
- if you have pre-existing anaemia, leukopenia, and/or thrombocytopenia or impaired bone marrow function.
- if you have severe skin reactions.
- if you are due for a vaccination.
- 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 ADCO.
- if you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

Children and adolescents

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

Other medicines and TERIFLUNOMIDE ADCO

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 drug 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, generalized 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 (to treat cholesterol).
- Atorvastatin (to treat cholesterol).
- Pravastatin (to treat cholesterol).

TERIFLUNOMIDE ADCO with food and drink

TERIFLUNOMIDE ADCO can be taken with or without food.

Pregnancy, breastfeeding and fertility

You should not use TERIFLUNOMIDE ADCO if you are pregnant or if you are a woman of childbearing age and you are not using reliable contraceptives. You should not become pregnant while taking TERIFLUNOMIDE ADCO.

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 ADCO.

TERIFLUNOMIDE ADCO remains in your blood for a long time after you stop taking it, so continue using effective birth control until blood levels of TERIFLUNOMIDE ADCO have been checked to be sufficiently low. Talk with your doctor about reliable methods of birth control that you should use during treatment.

If you suspect that you are pregnant or become pregnant while taking TERIFLUNOMIDE ADCO or in the two years after you have stopped treatment and have not taken certain medicines to remove TERIFLUNOMIDE ADCO 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 ADCO from the body, as this may decrease the risk to your baby.

Do not take TERIFLUNOMIDE ADCO when you are breastfeeding, as TERIFLUNOMIDE ADCO may pass into the breastmilk.

Fertility

Results of studies in animals have not shown an effect on the ability to have babies (fertility). Although information pertaining to humans are missing TERIFLUNOMIDE ADCO is not likely to have an effect on your ability to have babies.

Driving and using machines

TERIFLUNOMIDE ADCO 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 ADCO may interfere with your daily activities. You should ensure that you do not engage in the driving of a vehicle or use machines until you are aware of the measure to which TERIFLUNOMIDE ADCO affects you.

TERIFLUNOMIDE ADCO contains lactose monohydrate and sodium
TERIFLUNOMIDE ADCO 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.
TERIFLUNOMIDE ADCO contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium-free.'

3. How to take TERIFLUNOMIDE ADCO

Do not share medicines prescribed for you with any other person.
Always take TERIFLUNOMIDE ADCO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
The treatment should be initiated and supervised by a doctor experienced in multiple sclerosis.
Your doctor will decide on your starting dose. The recommended dose of TERIFLUNOMIDE ADCO is 14 mg orally once daily.
The film-coated tablet should be swallowed whole with some water.

Use in children and adolescents:
TERIFLUNOMIDE ADCO 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 ADCO will last. Do not stop treatment early. If you have the impression that the effect of TERIFLUNOMIDE ADCO is too strong or too weak, tell your doctor or pharmacist.

If you take more TERIFLUNOMIDE ADCO 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 a dose of TERIFLUNOMIDE ADCO
Do not take a double dose to make up for forgotten individual doses.

If you stop taking TERIFLUNOMIDE ADCO

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

4. Possible side effects

TERIFLUNOMIDE ADCO can have side effects.
Not all side effects reported for TERIFLUNOMIDE ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TERIFLUNOMIDE ADCO, please consult your doctor, pharmacist or other healthcare provider for advice.
If any of the following happens, stop taking TERIFLUNOMIDE ADCO 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 ADCO. 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),
- oral herpes (infection with the herpes simplex virus around the border of the lips),
- tooth infection,
- laryngitis (inflammation of your voice box),
- tinea pedis (a fungal infection that begins between the toes),
- neutropenia (an abnormally low count of a type of white blood cells),
- anaemia (a lack of red blood cells in the blood),
- paraesthesia (pins-and-needles in the arms, hands, legs or feet),
- neuralgia (pain that travel along the length of a nerve),
- palpitations (sensation that the heart is racing, pounding, fluttering or skipping a beat),
- alanine aminotransferase (ALT) increase (liver enzyme),
- gamma glutamyl transferase (GGT) increase (liver enzyme),
- aspartate aminotransferase increase (liver enzyme),

- neutrophil count decrease (type of white blood cell),
- white blood cell count decrease,
- blood creatine phosphokinase increased (indication of kidney function).

Less frequent side effects

- mild thrombocytopenia (low platelet count),
- peripheral neuropathy (weakness, numbness and pain in your hands or feet) due to nerve damage),
- post-traumatic pain.

Frequency not known:

- severe infections including sepsis (a potentially life-threatening type of infection) which might include symptoms of high fever, shaking, chills, reduced urine flow, or confusion
- pancreatitis (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,
- stomatitis (painful swelling and sores inside the mouth),
- acute hepatitis (inflammation of the liver) 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,
- interstitial lung disease (inflammation of the lungs which might include symptoms of shortness of breath or persistent cough),
- severe skin reactions
- psoriasis (including pustular)

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,
- sciatica (pain radiating along the sciatic nerve, which runs down one or both legs from the lower back),
- carpal tunnel syndrome (a numbness and tingling in the hand and arm caused by a pinched nerve in the wrist),
- hyperaesthesia (excessive physical sensitivity, especially of the skin),
- hypertension (high blood pressure),
- diarrhoea,
- nausea,
- upper abdominal pain,
- vomiting,

- toothache,
- alopecia (hair loss from the scalp or elsewhere on the body),
- acne,
- musculoskeletal pain (pain of the bones, muscles, ligaments, tendons and nerves),
- myalgia (pain in a muscle or group of muscles),
- arthralgia (pain in a joint),
- pollakiuria (the need to urinate more often than usual),
- menorrhagia (heavy or prolonged vaginal bleeding),
- pain,
- asthenia (decrease muscle strength),
- weight loss.

Less frequent side effects

- nail disorders.

Frequency not known:

- dyslipidaemia (abnormal elevated cholesterol or fats 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. 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 ADCO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store in the original package.

Keep the container in the outer carton

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 ADCO contains

The active substance(s) is teriflunomide.

The other ingredient(s) are:

Tablet core: Colloidal silicon dioxide, corn starch/maize starch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, sodium starch glycolate.

Film coating (Opadry blue 03F505097): Hypromellose 2910, indigo carmine aluminium lake/FD&C blue #2, iron oxide yellow, macrogol/PEG, titanium dioxide.

What TERIFLUNOMIDE ADCO looks like and contents of the pack

TERIFLUNOMIDE ADCO is presented as blue coloured, pentagonal shaped, biconvex, film coated tablets, debossed with "14" on one side and “T” on other side.

Packaging:

2 blisters per carton, 14 film-coated tablets per blister. 28 film-coated tablets per carton.

Alu-Alu blister pack comprises of cold formable foil and Hard Tempered Aluminium foil coated with heat seal lacquer on the sealing side and dull finish on the other side. Alu-Alu blister packs are packed into printed carton along with leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

30 June 2026

Registration/Application number

55/32.16/0245.244