- Abbreviated Summary of Product Characteristics (SPC)

- AUBAGIO (Teriflunomide) 14 mg film-coated tablets. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. PRODUCT COMPOSITION: Each film-coated tablet contains 14 mg of teriflunomide. Each film-coated tablet contains 72 mg of lactose (as monohydrate). INDICATIONS: AUBAGIO is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS). DOSAGE AND ADMINISTRATION: The treatment should be initiated and supervised by a physician experienced in the management of multiple sclerosis (MS). The recommended dose of teriflunomide is 14 mg once daily. The film-coated tablets are for oral use. The tablets should be swallowed whole with some water. AUBAGIO can be taken with or without food. Elderly population: AUBAGIO should be used with caution in patients aged 65 years and over due to insufficient data on safety and efficacy. Renal impairment: No dosage adjustment is necessary for patients with mild, moderate or severe renal impairment not undergoing dialysis. Hepatic impairment: Teriflunomide is contraindicated in patients with severe hepatic impairment. Paediatric population: The safety and efficacy of AUBAGIO in children aged from 10 to less than 18 years has not yet been established. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Severe hepatic impairment (Child-Pugh class C). Pregnant women, or women of childbearing potential not using reliable contraception during treatment with teriflunomide and thereafter as long as its plasma levels are above 0.02 mg/l. Breast-feeding women. Severe immunodeficiency states, e.g. AIDS, significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia. Severe active infection until resolution. Severe renal impairment undergoing dialysis, because insufficient clinical experience is available in this patient group. Severe hypoproteinaemia, e.g. in nephrotic syndrome. EDUCATIONAL GUIDANCE: Prior to prescribing AUBAGIO, physicians must familiarise themselves with educational materials which consist of a Healthcare Professional Guide, and a Prescriber Checklist and they should provide their patients with an Educational Card and Patient Leaflet. WARNINGS AND PRECAUTIONS: Monitoring: Before starting treatment with teriflunomide the following should be assessed: blood pressure, alanine aminotransferase / serum glutamic pyruvic transaminase (ALT/SGPT), complete blood cell count (CBC) including differential white blood cell and platelet count. Exclude pregnancy. During treatment the following should be monitored: blood pressure, ALT/SGPT. CBC should be performed based on clinical signs and symptoms. Accelerated elimination procedure: Without an accelerated elimination procedure, it takes an average of 8 months to reach plasma concentrations less than 0.02 mg/l, although due to individual variation in substance clearance it may take up to 2 years. An accelerated elimination procedure can be used at any time after discontinuation of teriflunomide (see SmPC). Hepatic effects: Assess liver enzymes before initiation of teriflunomide therapy - every two weeks during the first 6 months of treatment, and every 8 weeks thereafter or as indicated by clinical signs and symptoms. For ALT (SGPT) elevations between 2- and 3-fold the upper limit of normal, monitoring must be performed weekly. Teriflunomide therapy should be discontinued if liver injury is suspected; consider discontinuing teriflunomide therapy if elevated liver enzymes (greater than 3-fold ULN) are confirmed. Blood pressure: Must be checked before the start of teriflunomide treatment and periodically thereafter. Infections: Patients receiving AUBAGIO should be instructed to report symptoms of infections to a physician. Patients with active acute or chronic infections should not start treatment with AUBAGIO until the infection(s) is resolved. For patients testing positive in tuberculosis screening, treat by standard medical practice prior to therapy with AUBAGIO. Respiratory reactions: Due to the potential risk of interstitial lung disease, pulmonary symptoms, such as persistent cough and dyspnoea, may be a reason for discontinuation of the therapy and for further investigation, as appropriate. Haematological effects: Obtain complete blood count (CBC) including differential white blood cell count and platelets prior to initiation of treatment, thereafter CBC should be assessed as indicated by clinical signs and symptoms. Skin reactions: Cases of severe skin reactions have been reported with teriflunomide postmarketing (including Stevens-Johnson syndrome and toxic epidermal necrolysis). In case of ulcerative stomatitis, or if skin and /or mucosal reactions are observed which raise the suspicion of severe generalised major skin reactions, teriflunomide must be discontinued. In case of suspicion of severe generalised major skin reactions an accelerated elimination procedure should be initiated immediately. Peripheral neuropathy: In case of confirmed peripheral neuropathy, consider discontinuing AUBAGIO therapy and

