Package leaflet: Information for the patient

Teriflunomide 14 mg film-coated tablets
teriflunomide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Teriflunomide is and what it is used for
2. What you need to know before you take Teriflunomide
3. How to take Teriflunomide
4. Possible side effects
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1. What Teriflunomide is and what it is used for

What Teriflunomide is
Teriflunomide contains the active substance teriflunomide which is an immunomodulatory agent and adjusts the immune system to limit its attack on the nervous system.

What Teriflunomide is used for
Teriflunomide is used in adults and in children and adolescents (10 years of age and older) to treat relapsing remitting multiple sclerosis (MS).

What multiple sclerosis is
MS is a long-term illness that affects the central nervous system (CNS). The CNS is made up of the brain and spinal cord. In multiple sclerosis, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS. This loss of myelin is called demyelination. This stops nerves from working properly.

People with relapsing form of multiple sclerosis will have repeated attacks (relapses) of physical symptoms caused by their nerves not working properly. These symptoms vary from patient to patient but usually involve:
- difficulty walking
- vision problems
- balance problems.

Symptoms may disappear completely after the relapse is over, but over time, some problems may remain between relapses. This can cause physical disabilities that may interfere with your daily activities.

How Teriflunomide works
Teriflunomide helps to protect against attacks on the central nervous system by the immune system by limiting the increase of some white blood cells (lymphocytes). This limits the inflammation that leads to nerve damage in MS.

2. What you need to know before you take Teriflunomide

Do not take Teriflunomide:
- if you are allergic to teriflunomide or any of the other ingredients of this medicine (listed in section

6),
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking teriflunomide or leflunomide,
- if you have severe liver problems,
- if you are pregnant, think you may be pregnant, or are breast-feeding,
- 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)

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Teriflunomide 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. Please read section 4.
- you have high blood pressure (hypertension) whether it is controlled with medicines or not. Teriflunomide 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.
- you have an infection. Before you take Teriflunomide, your doctor will make sure you have enough white blood cells and platelets in your blood. As Teriflunomide 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 any infection. Herpes virus infections, including oral herpes or herpes zoster (shingles) may occur with teriflunomide treatment. In some cases, serious complications have occurred. You should inform your doctor immediately if you suspect you have any symptoms of herpes virus infections. Please read section 4.
- you have severe skin reactions.
- you have respiratory symptoms.
- you have weakness, numbness and pain in the hands and feet.
- you are going to have a vaccination.
- you take leflunomide with Teriflunomide.
- you are switching to or from Teriflunomide.
- you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

Talk to your doctor or pharmacist:
- if you develop skin ulcers or experience impaired wound healing while being treated with Teriflunomide.
- if you will have or have had recent major surgery, or if you still have an unhealed wound following surgery as Teriflunomide may impair wound healing.

Respiratory reactions
Tell your doctor if you have unexplained cough and dyspnoea (shortness of breath). Your doctor may perform additional tests

Children and adolescents
Teriflunomide is not intended for use in children under 10 years of age, as it has not been studied in MS patients in this age group.
The warnings and precautions listed above also apply to children. The following information is important for children and their caregivers:
- inflammation of the pancreas has been observed in patients receiving teriflunomide. Your child’s doctor may carry out blood tests if an inflammation to the pancreas is suspected.

Other medicines and Teriflunomide
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription.
In particular, tell your doctor or pharmacist if you are taking any of the following:
- leflunomide, methotrexate and other medicines that affect the immune system (often called immunosuppressants or immunomodulators)
- rifampicin (a medicine used to treat tuberculosis and other infections)
- carbamazepine, phenobarbital, phenytoin for epilepsy
- St John's wort (a herbal medicine for depression)
- repaglinide, pioglitazone, nateglinide, or rosiglitazone for diabetes
- daunorubicin, doxorubicin, paclitaxel, or topotecan for cancer
- duloxetine for depression, urinary incontinenece or in kidney disease in diabetics
- alosetron for the management of severe diarrhoea
- theophylline for asthma
- tizanidine, a muscle relaxant
- warfarin, an anticoagulant used to make the blood thinner (i.e. more fluid) in order to avoid blood clots
- oral contraceptives (containing ethinylestradiol and levonorgestrel)
- cefaclor, benzylpenicillin (penicillin G), ciprofloxacin for infections
- indometacin, ketoprofen for pain or inflammation
- furosemide for heart disease
- cimetidine for reducing gastric acid
- zidovudine for HIV infection
- rosuvastatin, simvastatin, atorvastatin, pravastatin for hypercholesterolemia (high cholesterol)
- sulfasalazine for inflammatory bowel disease or rheumatoid arthritis
- cholestyramine for high cholesterol or relief from itching in liver disease
- activated charcoal to reduce absorption of medicines or other substances

Pregnancy and breast-feeding
Do not take Teriflunomide if you are, or think you may be **pregnant**. If you are pregnant or become pregnant while taking Teriflunomide, the risk of having a baby with birth defects is increased. Women of childbearing potential must not take this medicine without using reliable contraceptive measures.
If your daughter reaches menses while taking Teriflunomide, 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 Teriflunomide, 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 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 physician that the blood level of Teriflunomide is low enough to allow you to become pregnant.

For further information on the laboratory testing please contact your doctor.

