Kynteles® ▼ (vedolizumab 300mg) powder for concentrate for solution for infusion**)** 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**.**

ABBREVIATED PRESCRIBING INFORMATION

Please refer India Package Insert, before prescribing.

Product Name: Vedolizumab 300mg
Active Ingredient: Each vial contains 300 mg of vedolizumab. After reconstitution, each mL contains 60 mg of vedolizumab.
Pharmaceutical Form: Powder for concentrate for solution for infusion. **Indication:** Ulcerative colitis (UC): Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. Crohn's Disease (CD): 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 tumour necrosis factor-alpha (TNFα) antagonist. **Dosage & Administration:** Treatment should be initiated and supervised by a specialist healthcare professional experienced in the diagnosis and treatment of ulcerative colitis or Crohn's disease. Patients should be monitored during and after infusion. Patient should be given the Prescribing Information and the Patient Alert Card. Ulcerative colitis: Recommended dose regimen is 300mg administered by intravenous infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter. Reconsider treatment if no evidence of therapeutic benefit at week 10. If patients experience a decrease in their response, they may benefit from an increased dosage frequency of 300mg every 4 weeks. Corticosteroids may be reduced/discontinued in patients who respond to treatment with Kynteles®. If therapy is interrupted and needs to be restarted, Kynteles® dosing every 4 weeks may be considered. Crohn's disease: Recommended dose regimen is 300mg administered by intravenous infusion over 30 minutes at 0, 2 and 6 weeks and then every 8 weeks thereafter. Patients who have not shown evidence of therapeutic benefit, may benefit from a dose at week 10. Continue therapy every 8 weeks from week 14 in responding patients. Therapy should be discontinued if no evidence of therapeutic benefit is observed at week 14. If therapy is interrupted and needs to be restarted, Kynteles® dosing every 4 weeks may be considered. Paediatric populations: No data is available on the safety and efficacy of Kynteles® in children aged 0-17 years. Elderly patients: No dosage adjustment required. Renal or hepatic impairment: Kynteles® has not been studied in these populations and no dose recommendation can be given. **Contraindications:** Hypersensitivity to Kynteles® or any of the excipients. Active infections such as tuberculosis (TB), sepsis, cytomegalovirus, listeriosis and opportunistic infections such as Progressive Multifocal Leukoencephalopathy (PML). Suspicion of active tuberculosis (TB) **Special Warnings and Precautions for use:** Patients should be observed continuously during infusions for signs/symptoms of hypersensitivity reactions. Patients should continue to be observed for two hours following infusion completion for the first two infusions and one hour for subsequent infusions. Infusion-related reactions (IRR): Hypersensitivity reactions have been reported; the majority were of mild to moderate severity. Discontinue treatment if anaphylaxis or other serious allergic reactions occur and institute appropriate treatment. In mild to moderate IRR, slow or interrupt infusion. Consideration for pre-treatment with antihistamine, hydrocortisone and/or paracetamol should be given prior to next infusion, for patients with history of mild/moderate IRR to Kynteles®. Infections: Kynteles® is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding in patients who develop a severe infection while on treatment with Kynteles®. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Kynteles® treatment. Progressive Multifocal Leukoencephalopathy (PML): No cases were observed in Kynteles® clinical trials, but PML a potential fatal opportunistic infection caused by John Cunningham (JC) virus has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. Monitor patients for any new or worsening neurological signs/symptoms. Malignancy: There is an increased risk of malignancy in UC and CD; immunomodulatory products may increase risk. No increased risk with vedolizumab to date. Long term evaluation on-going. Prior and concurrent use of biological products: No clinical data available for Kynteles® use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should normally wait at least 12 weeks prior to initiating Kynteles® therapy. Kynteles® not recommended for concomitant use with biologic immunosuppressants as no clinical data available. Live and oral vaccines: Patients may continue to receive non-live vaccines. Patients recommended to be up to date with all appropriate immunizations prior to initiating Kynteles®. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically meaningful effect on Kynteles® pharmacokinetics**. Elimination:** Population pharmacokinetic analyses based on intravenous and subcutaneous data indicate that the clearance of vedolizumab is approximately 0. 162 L/day (through linear elimination pathway) and the serum half-life of is 26 days. The exact elimination route of Kynteles® is not known. **Fertility, pregnancy and lactation:** There is limited amount of data from the use of vedolizumab in pregnant women. As a precautionary measure, it is preferable to avoid the use of Kynteles® during pregnancy unless the benefits clearly outweigh any potential risk to both the mother and foetus. Vedolizumab has been detected in human milk. The effect of vedolizumab on infants is unknown. The use of vedolizumab in lactating women should take into account the benefit of therapy to the mother and potential risks to the infant. In a milk-only lactation study assessing the concentration of vedolizumab in breast milk of lactating women with active ulcerative colitis or Crohn's disease receiving vedolizumab, the concentration of vedolizumab in human breast milk was approximately 0.4% to 2.2% of the maternal serum concentration obtained from historical studies of vedolizumab. The estimated average daily dose of vedolizumab ingested by the infant was 0.02 mg/kg/day, (which is approximately 21% of the body weight-adjusted average maternal daily dose) **Effects on ability to drive and use machines:** Kynteles® has minor influence on the ability to drive and use machines, as dizziness has been reported in a small number of patients. **Special population data:** Age does not impact the vedolizumab clearance in ulcerative colitis and Crohn's disease patients based on the population pharmacokinetic analyses. No formal studies have been conducted to examine the effects of either renal or hepatic impairment on the pharmacokinetics of vedolizumab. The safety and efficacy of vedolizumab in children aged 0 to 17 years old have not been established. No data are available. **Undesirable Effects:** Very Common (>1/10): nasopharyngitis, headache, arthralgia. Common (>1/100, <1/10): Pneumonia, Clostridium difficile infection, bronchitis, gastroenteritis, URTI, influenza, sinusitis, pharyngitis, herpes zoster, paraesthesia, hypertension, oropharyngeal pain, nasal congestion, cough, anal abscess, anal fissure, nausea, dyspepsia, constipation, abdominal distension, flatulence, haemorrhoids, rash, pruritus, eczema, erythema, night sweats, acne, muscle spasm, back pain, muscular weakness, fatigue, pain in the extremeity, pyrexia, Infusion related reaction, Infusion site reaction (including:Infusion site pain and Infusion site irritation). Other serious undesirable effects: Respiratory tract infection, Vulvovaginal candidiasis, Oral candidiasis, Blurred vision, Folliculitis, Chills, Feeling cold infusion site reaction, infusion-related reaction. Overdosage/Overdose: Doses up to 10 mg/kg (approximately 2.5 times the recommended dose) have been administered in clinical trials. No dose-limiting toxicity was seen in clinical trials. **the PI for details on full side effect profile and interactions. Pharmacotherapeutic Classification:** Immunosuppressive, Selective Immunosuppressive, ATC-Code: L04AA33.
Imported and Marketed by: Takeda Biopharmaceuticals India Pvt. Ltd., Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E, 3B-3E and 4A-4E, Warehouse No. 1, Sector-76, Hasanpur Darbaripur, Gurugram – 122004, Haryana, India.

Adverse events should be reported to the authorities in your country as required by local law. Adverse events should also be reported to Takeda at AE.India@takeda.com

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