

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

AUBAMIDE 14 mg film-coated tablet

Teriflunomide

Contains sugar: Lactose monohydrate 76 mg

WARNING: LIVER DISEASE and RISK OF TERATOGENICITY

Hepatotoxicity:

Severe liver injury including fatal liver failure has been reported in patients taking leflunomide, which is indicated for rheumatoid arthritis. A similar risk would be expected for AUBAMIDE because recommended doses of AUBAMIDE and leflunomide result in a similar range of AUBAMIDE concentration found in the blood. Obtain transaminase (liver enzyme) and bilirubin (yellowish substance in you blood) levels within 6 months before initiation of AUBAMIDE and monitor alanine aminotransferase (liver enzyme) levels at least monthly for six months. If liver injury is caused by AUBAMIDE is suspected , discontinue AUBAMIDE treatment and start accelerated elimination procedure.

Risk of teratogenicity:

Based on animal data, AUBAMIDE may cause major birth abnormalities if used during pregnancy. AUBAMIDE is not recommended in pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during AUBAMIDE treatment.

Read all of this leaflet carefully before you start taking AUBAMIDE

- Keep this leaflet. You may need to read it again
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider
- AUBAMIDE 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.

What is in this leaflet

1. What AUBAMIDE is and what it is used for
2. What you need to know before you take AUBAMIDE

3. How to take AUBAMIDE
4. Possible side effects
5. How to store AUBAMIDE
6. Contents of the pack and other information

1. What AUBAMIDE is and what it is used for

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

AUBAMIDE is used to treat relapsing forms of multiple sclerosis (MS) in adults.

AUBAMIDE helps to reduce the number of relapses and to slow down the progression of physical disabilities due to MS.

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 MS 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.

AUBAMIDE does not cure MS.

2. What you need to know before you take AUBAMIDE

Do not take AUBAMIDE if you:

- you are allergic (hypersensitive) to teriflunomide, leflunomide or any other ingredients of AUBAMIDE (see **section 6**)
- have severe liver problems
- are taking leflunomide
- are a woman who is planning on becoming pregnant or is pregnant
- have a possibility of becoming pregnant but not using effective birth control methods
- you are a mother breastfeeding their babies.

If you become pregnant while taking AUBAMIDE stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking this medicine AUBAMIDE by using suitable contraceptive measures.

Warnings and precautions

Talk to your doctor or pharmacist before taking AUBAMIDE:

- if you have liver problems and / or you drink large amounts of alcohol
- if you have high blood pressure (hypertension) and whether it is controlled or not with medicines
- if you suffer from a serious infection or a serious problem affecting your immune system
- if you are planning on getting vaccinated

Liver function tests:

You should not take AUBAMIDE if you have severe liver problems.

AUBAMIDE may cause abnormal liver function tests results.

If you notice your skin and whites of your eyes becoming yellow, abnormal darkening of the urine or unexplained nausea and vomiting inform your doctor immediately.

If you have any of these symptoms after starting treatment on AUBAMIDE, tell your doctor immediately.

During the treatment period your doctor will regularly request to do blood tests to monitor your liver function. If your test results indicate a problem with your liver, your treatment with AUBAMIDE may have to be interrupted.

High blood pressure

AUBAMIDE may cause a rise in blood pressure, your doctor should test your blood pressure levels before initiating treatment on AUBAMIDE and during treatment with AUBAMIDE.

Infections

You may get infections more easily while taking AUBAMIDE.

Any existing infections may get become worse. Infections can be serious and potentially life-threatening. If you suspect you have an infection, have fever, or feel like you have the flu, call your doctor immediately.

Blood count

AUBAMIDE decreases the number of certain blood cells in your blood.

If you require to have any blood tests taken, notify the doctor that you are taking AUBAMIDE.

Otherwise, it may not be possible for the doctor to interpret the results of the test. Before you begin treatment on AUBAMIDE, your doctor will confirm whether you have enough of certain blood cells in your blood and may want to check regularly.

Children and adolescents:

AUBAMIDE, is not recommended for use in children and adolescents below 18 years old since it has not been studied in MS patients below 18 years old.

If any of the above applies to you (or if you are not sure): check with your doctor or pharmacist before you start taking any dose of AUBAMIDE.

Interstitial lung disease

Interstitial lung disease (ILD) has been reported with teriflunomide treatment.

ILD and worsening of existing ILD have been reported during treatment with leflunomide. The risk is higher in patients who had a history of ILD when treated with leflunomide.

ILD may happen at any time during treatment and shows in different ways. ILD may be fatal. New or worsening lung symptoms, such as persistent cough and difficulty breathing, may be a reason for stopping of the treatment and for further investigation, where appropriate.

Peripheral neuropathy (nerve damage)

Cases of nerve damage have been reported in patients taking AUBAMIDE. In most patients, this condition becomes better after stopping treatment with teriflunomide. However, in some patients the nerve damage stopped, and some patients had ongoing symptoms. If a patient taking AUBAMIDE develops peripheral neuropathy, consider stopping AUBAMIDE treatment.

Other medicines and AUBAMIDE

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

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

- medicines that affect the immune system (also called immunosuppressants or immunomodulators) such as ciclosporin and methotrexate
- rifampicin used for tuberculosis
- carbamazepine, phenobarbitone, phenytoin (medicines used for epilepsy)
- St John's wort – a herbal medicine used for depression

- repaglinide, pioglitazone, rosiglitazone used for diabetes
- paclitaxel, daunorubicin, doxorubicin, topotecan used for treating cancer
- duloxetine used for depression
- ethinylestradiol and levonorgestrel used as oral contraceptives
- theophylline (medicines used for asthma and other lung disease)
- tizanidine (used for muscle spasms)
- warfarin (used for blood clots)
- cefaclor, penicillin, ciprofloxacin (used as antibiotics)
- indomethacin, ketoprofen, used for pain and inflammation
- furosemide (used for high blood pressure)
- cimetidine (used for ulcers)
- zidovudine (used for viral infections)
- rosuvastatin, simvastatin, atorvastatin, pravastatin used for controlling high cholesterol
- sulfasalazine (used for treatment of bowel disease)
- leflunomide (used for rheumatoid arthritis).

