



## PACKAGE LEAFLET

### TERIGIO 14 mg film coated tablets

#### Taken by mouth

- **Active substance:** Each film-coated tablet contains 14 mg teriflunomide.
- **Excipients:** Lactose monohydrate (from cow's milk), maize starch, microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycolate (Type A), colloidal silicon dioxide, magnesium stearate, Opadry 03K205008 Blue: Hydroxypropyl methyl cellulose, triacetin, titanium dioxide, indigo carmine (Blue-2) Al-lacquer.

▼ This medicinal product is subject to additional monitoring. This triangle symbol will allow the new safety information to be established quickly. You can help by reporting any side effects that may occur. See the end of Section 4 to learn how to report side effects.

**Read all of this LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- This medicine has been prescribed for you. Do not pass it onto others.*
- *When you visit a doctor or hospital while using this medicine, tell them that you are using this medicine.*
  - *Please follow the instructions in this leaflet. Do not use any **higher or lower** doses than the recommended dose of this medicine.*

#### **What is in this leaflet:**

- 1. What TERIGIO is and what it is used for**
- 2. What you need to know before you use TERIGIO**
- 3. How to use TERIGIO**
- 4. Possible side effects**
- 5. How to store TERIGIO**

#### **1. What TERIGIO is and what it is used for**

TERIGIO consists of pale blue to pastel blue, biconvex, round film-coated tablets. It is presented in 2 blisters (each containing 14 tablets) of PA/ALU/PVC foil and aluminum foil, 28 tablets in total, in a cardboard box.

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

TERIGIO is used in adults, children with a body weight >40 kg, and adolescents (10 years of age and older) to treat relapsing remitting multiple sclerosis (MS).

#### **What is multiple sclerosis?**

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.

TERIGIO 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 use TERIGIO**

### **DO NOT use TERIGIO:**

- If you are allergic to the active substance or any of the other ingredients of this medicine,
- 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 have a serious problem that affects your immune system, such as Acquired Immune Deficiency Syndrome (AIDS),
- If you have a serious problem with your bone marrow, or if you have low numbers of red (anemia) or white (leukopenia, neutropenia) cells in your blood or a reduced number of blood platelets (thrombocytes),
- 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 (hypoproteinemia),

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

### **Use TERIGIO with SPECIAL CARE in the following conditions**

Talk to your doctor or pharmacist before taking TERIGIO:

- 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 TERIGIO (see Section 4).
- If you have high blood pressure (hypertension) whether it is controlled with medicines or not. TERIGIO can cause an increase in blood pressure. Your doctor will check your blood pressure before the start of treatment and regularly thereafter (See Section 4).

- If you have an infection. Before you take TERIGIO, your doctor will make sure you have enough white blood cells and platelets (thrombocytes) in your blood. As TERIGIO 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 (see section 4).
- If you have severe skin reactions,
- If you have respiratory symptoms,
- If you have weakness, numbness and pain in the hands and feet,
- If you are going to have a vaccination,
- If you take leflunomide with TERIGIO,
- If you are switching to or from TERIGIO,
- If you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

### **Respiratory reactions**

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

### **Children and adolescents**

TERIGIO 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.

If any of these warnings apply to you, even if in the past, please consult your doctor.

### **Using TERIGIO with food and drink**

TERIGIO may be taken on an empty or full stomach.

### **Pregnancy**

*Ask your doctor or pharmacist before you start to use this medicine.*

Do not use TERIGIO if you are pregnant or think you may be pregnant. If you are or become pregnant while using TERIGIO, the risk of having a baby with birth defects increases. Women of childbearing potential must not take TERIGIO without using reliable contraceptive measures. If your daughter reaches menses while taking TERIGIO, you should inform the doctor, who will provide specialist counseling regarding contraception and the potential risks in case of pregnancy.

Tell your doctor if you plan to become pregnant after stopping treatment with TERIGIO, as you need to ensure that most of TERIGIO 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 TERIGIO from your body.

In either case, it should be confirmed by a blood test that TERIGIO has been sufficiently removed from your body and you need confirmation from your treating physician that the blood level of TERIGIO 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 TERIGIO or in the two years after you have stopped treatment, you must discontinue TERIGIO 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 TERIGIO rapidly and sufficiently from your body, as this may decrease the risk to your baby.

### Birth control

You should use an effective birth control method during and after treatment with TERIGIO. Teriflunomide remains in your blood for a long time after you stop taking it. Continue to use effective birth control after you stop treatment.

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

*If you notice that you are pregnant during the treatment, tell your doctor or pharmacist immediately.*

### **Breastfeeding**

*Ask your doctor or pharmacist before you start to use this medicine.*

Since teriflunomide passes into breast milk, do not use TERIGIO while breastfeeding.

### **Driving and using machines**

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

### **Important information about some of the excipients of TERIGIO**

TERIGIO contains lactose. If your doctor previously told you that you have intolerance to certain forms of sugar, talk to your doctor before taking this medicine.

