For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

Teriflunomide Tablets

AUBAGIO®

COMPOSITION: Each film coated tablet contains teriflunomide 14 mg.

THERAPEUTIC INDICATION

Aubagio® is indicated for the treatment of patients with relapsing forms of multiple sclerosis

DOSAGE & ADMINISTRATION

The recommended dose of Aubagio® is 14 mg orally once daily. Aubagio® can be taken with or without food**.** The safety and effectiveness of Aubagio® in pediatric patients with MS below the age of 18 years have not yet been established. Aubagio® should be used with caution in patients aged over 65 years. No dosage adjustment is necessary for patients with mild and moderate hepatic impairment. Teriflunomide is contraindicated in patients with severe hepatic impairment. No dosage adjustment is necessary for patients with severe renal impairment

SAFETY RELATED INFORMATION

Contraindications: Aubagio® is contraindicated in patients with: known hypersensitivity to teriflunomide, leflunomide or to any of the inactive ingredients in the formulation, severe hepatic impairment, pregnant women, or women of childbearing potential who are not using reliable contraception, during treatment with teriflunomide and thereafter as long as its plasma levels are above
0.02 mg/l.

Pregnancy: Aubagio® may increase the risk of fetal death or teratogenic effects when administered to pregnant women. Teriflunomide is contraindicated in pregnancy. Prospectively reported data (from clinical trials and postmarketing reports) from >150 pregnancies in patients treated with teriflunomide and >300 pregnancies in patients treated with leflunomide have not demonstrated an increased rate of congenital malformations or miscarriage following teriflunomide exposure in the early first trimester when followed by an accelerated elimination procedure.

Lactation: Because of the potential for serious adverse reactions in nursing infants from Aubagio®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother

Warnings: Elevations of liver enzymes have been observed in patients receiving Aubagio®

Obtain serum transaminase and bilirubin levels within 6 months before initiation of Aubagio® therapy. Monitor ALT levels at least monthly for six months after starting Aubagio®. Consider monitoring when Aubagio® is given with other potentially hepatotoxic drugs. Consider discontinuing Aubagio® if serum transaminase increase (greater than three times the ULN) is confirmed. Monitor serum transaminase and bilirubin on Aubagio® therapy, particularly in patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine. If liver injury is suspected to be Aubagio® induced, discontinue teriflunomide and start an accelerated elimination procedure and monitor liver tests weekly until normalized.

Women of childbearing potential must use effective contraception to avoid pregnancy while taking Aubagio®. If Aubagio® is stopped, women should continue contraception until teriflunomide plasma concentrations have been checked to be equal to 0.02 μg/mL or lower. Women, who are planning a pregnancy or are pregnant, should be advised that an accelerated elimination procedure can be used to quickly decrease the plasma concentration of teriflunomide.

In addition to a case of "toxic hepatitis" in clinical trials, cases of drug-induced liver injury (DILI) have been observed in the post-marketing setting, sometimes life-threatening, often in combination with other hepatotoxic drugs.

Precautions: Check blood pressure before start of Aubagio® and periodically thereafter. Blood pressure elevation should be appropriately managed during treatment with Aubagio®.

Based on the immunomodulatory effect of Aubagio® if a patient develops a serious infection, consider suspending treatment with Aubagio®, and reassess the benefits and risks prior to re-initiation of therapy. Due to the prolonged half-life of elimination of teriflunomide, accelerated elimination with cholestyramine or charcoal may be considered. Patients with active acute or chronic infections should not start treatment Aubagio® until the infection(s) is resolved. Aubagio® is not recommended with severe immunodeficiency, bone marrow disease, or severe, uncontrolled infections. Interstitial lung disease, including acute interstitial pneumonitis, has been reported with AUBAGIO in the postmarketing setting. New onset or worsening pulmonary symptoms, such as cough and dyspnea, with or without associated fever, may be a reason for discontinuation of the therapy and for further investigation as appropriate. If discontinuation of the drug is necessary, consider initiation of an accelerated elimination procedure. The use of live attenuated vaccines may

carry a risk of infections and should therefore be avoided. Severe cutaneous adverse reactions (SCARs)

Cases of serious skins reactions sometimes fatal including Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with teriflunomide. If skin and /or mucosal reactions (ulcerative stomatitis) are observed which raise the suspicion of severe generalised major skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis-Lyell's syndrome, or drug reaction with eosinophilia and systemic symptoms teriflunomide and any other possibly associated treatment must be discontinued, and an accelerated elimination procedure initiated immediately. Cases of peripheral neuropathy have been reported in patients receiving AUBAGIO. If a patient taking AUBAGIO develops a confirmed peripheral neuropathy, consider discontinuing AUBAGIO therapy and performing the accelerated elimination procedure. As leflunomide is the parent compound of teriflunomide, co-administration of teriflunomide with leflunomide is not recommended. Co-administration with antineoplastic or immunosuppressive therapies used for treatment of multiple sclerosis has not been evaluated. Safety studies, in which teriflunomide was concomitantly administered with other immune modulating therapies for up to one year (interferon beta, glatiramer acetate) did not reveal any specific safety concerns.

ADVERSE REACTIONS:

Clinical trial experience: Influenza, Sinusitis, Gastroenteritis viral, Neutropenia, Headache, Paraesthesia, Palpitations, Hypertension, Diarrhoea, Nausea, Abdominal pain upper, Toothache**,** Alopecia, Rash, Arthralgia, Musculoskeletal pain, Myalgia, Menorrhagia, Alanine aminotransferase increased, Aspartate aminotransferase increased, Gamma-glutamyltransferase increased, Weight decreased, Neutrophil count decreased, Blood creatine phosphokinase increased, White blood cell count decreased, Polyneuropathy.

Post marketing experience: Hypersensitivity reactions (immediate or delayed) some of which were severe, such as anaphylaxis, and angioedema, Severe skin reactions including toxic epidermal necrolysis(TEN) and Stevens-Johnson syndrome(SJS) and drug reaction with eosinophilia and systemic symptoms(DRESS), Psoriasis (including pustular psoriasis and nail psoriasis), nail disorders Interstitial Lung Disease (ILD), pulmonary hypertension, Stomatitis (such as aphthous or ulcerative), Pancreatitis ,Colitis and Drug-induced liver injury (DILI).

For full prescribing information please contact Sanofi Healthcare India Private Ltd, Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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