If you get admitted into a hospital or receive treatment for another condition, inform your doctor or pharmacist that you are taking AUBAMIDE.

Pregnancy, breast-feeding and fertility

You should not become pregnant while taking AUBAMIDE.

AUBAMIDE remains in your blood for a long time even after you have stopped taking it, hence you should continue using effective contraceptive methods until your AUBAMIDE blood levels have been tested to be sufficiently low. Talk to your doctor about effective and reliable methods of birth control that you should use while on treatment with AUBAMIDE.

If you become pregnant or suspect a pregnancy during treatment with AUBAMIDE or within two years after you have stopped taking it and have not taken certain medicines to help remove AUBAMIDE from your blood, you must call your doctor immediately for a pregnancy test.

Should the pregnancy test confirm a pregnancy, your doctor might suggest treatment with certain medication to accelerate the removal of AUBAMIDE from the body, as this may reduce the potential risk to your baby.

Do not take AUBAMIDE if you are breastfeeding as teriflunomide may pass into the breast milk.

If you are breastfeeding or pregnant , suspecting you may be pregnant or planning on having a baby, talk to your doctor or pharmacist for advice before taking AUBAMIDE.

Driving and using machines

AUBAMIDE may cause dizziness and affect the ability to concentrate properly. In such cases, patients should refrain from driving and using machines.

AUBAMIDE and (sugar) lactose

If you have been informed by your doctor that you have an intolerance to some sugars (e.g lactose), you should contact your doctor before taking AUBAMIDE.

3. How to take AUBAMIDE

Always take AUBAMIDE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Treatment with AUBAMIDE should be overseen by a doctor who is experienced in treating MS.

The recommended dose for adults is to take one tablet a day. You should swallow the tablet whole with water.

If you take more AUBAMIDE than you should

Contact your doctor or the emergency department at the nearest hospital. You may experience side effects similar to those listed in **section 4**.

Take the remaining tablets and this leaflet with you so the doctor will know what you have taken.

If you forget to take AUBAMIDE

Should you forget to take a dose of AUBAMIDE, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take your tablet at the scheduled time.

Do not take a double dose to make up for the missed tablet.

If you stop taking AUBAMIDE

First consult your doctor before you decide to stop taking AUBAMIDE or change your dose.

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

4. Possible side effects

Not all side effects reported for AUBAMIDE are included in this leaflet. Should your general health worsen or if you experience any unwanted effects while taking AUBAMIDE, please consult your health care provider for advice. The following side effects are listed in order of decreasing seriousness.

If any of the following happens, stop taking / using AUBAMIDE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may result in difficulty breathing or swallowing
- itching or rash
- fainting.

The above mentioned are all very serious side effects. If you experience any of them, you may have had a serious allergic reaction to AUBAMIDE. You may need to receive urgent medical attention or hospitalisation.

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

Frequent side effects:

- weakness, numbness or burning sensation in some areas of the body
- pins and needles
- frequent urge to urinate
- headache
- influenza
- upper respiratory tract infection
- urinary tract infection
- diarrhoea
- nausea
- increased ALT (increased liver enzymes)
- hair thinning.

Less frequent side effects

- bronchitis, sinusitis, sore throat and discomfort when swallowing
- cystitis, viral gastroenteritis, oral herpes, tooth infection, laryngitis
- anaemia
- seasonal allergy
- anxiety
- sciatica, carpal tunnel syndrome
- pain in joints
- rise in blood pressure
- fast , irregular heartbeat
- stomach cramps
- vomiting

- toothache
- abnormal liver blood test results
- acne
- muscle pain
- abnormal physical weakness or lack of energy
- frequent urge to urinate
- excessively heavy menstrual bleeding
- pain
- decreased weight
- decrease in white blood cell count.

Rare side effects:

- extremely serious allergic reaction with blisters on the skin, mouth, eyes and genitals
- inflammation of the lungs causing shortness of breath and a chronic dry cough
- inflammation of the pancreas which causes severe pain in the abdomen and back.

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

- painful sores with swelling and redness in the mouth

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

Reporting of side effects

If you get any 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 directly via the “6.04 Adverse Drug Reactions Reporting Form”, found under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8n> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com .By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AUBAMIDE

Store all medicines out of reach of children.

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

Store at or below 25 °C.

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 to protect the environment.

6. Contents of the pack and other information

What AUBAMIDE contains

The active substance is teriflunomide 14 mg .

The other ingredients are lactose monohydrate, maize starch, hydroxypropyl cellulose, microcrystalline cellulose, sodium starch glycolate(type A), colloidal silicon dioxide, magnesium stearate and tablet coating (Opadry yellow: hypromellose (E464), titanium dioxide (E171), macrogol (E1521), iron oxide yellow (E172), iron oxide red (E172).

What AUBAMIDE looks like and contents of the pack

AUBAMIDE 14 mg film-coated tablets are light yellow, round shaped, biconvex film coated tablets, debossed with “A” on one side and “14” on the other side.

There are 30 tablets in each carton packaged in blisters. The blister packaging is made of aluminium and PVC. Each blister set has 10 tablets and three blister sets are packed into the carton.

There are 100 film-coated tablets packed into a round, non-transparent, HDPE bottle. The bottle has a child-resistant screw cap with CR-02 liner.

Holder of Certificate of registration

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