Prescribing Information.

Otulfi▼(ustekinumab). This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Ustekinumab 130 mg in 26 mL (5 mg/mL) solution for infusion, 45 mg solution for injection in pre-filled syringe and 90 mg solution for injection in pre-filled syringe. Consult the Summary of Product Characteristics (SmPC) before prescribing. Additional information is available on request. **Presentations and Active Ingredients:** Each vial contains 130 mg ustekinumab in 26 mL (5 mg/mL) and pre-filled syringe contains 45 mg ustekinumab in 0.5 mL and 90 mg ustekinumab in 1 mL. **Indication**: ***Solution for infusion & Pre-filled syringe:*** Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. ***Pre-filled syringe:*** Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A). Treatment of moderate to severe plaque psoriasis in children and adolescent patients ≥6 years, and who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. Treatment of active psoriatic arthritis in adult patients, alone or in combination with MTX, when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate . Treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies. **Posology:** ***Solution for infusion:*** For intravenous administration only, the infusion should be given over at least one hour. Treatment to be initiated with a single intravenous dose based on body weight: *Body weight of patient at the time of dosing: ≤55 kg, recommended dose:* 260 mg (2 vials); *>55 kg to ≤85 kg, recommended dose: 390 mg (3 vials); and >85 kg, recommended dose: 520 mg (4 vials).* First subcutaneous dose to be given at week 8 following the intravenous dose. ***Pre-filled syringe:*** For subcutaneous injection only. *Plaque psoriasis & Psoriatic arthritis (PsA):* Initial dose of 45 mg administered subcutaneously, followed by a 45 mg dose 4 weeks later, and then every 12 weeks thereafter. *≥100 kg*: Initial dose of 90 mg administered subcutaneously, followed by a 90 mg dose 4 weeks later, and then every 12 weeks thereafter. *Paediatric plaque psoriasis (≥6 years):* Week 0 and 4, then every 12 weeks thereafter based on body weight. *≥60 - <100 kg:* 45 mg; *≥100 kg:* 90 mg. Otulfi does not offer weight-based dosing for paediatric patients under 60 kg. Treatment to be discontinued in patients with no response after 28 weeks. *Crohn's Disease:* First dose of Otulfi is administered intravenously. Administer 90 mg of Otulfi subcutaneously at week 8 following the intravenous dose, then every 12 weeks. *Elderly (≥65 years):* No dose adjustment is needed for elderly patients. *Renal and hepatic impairment:* Not been studied in these patient populations. No dose recommendations can be made. *Paediatric population:* The safety and efficacy in children <18 years have not yet been established. Safety and efficacy of ustekinumab in children with psoriasis <6 years of age or in children not yet been established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients *(See SmPC)*. Clinically important, active infection (e.g. active tuberculosis; *see SmPC*). **Warnings and Precautions:** Ustekinumab may increase the risk of infections and reactivate latent infections. Serious bacterial, fungal, and viral infections have been observed in patients with psoriasis receiving ustekinumab in clinical and post-marketing observational study. Opportunistic infections including reactivation of tuberculosis, other opportunistic bacterial infections (including atypical mycobacterial infection, listeria meningitis, pneumonia legionella, and nocardiosis), opportunistic fungal infections, opportunistic viral infections (including encephalitis caused by herpes simplex 2), and parasitic infections (including ocular toxoplasmosis) have been reported in patients treated with ustekinumab. Caution advised when considering the use of Otulfi in patients with a chronic infection or a history of recurrent infection. Before initiating treatment with Otulfi, patients should be evaluated for tuberculosis infection. Otulfi must not be given to patients with active tuberculosis.

