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KESIMPTA - Home - HCP

Prescribing information

Image

Image

KESIMPTA®▼ (ofatumumab)

KESIMPTA is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis with active disease defined by clinical or imaging features.[1]

Efficacy profile you can trust[1-3]

KESIMPTA is a subcutaneous B-cell therapy with an established long-term efficacy and safety profile (up to 6 years)[1-3]

Image

At Year 6, 90% of KESIMPTA-treated patients achieved NEDA-3*†[2]

NEDA-3 (post-hoc analysis) at Year 6. Continuous KESIMPTA: 91.9% of patients achieved NEDA-3 (n=655). Teriflunomide–KESIMPTA: 91.2% of patients achieved NEDA-3 (n=599); p=0.599 (nominal p value).[2]

KESIMPTA met the primary endpoint in ASCLEPIOS I/II, with up to 58% reduction in ARR vs teriflunomide (ASCLEPIOS I: 51% [0.11 vs 0.22]; RR: 0.49, ASCLEPIOS II: 58% [0.10 vs 0.25]; RR: 0.42; both p<0.001).[3]

Image

KESIMPTA demonstrated a generally well-tolerated safety profile, and mean IgG and IgM levels remained above the LLN in the majority of patients (93% and 66%, respectively) for up to 6 years[1–3]

Post-hoc analysis showed that mean IgM levels decreased but remained above the LLN in 65.9% of the patients for up to 6 years.[2]

KESIMPTA was associated with a transient decrease of 4.3% in mean IgG levels after 48 weeks of treatment but an increase of 2.2% after 96 weeks.[1] Mean serum IgG levels remained stable for up to 6 years of treatment and the majority of patients (97.2%) had IgG levels above the LLN.[2] In the Phase III clinical studies, a decrease in mean value of IgM (30.9% decrease after 48 weeks and 38.8% decrease after 96 weeks) was observed and no association with risk of infections, including serious infections, was shown.[1]

The most important and frequently reported adverse reactions are upper respiratory tract infections (39.4%), systemic injection-related reactions (20.6%), injection-site reactions (10.9%) and urinary tract infections (11.9%).[1]

Image

Following the initial dosing period, KESIMPTA offers 1 minute-a-month self-administration (after preparation), at home or on the go, giving patients the independence to administer their treatment in an appropriate environment of their choice‡1,4

KESIMPTA is intended for patient self-administration, with initial guidance from an appropriately trained HCP.[1]

The flexibility to self-administer without the need for ongoing HCP involvement means dosing can occur at home or elsewhere appropriate outside the hospital setting.

‘1 minute a month’ refers to the time it takes for a patient to inject a full dose of KESIMPTA; based on stability data.[4]

Here you can find a range of information about KESIMPTA, including:

Image

Efficacy outcomes

Image

Safety profile

Image

Downloadable resources

What is KESIMPTA?

KESIMPTA is indicated for adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. KESIMPTA is a self-administered once-monthly (20 mg) subcutaneous (SC) B-cell therapy for RMS.[1]

The recommended dose is 20 mg KESIMPTA administered by subcutaneous injection with:[1]

- initial dosing at Weeks 0, 1 and 2, followed by
- subsequent monthly dosing, starting at Week 4

The first injection should be performed under the guidance of a healthcare professional.[1]

It is an anti-CD20 monoclonal antibody that selectively binds to sites on CD20 molecules expressed on B-cells. KESIMPTA mechanism of action results in lysis of CD20-expressing cells leading to a depletion of B cells.[1]

Please refer to the KESIMPTA Summary of Product Characteristics (SmPC) for further information.[1]

What are the benefits of KESIMPTA?

- **Efficacy:** KESIMPTA has demonstrated efficacy in ASCLEPIOS I and II (2-year core studies), two Phase III randomised, double-blind, double-dummy, active comparator-controlled, parallel-group, multicentre pivotal trials, comparing a range of outcomes to active comparator teriflunomide in 1882 patients with relapsing MS, following patients for up to 6 years (including the 4-year extension phase, ALITHIOS study).[1-3] ALITHIOS

is an ongoing, open-label, single-arm, umbrella-extension, Phase IIIb study assessing the risk–benefit profile of KESIMPTA (20 mg subcutaneously every 4 weeks) and its tolerability in patients with RMS. The study enrolled 1703 patients with RMS from the APLIOS, APOLITOS and ASCLEPIOS I/II trials who continued KESIMPTA treatment.[2,5] The primary endpoint, annualised relapse rate, was defined as the number of confirmed relapses of multiple sclerosis per year, according to pre-specified criteria. Secondary endpoints included disability worsening confirmed at 3 months and 6 months, disability improvement confirmed at 6 months, the number of gadolinium-enhancing lesions per T1-weighted magnetic resonance imaging (MRI) scan, the annualised rate of new or enlarging lesions on T2-weighted MRI, serum neurofilament light chain levels at Month 3, and change in brain volume[3]

