Great Britain Prescribing Information:

Kesimpta®▼(ofatumumab)

Important note: Before prescribing Kesimpta 20 mg solution for injection in pre-filled pen consult Summary of Product Characteristics (SmPC).

Presentation: Solution for injection in pre-filled pen. Each pre-filled pen contains 20 mg ofatumumab in 0.4 ml solution (50 mg/ml). Ofatumumab is a fully human monoclonal antibody produced in a murine cell line (NS0) by recombinant DNA technology.

I**ndication(s)**: Kesimpta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Dosage and administration: Treatment should be initiated by a physician experienced in the management of neurological conditions and the first injection should be performed under the guidance of an appropriately trained healthcare professional. The product is intended for patient self-administration by subcutaneous injection. The recommended dose is 20 mg ofatumumab with initial dosing at weeks 0, 1 and 2, followed by subsequent monthly dosing, starting at week 4. *Paediatric population:* The safety and efficacy of ofatumumab in children aged 0 to 18 years have not yet been established.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Patients in a severely immunocompromised state. Severe active infection until resolution. Known active malignancy.

Warnings/Precautions: *Injection-related reactions:* Patients should be informed that systemic injection-related reactions (SIRRs) could occur, generally within 24 hours and predominantly following the first injection. From clinical studies the most frequently reported symptoms include fever, headache, myalgia, chills, fatigue and were predominantly (99.8%) mild to moderate in severity. There were no life-threatening SIRRs reported in RMS clinical studies. Additional SIRRs reported in the post-marketing setting include rash, urticaria, dyspnoea and angioedema (e.g. tongue, pharyngeal or laryngeal swelling), and rare cases which were reported as anaphylaxis. While there were some cases which were serious and resulted in discontinuation of ofatumumab treatment, there were also serious cases where patients were able to continue ofatumumab treatment without further incidents. Some SIRR symptoms may be clinically indistinguishable from Type 1 acute hypersensitivity reactions (IgE-mediated). A hypersensitivity reaction may present during any injection, although typically would not present with the first injection. For subsequent injections, more severe symptoms than previously experienced, or new severe symptoms, should prompt consideration of a potential hypersensitivity reaction. Patients with known IgE-mediated hypersensitivity to ofatumumab must not be treated with ofatumumab. Injection-related reactions can be managed with symptomatic treatment, use of premedication is not required. Injection site reaction (local) symptoms observed in clinical studies included erythema, swelling, itching and pain. *Infections:* It is recommended to evaluate the patient's immune status prior to initiating therapy. Based on its mode of action and available clinical experience, ofatumumab has the potential for an increased risk of infections. Administration should be delayed in patients with an active infection until the infection is resolved. Since John Cunningham (JC) virus infection resulting in progressive multifocal leukoencephalopathy (PML) has been observed in patients treated with anti-CD20 antibodies, other MS therapies, and ofatumumab at substantially higher doses in oncology indications, physicians should be vigilant for medical history of PML and for any clinical symptoms or MRI findings that may be suggestive of PML. If PML is suspected, treatment with ofatumumab should be suspended until PML has been excluded. Hepatitis B reactivation has occurred in patients treated with anti-CD20 antibodies. Patients with active hepatitis B disease should not be treated with ofatumumab. HBV screening should be performed in all patients before initiation of treatment. Patients with positive hepatitis B serology (either HBsAg or HBcAb) should consult a liver disease expert before the start of treatment. Patients in a severely immunocompromised state must not be treated until the condition resolves. It is not recommended to use other immunosuppressants concomitantly with ofatumumab except corticosteroids for symptomatic treatment of relapses. *Vaccinations:* All immunisations should be administered according to immunisation guidelines at least 4 weeks prior to initiation of ofatumumab for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of ofatumumab for inactivated vaccines. Ofatumumab may interfere with the effectiveness of inactivated vaccines. The safety of immunisation with live or live-attenuated vaccines following ofatumumab therapy has not been studied. Vaccination with live or live-attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion. In infants of mothers treated with ofatumumab during pregnancy live or live-attenuated vaccines should not be administered before the recovery of B-cell counts has been confirmed. Depletion of B cells in these infants may increase the risks from live or live-attenuated vaccines. Inactivated vaccines may be administered as indicated prior to recovery from B-cell depletion.

Interactions: No interaction studies have been performed, as no interactions are expected via cytochrome P450 enzymes, other metabolising enzymes or transporters. The response to vaccination could be impaired when B cells are depleted. The risk of additive immune system effects should be considered when co-administering immunosuppressive therapies with ofatumumab.

Fertility, pregnancy and lactation: Women of childbearing potential should use effective contraception while receiving ofatumumab and for 6 months after the last product administration. There is a limited amount of data from the use of ofatumumab in pregnant women. Treatment with ofatumumab should be avoided during pregnancy unless the potential benefit to the mother outweighs the potential risk to the foetus. The use of ofatumumab in women during lactation has not been studied. It is unknown whether ofatumumab is excreted in human milk. There are no data on the effect of ofatumumab on human fertility.

Undesirable effects: Very common (≥1/10): upper respiratory tract infections, urinary tract infections, injection-site reactions (local), Injection-related reactions (systemic). Common (≥1/100 to <1/10): oral herpes, blood immunoglobulin M decreased. Not known (cannot be estimated from available data): Hypersensitivity reactions.

Legal classification: POM

Marketing Authorisation (MA) number, quantities and price:

PLGB 00101/1201 - unit pack of Kesimpta 20 mg solution for injection in pre-filled pen containing 1 pre-filled pen: £1,492.50.

Date of last revision of prescribing information: May 2024

Full Prescribing Information available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

UK | May 2024 | 447544

Adverse Event Reporting:
Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.report.novartis.com

UK | July 2024 | FA-11229013

Northern Ireland Prescribing Information:

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UK(NI) | July 2024 | FA-11227994

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