DOSING AND ADMINISTRATION GUIDE

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]

POSOLOGY

The recommended dose of KESIMPTA is 20 mg administered by subcutaneous injection with initial dosing at Weeks 0, 1 and 2, followed by monthly dosing starting at Week 4.[1]

KESIMPTA is intended for patient self-administration with initial guidance of an appropriately trained healthcare professional.[1]

WHEN TO INJECT[1]

Starting doses
Week

0 ✓ 1 ✓ 2 ✓ 3 ✗ Skip

Monthly dosing
Starting at Week 4

4 ↻ Take on the same date every month

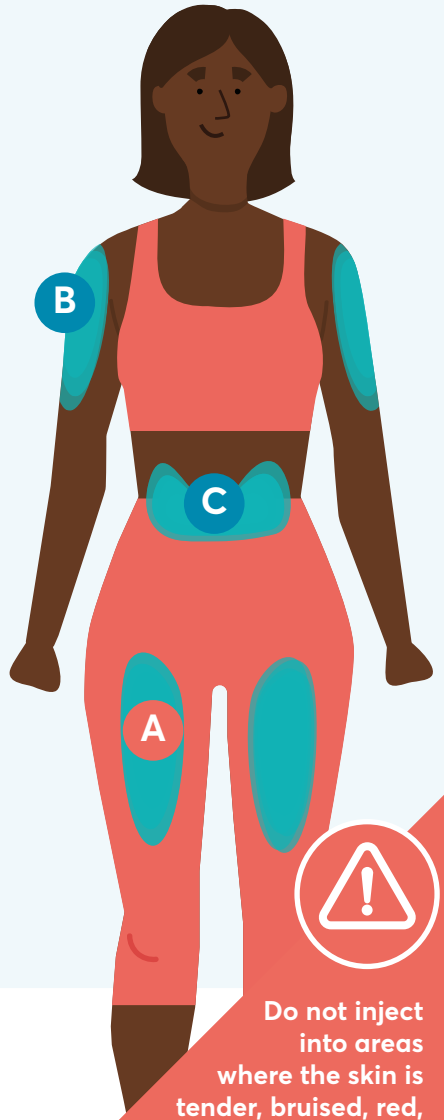
WHERE TO INJECT

- **A** **Front of thigh (preferred site)**
- **B** **Upper arm** (patients should not self-administer via this site)
- **C** **Lower abdomen** (except the area 5 cm around the navel)

Note, a different site should be used for each injection.[2]

MANAGING MISSED DOSES

If an injection is missed, it should be administered as soon as possible without waiting until the next scheduled dose. Subsequent doses should be administered at the recommended intervals.[1]



Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars, stretch marks or infection sites[2]

Please refer to the Summary of Product Characteristics (SmPC) for full information on dosing and administration.

Scan or click the QR code for Prescribing Information

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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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Kesimpta® ofatumumab

KESIMPTA PEN

Concealed 29 gauge (0.33 mm) needle[3]
Press against the skin to start[2]

Viewing window[2]
Green indicator window confirms the dose has been administered fully

Audible clicks[2]
Signal when the administration has started and when it has almost finished

20 mg/0.4 mL formulation[1]

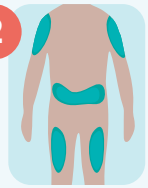
HOW TO STORE

- Keep the KESIMPTA pen in its outer carton in order to protect from light[1]
- Store in the refrigerator between 2°C and 8°C. Do not freeze[1]
- 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[1]
- Keep this medicine out of the sight and reach of children[2]
- KESIMPTA pre-filled pens are for single use only[2]

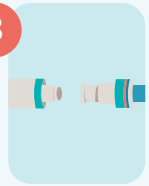
HOW TO USE

1 

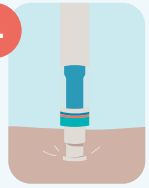
Take the pen out of the fridge 15 to 30 minutes before injection to allow it to reach room temperature.[2] **Do not use if the liquid has visible particles or is cloudy.** The liquid should be clear to slightly opalescent and colourless to slightly brownish-yellow. You may see a small air bubble, which is normal. **Do not use if the pen has expired.**[2]

2 

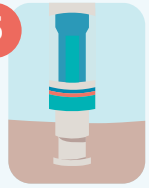
Pick and clean your injection site. Wash your hands with soap and water. Using a circular motion, clean the injection site with the alcohol wipe. Let it dry completely. Do not touch the injection site again before injecting.[2]

3 

Remove the cap and throw it away. Twist off the cap in the direction of the arrow. Don't try to reattach it. Make sure you **use the pen within 5 minutes** of removing the cap and do not shake. You may see a few drops of medicine come out of the needle. This is normal.[2]

4 

Hold the pen at a 90° angle to the cleaned injection site, **press down** to activate the pen and **hold**. You will hear the first click and the green indicator will start moving.[2] When the injection is almost complete, a second click will occur.

5 

The green indicator will be full when the injection is complete. If there is blood at the injection site, press down with cotton/gauze – do not rub.[2] The injection site may be covered with a small adhesive plaster, if the bleeding continues. If the green indicator does not fill the window, the full dose may not have been administered.[2]

Dispose of the pen in a sharps disposal container.[2]
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.[1]

DOSING IN SPECIAL POPULATIONS

Adults over 55 years old
No studies have been performed in multiple sclerosis patients over 55 years old. Based on the limited data available, no dose adjustment is considered necessary in patients over 55 years old.[1]

Renal/hepatic impairment
Patients with renal or hepatic impairment are not expected to require dose modification.[1]

Paediatric population
The safety and efficacy of KESIMPTA in children aged 0 to 18 years have not been established. No data are available.[1]

Please refer to the SmPC for full information on dosing and administration.

KESIMPTA is contraindicated in patients with hypersensitivity to the active substance or any of the excipients listed in the SmPC, patients in a severely immunocompromised state, patients with severe active infection until resolution and those with known active malignancy.[1]

SmPC, summary of product characteristics.

References:
1. KESIMPTA (ofatumumab) Summary of Product Characteristics; 2. KESIMPTA (ofatumumab) Patient Information Leaflet; 3. Novartis Data on File. Ofatumumab (OFA22). June 2024.