    - KESIMPTA met the primary endpoint in ASCLEPIOS I/II, with up to 58% reduction in ARR vs teriflunomide (ASCLEPIOS I: 51% [0.11 vs 0.22]; RR: 0.49 [95% CI: 0.37–0.65]; ASCLEPIOS II: 58% [0.10 vs 0.25]; RR: 0.42 [95% CI: 0.31–0.56]; both $p<0.001$)[3]

    - At Year 6, KESIMPTA reduced the ARR to an equivalent of one relapse every 18.5 patient-years. ARR data at Year 6 – continuous KESIMPTA: ARR: 0.054 (95% CI: 0.041–0.071) [n=690]; teriflunomide–switch to KESIMPTA: ARR: 0.060 (95% CI: 0.046–0.079) [n=677]; p=0.416 (nominal p value)[§2]

    - At Year 6, 90% of KESIMPTA-treated patients achieved NEDA-3.[†] NEDA-3[†] (post-hoc analysis) at Year 6 – continuous KESIMPTA: 91.9% of patients achieved NEDA-3 (n=655); teriflunomide–KESIMPTA: 91.2% of patients achieved NEDA-3 (n=599); p=0.599 (nominal p value)[2]

- **Safety profile:** Across the pooled analysis of ASCLEPIOS clinical trials, ofatumumab exhibited a comparable safety profile to teriflunomide.[1] In the ALITHIOS open-label extension, KESIMPTA's safety profile remained consistent over 6 years and no unexpected safety signals were observed.[2] Please refer to the KESIMPTA safety profile for more information

- **Self-administration:** Following the initial dosing period, KESIMPTA offers 1 minute-a-month self-administration (after preparation), at home or on the go, giving patients the independence to administer their treatment in an appropriate environment of their choice.[‡1,4] KESIMPTA is intended for self-administration, with initial guidance from an appropriately trained HCP.[1] The flexibility to self-administer without the need for HCP involvement means dosing can occur at home or elsewhere appropriate outside the hospital setting. ‘1 minute a month’ refers to the time it takes for a patient to inject a full dose of KESIMPTA; based on stability data[4]

What are the key considerations before prescribing KESIMPTA?

Contraindications[1]

- Hypersensitivity to the active substance or to any of the excipients listed in the KESIMPTA SmPC
- Patients in a severely immunocompromised state
- Severe active infection until resolution
- Known active malignancy

Special warnings and precautions for use[1]

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Injection-related reactions

Patients should be informed that injection-related reactions (systemic) could occur, generally within 24 hours and predominantly following the first injection. Only limited benefit of premedication with steroids was seen in RMS clinical studies. Injection-related reactions can be managed with symptomatic treatment, should they occur. Therefore, use of premedication is not required.

Injection site reaction (local) symptoms observed in clinical studies included erythema, swelling, itching and pain.

The first injection should be performed under the guidance of an appropriately trained healthcare professional.

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, KESIMPTA has the potential for an increased risk of infections.

Administration should be delayed in patients with an active infection until the infection is resolved.

KESIMPTA must not be given to patients in a severely immunocompromised state (e.g. significant neutropenia or lymphopenia).

Progressive multifocal leukoencephalopathy

Since John Cunningham virus infection resulting in progressive multifocal leukoencephalopathy (PML) has been observed in patients treated with anti-CD20 antibodies, other MS therapies, and KESIMPTA 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 KESIMPTA should be suspended until PML has been excluded.

Hepatitis B virus reactivation

Hepatitis B reactivation has occurred in patients treated with anti-CD20 antibodies, which in some cases resulted in fulminant hepatitis, hepatic failure and death.

Patients with active hepatitis B disease should not be treated with KESIMPTA. HBV screening should be performed in all patients before initiation of treatment. As a minimum, screening should include hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) testing. These can be complemented with other appropriate markers as per local guidelines. Patients with positive hepatitis B serology (either HBsAg or HBcAb) should consult a liver disease expert before the start of treatment and should be monitored and managed following local medical standards to prevent hepatitis B reactivation.