performing the accelerated elimination procedure. Immunosuppressive / Immunomodulating therapies: Co-administration with leflunomide is not recommended. Co-administration with antineoplastic or immunosuppressive therapies has not been evaluated. Concomitantly administered with interferon beta or with glatiramer acetate for up to one year did not reveal any specific safety concerns, but a higher adverse reaction rate as compared to teriflunomide monotherapy was observed. Vaccination: Vaccinations to inactivated neoantigen or recall antigen during AUBAGIO treatment were safe and effective in two studies. Live attenuated vaccines should be avoided. CONCOMITANT USE AND DRUG INTERACTION: Co-administration of teriflunomide with leflunomide is not recommended. Rifampicin and other known potent CYP and transporter inducers, medicinal products metabolised by CYP2C8, oral contraceptives, medicinal products metabolised by CYP1A2, OAT3 substrates, BCRP substrates and OATP substrates should be used with caution during treatment with teriflunomide. For patients receiving teriflunomide treatment with cholestyramine or activated charcoal is not recommended. For co-administration of warfarin with teriflunomide, close INR follow-up and monitoring is recommended. PREGNANCY AND LACTATION: Pregnancy: Women of childbearing potential must use effective contraception during treatment and after treatment as long as teriflunomide plasma concentration is above 0.02 mg/l. In case of suspicion of pregnancy, patient must notify the physician. In case of pregnancy, the physician and patient must discuss the risk to the pregnancy and the accelerated elimination procedure. In women wishing to become pregnant, teriflunomide should be stopped and an accelerated elimination procedure is recommended (see SmPC). Both cholestyramine and activated powdered charcoal may influence the absorption of oestrogens and progestogens during the accelerated elimination procedure. Use of alternative contraceptive methods is recommended. Lactation: Teriflunomide is contraindicated during breast-feeding. UNDESIRABLE EFFECTS: Based on placebo-controlled studies. Very common (≥ 1/10) Headache, diarrhoea, nausea, ALT increase, alopecia. Common (≥ 1/100 to < 1/10); Influenza, upper respiratory tract infection, urinary tract infection, bronchitis, sinusitis, pharyngitis, cystitis, gastroenteritis viral, oral herpes, tooth infection, laryngitis, tinea pedis, neutropenia, anaemia, mild allergic reactions, anxiety, paraesthesia, sciatica, carpal tunnel syndrome, palpitations, hypertension, abdominal pain upper, vomiting, toothache, GGT increase, AST increase, rash, acne, musculoskeletal pain, myalgia, arthralgia, pollakiuria, menorrhagia, pain, weight decrease, neutrophil count decrease, WBC decrease, blood creatine phosphokinase increase. Uncommon (≥ 1/1,000 to < 1/100); Mild thrombocytopenia, hyperaesthesia, neuralgia, peripheral neuropathy, post-traumatic pain. Not known (cannot be estimated from post-marketing data); Severe infections including sepsis, hypersensitivity reactions (immediate or delayed) including anaphylaxis and angioedema, interstitial lung disease, pancreatitis, stomatitis, acute hepatitis, severe skin reactions, nail disorders, asthenia. For further information on warning and precautions, please refer to the full SmPC. LEGAL CLASSIFICATION: POM (Prescription Only Medicine). MARKETING AUTORISATION HOLDER: sanofi-aventis groupe. 54, rue La Boétie. F-75008 Paris. France.

- Please refer to the full text of the SPC.
- This leaflet was last revised in: OCT 2019