If you suspect that you are pregnant while taking Teriflunomide or in the two years after you have stopped treatment, you must discontinue Teriflunomide and 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 remove Teriflunomide rapidly and sufficiently from your body, as this may decrease the risk to your baby.

<u>Contraception</u>
You must use an effective method of contraception during and after treatment with Teriflunomide. 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 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 when you are breast-feeding, as teriflunomide passes into the breast milk.

Driving and using machines
Teriflunomide might make you feel dizzy which may impair your ability to concentrate and react. If you are affected, do not drive or use machines.

Teriflunomide contains lactose
Teriflunomide contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Teriflunomide contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Teriflunomide

Treatment with Teriflunomide will be overseen by a doctor who is experienced in the treatment of multiple sclerosis.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Adults
The recommended dose is one 14 mg tablet daily.

Children and adolescents (10 years of age and above)
The dose depends on body weight:
- Children with body weight greater than 40 kg: one 14 mg tablet daily.
- Children with body weight less than or equal to 40 kg: one 7 mg tablet daily.

Teriflunomide 14 mg is not suitable for paediatric patients with a body weight ≤40 kg; other medicinal products are available in a lower strength (as 7 mg film-coated tablets).

Children and adolescents who reach a stable body weight above 40 kg will be instructed by their doctor to switch to one 14 mg tablet daily.

Route/method of administration
Teriflunomide is for oral use. Teriflunomide is taken every day as a single dose at any time of the day. You should swallow the tablet whole with some water.

Teriflunomide may be taken with or without food.

If you take more Teriflunomide than you should
If you have taken too much Teriflunomide, call your doctor straight away. You may experience side effects similar to those described in section 4 below.

If you forget to take Teriflunomide
Do not take a double dose to make up for a forgotten tablet. Take your next dose at the scheduled time.

If you stop taking Teriflunomide
Do not stop taking Teriflunomide or change your dose without talking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Serious side effects

Some side effects could be or could become serious, if you experience any of these, **tell your doctor immediately.**

Common (may affect up to 1 in 10 people)
- inflammation of the pancreas which might include symptoms of pain in the abdominal area, nausea, or vomiting (the frequency is common in paediatric patients and uncommon in adult patients).

Uncommon (may affect up to 1 in 100 people)
- allergic reactions which might include symptoms of rash, hives, swelling of lips, tongue or face or sudden difficulty breathing.
- severe skin reactions which might include symptoms of skin rash, blistering, fever, or ulcers in your mouth
- 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

Not known (frequency cannot be estimated from the available data):
- 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

Other side effects can occur with the following frequencies:
Very common (may affect more than 1 in 10 people)
- Headache
- Diarrhoea, feeling sick
- Increase in ALT (increase in blood levels of certain hepatic enzymes) shown in tests
- Hair thinning

Common (may affect up to 1 in 10 people)
- Influenza, upper respiratory tract infection, urinary tract infection, bronchitis, sinusitis, sore throat and discomfort when swallowing, cystitis, gastroenteritis viral, tooth infection, laryngitis, fungal infection of the foot
- Herpes virus infections, including oral herpes and herpes zoster (shingles) with symptoms such as blisters, burning, itching, numbness or pain of the skin, typically on one side of the upper body or face, and other symptoms, like fever and weakness
- Laboratory values: a decrease in the number of red blood cells (anaemia), changes in liver and white blood cell test results (see section 2), as well as elevations in a muscle enzyme (creatine phosphokinase) have been observed.
- Mild allergic reactions
- Feeling anxious
- 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)
- Feeling your heartbeat
- Increase in blood pressure
- Being sick (vomiting), toothache, upper abdominal pain
- Rash, acne
- Pain of the tendons, joints, bones, muscle pain (musculoskeletal pain),
- Needing to urinate more often than usual
- Heavy periods
- Pain
- Lack of energy or feeling weak (asthenia)
- Weight loss

Uncommon (may affect up to 1 in 100 people)
- 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)

- Nail disorders, severe skin reactions
- Post-traumatic pain
- Psoriasis
- Inflammation of mouth/lips
- Abnormal levels of fats (lipids) in the blood
- Inflammation of the colon (colitis)

Rare (may affect up to 1 in 1,000 people)
- Inflammation or injury of the liver

Not known (frequency cannot be estimated from the available data)
- Respiratory hypertension

Children (10 years of age and above) and adolescents
The side effects listed above also apply to children and adolescents. The following additional information is important for children, adolescents, and their caregivers:

Common (may affect up to 1 in 10 people)
- Inflammation of the pancreas

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teriflunomide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Teriflunomide contains
The active substance is teriflunomide.

Teriflunomide 14 mg film-coated tablets
- Each tablet contains 14 mg of teriflunomide.
- The other ingredients are:
  Lactose monohydrate (see section 2 "Teriflunomide contains lactose"), maize starch, sodium starch glycolate (Type A), hydroxylpropylcellulose, magnesium stearate, silica, colloidal anhydrous, hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172), macrogol 6000 and indigo carmine aluminum lake (E132)

What Teriflunomide looks like and contents of the pack

Blue coloured, pentagonal shaped, biconvex, film-coated tablets, debossed with "14" on one side and "T" on other side.

Teriflunomide 14 mg film-coated tablets are available in cardboard cartons containing:
- 14, 28, 84 and 98 tablets in calendar blisters;
- 10x1 tablet in unit-dose blisters.

Not all pack sizes may be marketed.

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