Treatment of severely immunocompromised patients

Patients in a severely immunocompromised state must not be treated until the condition resolves.

It is not recommended to use other immunosuppressants concomitantly with KESIMPTA 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 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.

The safety of immunisation with live or live-attenuated vaccines following KESIMPTA therapy has not been studied. Vaccination with live or live-attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion. The median time to B-cell recovery to the lower limit of normal (LLN, defined as 40 cells/l) or baseline value is 24.6 weeks post treatment discontinuation based on data from Phase III studies.

Vaccinations of infants born to mothers treated with KESIMPTA during pregnancy

In infants of mothers treated with KESIMPTA 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; however, assessment of vaccine immune responses, including consultation with a qualified specialist, should be considered to determine whether a protective immune response was mounted.

Sodium content

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

Please refer to KESIMPTA Prescribing Information and SmPC for further information.

What are the recommendations from the National Institute for Health and CareExcellence (NICE) and Scottish Medicines Consortium (SMC)?

NICE recommendations:[6]

In England, Wales and Northern Ireland, KESIMPTA is now reimbursed following NICE Technology Appraisal Guidance recommending KESIMPTA as a treatment option for adults with relapsing-remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features. This is only if the company provides KESIMPTA according to the commercial arrangement.

This recommendation is not intended to affect treatment with KESIMPTA that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

SMC advice: following a full submission[7]

KESIMPTA is accepted for restricted use within NHSScotland.

Indication under review: treatment of adult patients with RMS with active disease defined by clinical or imaging features.

SMC restriction: treatment of RRMS with active disease defined by clinical or imaging features.

Two Phase III studies demonstrated superiority of ofatumumab in reducing annualised relapse rate when compared with another disease-modifying treatment (DMT) in adult patients with RMS.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.

*ASCLEPIOS I and II were two Phase III, randomised, double-blind, double-dummy, active comparator-controlled, parallel-group, multicentre pivotal trials.[3] ALITHIOS is an ongoing, open-label, single-arm, umbrella-extension, Phase IIIb study assessing the risk–benefit profile of KESIMPTA (20 mg subcutaneously every 4 weeks) and its tolerability in patients with RMS. The study enrolled 1703 patients with RMS from the APLIOS, APOLITOS and ASCLEPIOS I/II trials who continued KESIMPTA treatment.[5]
[†]NEDA-3 is defined as no 6-month confirmed disability worsening, no confirmed MS relapse, no new or enlarging T2 lesions and no T1 Gd+ lesions.[2]
[‡]Patient must take the pen out of the refrigerator about 15–30 minutes before self-administration to allow it to reach room temperature. Additional time is required to prepare the pen and cleanse. Store in a refrigerator (2°C–8°C). Do not freeze. If necessary, KESIMPTA may be stored unrefrigerated for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, KESIMPTA can then be returned to the refrigerator for a maximum of 7 days. Please refer to the SmPC for full administration details.[1]
[§]ARR was defined as the number of confirmed MS relapses per year, according to prespecified criteria. Confirmed relapses are those accompanied by a clinically relevant change in EDSS.[3]

ARR, annualised relapse rate; CD20, cluster of differentiation 20; CI, confidence interval; DMT, disease-modifying treatment; EDSS, expanded disability status scale; GD, gadolinium; HBV, hepatitis B virus; HCP, healthcare professional; IgG, immunoglobulin G; IgM, immunoglobulin M; LLN, lower limit of normal; MRI, magnetic resonance imaging; MS, multiple sclerosis; NEDA-3, no evidence of disease activity-3; NICE, National Institute for Health and Care Excellence; OR, odds ratio; PAS, patient access scheme; RMS, relapsing forms of multiple sclerosis; RR, rate ratio; RRMS, relapsing-remitting multiple sclerosis; SC, subcutaneous; SMC, Scottish Medicines Consortium; SmPC, summary of product characteristics.

References

1. KESIMPTA (ofatumumab) Summary of Product Characteristics.

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6. National Institute for Health and Care Excellence 2021. Ofatumumab for treating relapsing multiple sclerosis (NICE guideline 699). Available at: https://www.nice.org.uk/guidance/ta699 [Accessed January 2025].

7. Scottish Medicines Consortium 2022. Advice following a full submission ofatumumab (Kesimpta®) is accepted for restricted use within NHS Scotland. Available at: https://scottishmedicines.org.uk/media/6108/ofatumumab-kesimpta-final-june-2021-for-website.pdf [Accessed January 2025].

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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 online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

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