NOVARTIS

Regulatory Affairs

KESIMPTA® (ofatumumab)
20 mg Solution for injection in a pre-filled syringe
or pre-filled pen

Basic Succinct Statement (BSS)

Version 2.1

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Kesimpta® 20 mg/0.4 mL solution for injection

Important note: Before prescribing, consult full prescribing information.

Presentation:

20 mg/0.4 mL Solution for injection in a pre-filled syringe

20 mg/0.4 mL Solution for injection in a pre-filled pen

Each pre-filled syringe and pre-filled pen contains 20 mg ofatumumab solution for injection (0.4 mL of 50 mg/mL solution).

Indications:

Kesimpta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS).

Dosage and administration:

Adults: The recommended dose is 20 mg Kesimpta administered by subcutaneous injections with initial dosing at weeks 0, 1 and 2, followed by subsequent monthly dosing, starting at week 4.

Contraindications:

♦History of confirmed hypersensitivity to Kesimpta.

Warnings and precautions:

♦Injection site reaction (local) symptoms observed in clinical studies include erythema, swelling, itching and pain. ♦Systemic injection-related reactions (SIRRs) occurred predominantly with the first injection. Symptoms observed include fever, headache, myalgia, chills and fatigue and were predominantly (99.7%) non-serious and mild to moderate in severity. ♦Additional SIRRs reported in the post-marketing setting include rash, urticaria, dyspnea, angioedema (e.g., tongue, pharyngeal or laryngeal swelling), and rare cases which were reported as anaphylaxis. Most of the cases were non-serious and occurred with first injection. While there were some cases which were serious and resulted in discontinuation of Kesimpta treatment, there were also serious cases where patients were able to continue Kesimpta treatment without further incidents. ♦Some SIRR symptoms may be clinically indistinguishable from Type 1 acute hypersensitivity reactions (IgE-mediated). ♦Inform patients that injection-related reactions generally occur within 24 hours and predominantly following the first injection. SIRRs can be managed with symptomatic treatment, should they occur. ♦A hypersensitivity reaction may present with 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 Kesimpta must not be treated. ♦First injection should be performed under the guidance of an appropriately trained healthcare professional. ♦It is recommended to evaluate the patient's immune status prior to initiating therapy. Kesimpta has the potential for an increased risk of infections. Kesimpta administration should be delayed in patients with active infection until the infection is resolved. ♦Vigilance is advised for clinical symptoms or MRI findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with

Kesimpta should be suspended. ♦Kesimpta treatment should not be initiated in patients with active hepatitis B (HBV) infection until the infection has been adequately treated. Perform HBV screening in all patients before initiation of treatment with Kesimpta. Patients with positive serology should consult liver disease experts before start of treatment. ♦Vaccinations: Administer all required immunizations at least 4 weeks prior to initiation of Kesimpta for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of Kesimpta for inactivated vaccines. Kesimpta may interfere with the effectiveness of inactivated vaccines. Administering live or live-attenuated vaccines to neonates and infants exposed to ofatumumab in utero should be avoided until B-cell recovery occurs.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: There are no or limited amount of data from the use of Kesimpta in pregnant women. Ofatumumab may cause fetal B-cell depletion.

Lactation: Published data suggest that antibodies in breast milk do not enter the neonatal and infant circulations in substantial amounts. The potential for absorption of ofatumumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Kesimpta and any potential adverse effects on the breast-fed infant from Kesimpta.

Females and males of reproductive potential: Women of childbearing potential should use effective contraception while receiving Kesimpta and for 6 months after the last treatment of Kesimpta.

Adverse drug reactions:

- ***Very common (≥10%)****:* upper respiratory tract infections, injection site reactions (local) injection-related reactions (systemic).
- ***Common (≥1 to <10%)***: immunoglobulin M decreased.
- ***Unknown:*** hypersensitivity reaction.

Interactions:

The risk of additive immune system effects should be considered when coadministering immune-modulating or immunosuppressive therapies with Kesimpta. When switching from drugs with prolonged immune effects, such as ocrelizumab, cladribine, fingolimod, natalizumab, teriflunomide, mitoxantrone or dimethyl fumarate, the duration and mode of action of these drugs should be considered because of potential additive immunosuppressive effects when initiating Kesimpta.

Packs and prices: Country-specific.

Legal classification: Country-specific.

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