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
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.
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. No cases of severe skins reactions have been reported with teriflunomide in the clinical trials. Cases have been reported rarely in the postmarketing setting (including Stevens-Johnson syndrome, and toxic epidermal

necrolysis). In patients treated with leflunomide, the parent compound, very rare cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have also been reported. In case of ulcerative stomatitis, teriflunomide administration should be discontinued. If skin and /or mucosal reactions are observed which raise the suspicion of severe generalised major skin reactions (Stevens-Johnson syndrome, or toxic epidermal necrolysis-Lyell's syndrome), 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 and Stevens-Johnson syndrome, Interstitial Lung Disease (ILD), Stomatitis (such as aphthous or ulcerative), Pancreatitis.

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

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