Treatment of latent tuberculosis infection should be initiated prior to administering Otulfi. Anti-tuberculosis therapy should also be considered prior to initiation of Otulfi in patients with a history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Otulfi should be monitored closely for signs and symptoms of active tuberculosis during and after treatment. Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and Otulfi should not be administered until the infection resolves. Ustekinumab has the potential to increase the risk of malignancy. The risk of malignancy may be higher in psoriasis patients who have been treated with other biologics during the course of their disease. Caution should be exercised when considering the use of Otulfi in patients with a history of malignancy or patients who develop malignancy while receiving ustekinumab. All patients, especially >60 years of age, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of non-melanoma skin cancer. Serious hypersensitivity reactions, serious infusion-related reactions including anaphylactic reactions to the infusion have been reported. Anaphylaxis and angioedema have occurred. Appropriate therapy should be instituted and Otulfi should be discontinued in case of an anaphylactic or other serious hypersensitivity reaction. Cases of allergic alveolitis, eosinophilic pneumonia, and non-infectious organising pneumonia have been reported. Serious outcomes have included respiratory failure and prolonged hospitalisation. Improvement has been reported after discontinuation of ustekinumab and, in some cases, administration of corticosteroids. If infection has been excluded and diagnosis is confirmed, discontinue ustekinumab and institute appropriate treatment. Cardiovascular events including myocardial infarction and cerebrovascular accident have been observed in patients with psoriasis. Risk factors for cardiovascular disease should be regularly assessed during treatment with Otulfi. Live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin (BCG)) should not be given concurrently with Otulfi. Before live viral or live bacterial vaccination, treatment with Otulfi should be withheld for at least 15 weeks after the last dose and can be resumed at least 2 weeks after vaccination. Patients receiving Otulfi may receive concurrent inactivated or non-live vaccinations. Long term treatment with Otulfi does not suppress the humoral immune response to pneumococcal polysaccharide or tetanus vaccines. Caution should be exercised when considering concomitant use of other immunosuppressants and Otulfi or when transitioning from other immunosuppressive biologics. Ustekinumab has not been evaluated in patients who have undergone allergy immunotherapy. It is not known whether Otulfi may affect allergy immunotherapy. In patients with psoriasis, exfoliative dermatitis has been reported following ustekinumab treatment. As part of the monitoring of the patient's psoriasis, physicians should be alert for symptoms of erythrodermic psoriasis or exfoliative dermatitis. If these symptoms occur, appropriate therapy should be instituted. Otulfi should be discontinued if a drug reaction is suspected. Cases of lupus-related conditions have been reported in patients treated with ustekinumab. Otulfi should be discontinued, and appropriate treatment initiated if diagnosis of a lupus-related condition is confirmed. Caution should be used in treating the elderly (≥65 year) due to higher incidence of infections in this population. Otulfi solution for infusion is diluted in sodium chloride 9 mg/mL (0.9%) solution for infusion. To be taken into consideration for patients on a controlled sodium diet. To improve the traceability of biological medicinal products, the tradename and the batch number of the administered product should be clearly recorded. **Interactions:** Live vaccines should not be given concurrently with Otulfi. No interaction studies have been performed in humans. Pharmacokinetics of ustekinumab was not impacted by concomitant use of MTX, NSAIDs, 6-mercaptopurine, azathioprine and oral corticosteroids in patients with psoriatic arthritis, Crohn's disease, or prior exposure to anti-TNFα agents, in patients with psoriatic arthritis or Crohn's disease. In psoriasis studies, the safety and efficacy of ustekinumab in combination with immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of ustekinumab. In Crohn's disease studies, concomitant use of immunosuppressants or corticosteroids did not appear to influence the safety or efficacy

of ustekinumab. **Pregnancy and lactation:** It is preferable to avoid the use of Otulfi in pregnancy. Ustekinumab crosses the placenta and has been detected in the serum of infants born to female patients treated with ustekinumab during pregnancy. Administration of live vaccines (such as the BCG vaccine) to infants exposed in utero to ustekinumab is not recommended for 6 months following birth or until ustekinumab infant serum levels are undetectable. Ustekinumab is excreted in human breast milk. A decision on whether to discontinue breast-feeding during treatment and up to 15 weeks after treatment or to discontinue therapy with Otulfi must be made considering the benefit of breast-feeding to the child and the benefit of Otulfi therapy to the woman. **Adverse Reactions:** Common ≥ 1/100 to <1/10: Upper respiratory tract infection, nasopharyngitis, sinusitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea and vomiting pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain. Serious hypersensitivity reactions reported (including anaphylaxis, angioedema). Other uncommon and rarely reported adverse reactions are listed in the SmPC. **Pack Sizes:** Pack quantities and costs: 45 mg solution for injection in pre-filled syringe: Pack size 1 (€1513.57); 90 mg solution for injection in pre-filled syringe: Pack size 1 (€1556.21); 130 mg concentrate for solution for infusion: Pack size 1 (€1483.11). **Legal Category:** POM. **Marketing Authorisation Number:** ***Solution for infusion***: EU/1/24/1863/003; ***45 mg solution for injection in pre-filled syringe:*** EU/1/24/1863/001; ***90 mg solution for injection in pre-filled syringe:*** EU/1/24/1863/002. **Marketing Authorisation Holder:** Fresenius Kabi Deutschland GmbH, Else-Kroener-Strasse 1, 61352 Bad Homburg v.d.Hoehe, Germany. **Further Information:** See the SmPC for further details. Job Code: IE-OTU-2500001 | Date of Preparation February 2025

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353-1-6764061. Website: www.hpra.ie , E-mail: medsafety@hpra.ie
Adverse events should also be reported to Fresenius Kabi Ltd. Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT, Tel +44 (0)1928 533 575 or email pharmacovigilance.gb@fresenius-kabi.com