### **Using with other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken 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 (an herbal medicine for depression)
- Repaglinide, pioglitazone, nateglinide or rosiglitazone for diabetes
- Daunorubicin, doxorubicin, paclitaxel or topotecan for cancer
- Duloxetine for depression, urinary incontinence or in kidney disease in diabetics
- Alosetron for the treatment of severe diarrhea
- 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
- Indomethacin, ketoprofen for pain or inflammation
- Furosemide, a diuretic for heart disease
- Cimetidine for reducing gastric acid (stomach acid)
- Zidovudine for HIV infection (AIDS)
- 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

*Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

### **3. How to use TERIGIO**

#### **Instructions for appropriate use and dose/frequency of administration:**

Treatment with TERIGIO 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 tablets daily.

#### **Children and adolescents (10 years and older)**

The dose depends on the body weight:

- Children with a body weight over 40 kg: one 14 mg tablet daily
- Children with a body weight less than or equal to 40 kg: one 7 mg tablet daily

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 and method of administration:**

TERIGIO is for oral use. TERIGIO is taken every day as a single dose at any time of the day.

You should swallow the tablet whole with some water.

TERIGIO may be taken with or without food.

#### **Special age groups:**

##### **Use in children:**

TERIGIO 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.



**Use in the elderly:**

TERIGIO should be used with caution in patients aged 65 and over.

**Special conditions for use:**

**Kidney/Liver failure:**

No dose adjustment is necessary for patients with kidney failure who are not on dialysis. TERIGIO should not be used in patients with severe kidney problems that require dialysis.

TERIGIO should not be used in patients with severe liver failure.

If you think the effect of TERIGIO is too strong or too weak, talk to your physician or pharmacist.

**If you use more TERIGIO than you should:**

If you have taken too much TERIGIO, call your doctor straight away. You may experience side effects similar to those described in Section 4.

If you have taken more TERIGIO than you should, talk to your doctor or pharmacist.

**If you forget to use TERIGIO**

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

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

**Possible effects when you stop treatment with TERIGIO:**

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

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

**4. Possible side effects**

Like all medicines, TERIGIO may cause side effects in people with hypersensitivity to its ingredients.

Side effects are listed as shown in the categories below:

Very common: May occur at least 1 in 10 patients.

Common: May occur less than one in 10 but more than one in 100 patients.

Uncommon: May occur less than one in 100 but more than one in 1,000 patients.

Rare: May occur less than one in 1,000 but more than one in 10,000 patients.

Very rare: May occur in less than one in 10,000 patients.

Unknown: Frequency cannot be established with the available data.

The following side effects may occur with this medicine:

**If you get any of the following symptoms, stop using TERIGIO and IMMEDIATELY tell your doctor or refer to the nearest hospital's emergency department:**

### **Common**

- Inflammation of the pancreas which might include symptoms of pain in the abdominal area, nausea, or vomiting (the frequency is common in pediatric patients and uncommon in adult patients).

### **Uncommon**

- 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 such as shortness of breath or persistent cough

### **Unknown**

- 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

If you notice any of the above side effects, tell your doctor immediately.

These are all very serious side effects. You may need emergency medical intervention or hospitalization.

These very serious side effects occur quite rarely.

### **If you notice any of the following, tell your doctor:**

#### **Very common**

- Headache
- Diarrhea, feeling sick
- Increase in ALT (increase in blood levels of certain liver enzymes)
- Hair thinning

#### **Common**

- Influenza, upper respiratory tract infection, urinary tract infection, bronchitis (inflammation of the bronchi), sinusitis (inflammation of the sinuses), sore throat and discomfort when swallowing, cystitis (inflammation of the urinary bladder), viral gastroenteritis (infection of stomach and intestines with diarrhea and vomiting, caused by viruses), oral herpes (cold sores), tooth infection, laryngitis (inflammation of the larynx), fungal infection of the foot
- Laboratory values: a decrease in the number of red blood cells (anemia), 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
- Upper abdominal pain, being sick (vomiting), toothache
- Rash, acne
- Pain of the tendons, joints, bones and muscle (musculoskeletal pain),
- Needing to urinate more often than usual
- Heavy periods
- Pain
- Lack of energy or feeling weak (asthenia)
- Weight loss

#### **Uncommon**

- Decrease in the number of blood platelets (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
- Pain after injury (post-traumatic pain)
- Psoriasis
- Inflammation of mouth/lips
- Abnormal levels of fats (lipids) in the blood
- Inflammation of the colon (colitis)

#### **Rare**

- Inflammation or injury of the liver

#### **Unknown**

- 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**

- Inflammation of the pancreas

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

#### Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.





## 5. How to store TERIGIO

*Keep TERIGIO out of the reach and sight of children and store in the original package.  
Store at room temperature below 30°C.*

### **Use your medicine observing the expiry date.**

*Do not use TERIGIO after / use TERIGIO before the expiry date which is stated on the packaging/carton/bottle.*

The expiry date refers to the last day of that month.

*To protect the environment, do not throw TERIGIO into city water or waste bin.  
Consult your pharmacist about this.*

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.

### **Marketing authorization holder:**

Saba İlaç San. ve Tic. A.Ş.  
Küçükçekmece/İSTANBUL  
Phone : 0 212 692 92 92  
Fax : 0 212 697 00 24  
E-mail: saba@sabailac.com.tr

### **Manufacturing site:**

Deva Holding A.Ş.  
Kapaklı/TEKİRDAĞ

*This leaflet was approved on 20/04/2022.*