Kesimpta® (ofatumumab)

KESIMPTA® (ofatumumab) pen

Healthcare Professional Instructions

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[1]

Scan or click (if viewing digitally) the QR code to view the Prescribing Information

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.

Demonstration kit

This leaflet has been developed and funded by Novartis Pharmaceuticals UK Limited.
This leaflet is intended for UK healthcare professionals only. It must not be given to patients.
This booklet does not replace the Patient Information Leaflet (PIL) that comes with the medication.
Patients should be advised to read the PIL carefully before using the medication.

KESIMPTA Pen Support

This booklet contains a step-by-step guide to help you support your patients with using the KESIMPTA pen.

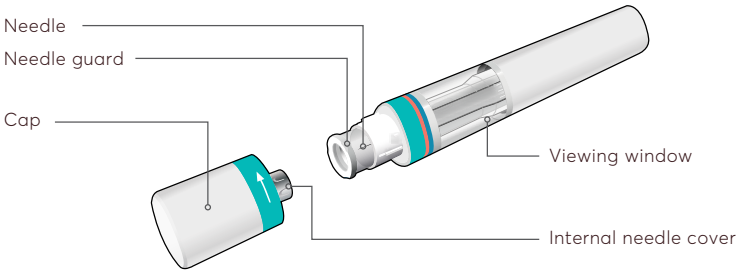
It also includes instructions on using and resetting the demonstration device.

KESIMPTA is intended for patient self-administration by subcutaneous injection with initial healthcare professional guidance.

For full information on Kesimpta, please refer to the Summary of Product Characteristics.

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

Getting to know the KESIMPTA pen



The KESIMPTA pen is shown with the cap removed.

The cap should not be removed until the patient is ready to inject.[1,2]

- They should store the pen carton in a refrigerator between 2°C and 8°C. If necessary, Kesimpta can be left out of the refrigerator 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.[1,2]
- The pen should not be used if either the seal on the outer carton or the seal on the pen is broken. Ensure the patient keeps the pen in the sealed outer carton until ready to use.[1,2]
- **KESIMPTA should be kept out of the sight and reach of children.**[2]

The pen should not be shaken.[2]

The pen should not be frozen.[1,2]

If the pen is dropped, the patient should not not use it if it looks damaged, or if it was dropped with the cap removed.[2]

What's included in this pack?[2]

1 x KESIMPTA demonstration pen

What's not included in this pack?[2]

Alcohol wipe

Cotton ball or gauze

Sharps disposal container

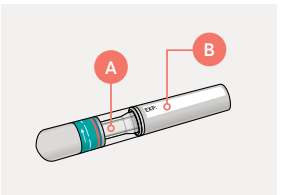
This is a demonstration pen only. Does not contain medication or needle.

Using the KESIMPTA pen

Before injection

01 Important safety checks

The pen should be taken out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.[1,2]

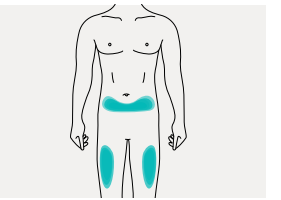


A. When they look through the viewing window, the liquid should be clear to slightly opalescent. Its colour may vary from colourless to slightly brownish-yellow. The pen should **not** be used if the liquid contains visible particles or is cloudy. They may see a small air bubble, which is normal[1,2]

B. The pen should **not** be used if the pen if the **expiry date** has passed (it can be found on the carton and label after EXP. The expiry date refers to the last day of that month)[2]

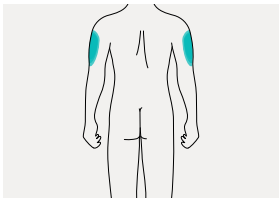
The patient should contact their pharmacist or healthcare professional if the pen fails any of these checks.

02A Choosing the injection site



- The recommended site is the front of the thighs. The patient may also use the lower stomach area (lower abdomen), but not the area 5 centimetres around the navel (belly button)[2]
- A different site should be chosen each time an injection is given[2]
- Areas where the skin is tender, bruised, red, scaly or hard **should not** be injected into. Areas with scars, stretch marks or infection sites should be avoided [2]
- The patient should be given the '**Getting to know KESIMPTA**' patient information leaflet on commencing treatment, which contains a treatment diary to help them track where they have injected

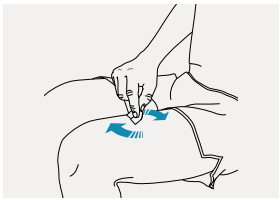
02B Healthcare professionals and caregivers only



- The upper outer arm can also be used as an injection site if administered by a **healthcare professional or caregiver**[2]

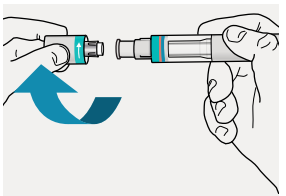
The injection

03 Cleaning the injection site



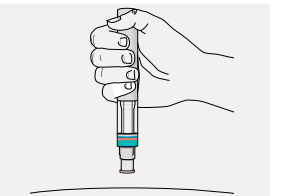
- Patients and carers should be advised to wash their hands with soap and water before injecting[2]
- They should use circular motion, the injection site should be cleaned with the alcohol wipe and left to dry before injecting[2]
- They should ensure the cleaned area is not touched again before injecting[2]

04 Removing the cap

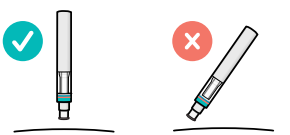


- The cap should only be removed when ready to use the pen[1,2]
- The cap should be twisted off in the direction of the arrow[2]
- Once removed, the cap can be thrown away. The patient should **not try to re-attach the cap**[2]
- The pen should be used within 5 minutes of removing the cap[2]
- The patient may see a few drops of medicine come out of the needle. This is normal[2]

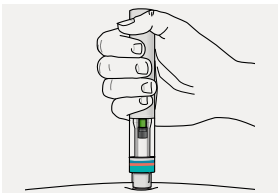
05 Holding the pen



- The pen should be held at 90 degrees to the cleaned injection site[2]



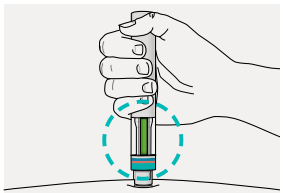
06 Starting the injection



The pen can then be pressed firmly against the skin to start the injection.[2]

- **The first click** indicates the injection has started[2]
- The pen should be **kept held** firmly against the skin[2]
- **The green indicator** shows the progress of the injection[2]

07 Completing the injection



- The patient must listen for the **second click.** This indicates the injection is **almost** complete[2]
- The **green indicator** should be checked to ensure it fills the window and has stopped moving[2]
- The patient can now remove the pen[2]

Key points:[2]

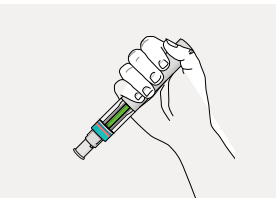
During the injection, the patient will hear two loud clicks.

The **first click** indicates that the injection has started. The **second click** will indicate that the injection is almost finished.

Keep holding the pen firmly against the skin until a green indicator fills the window and stops moving.

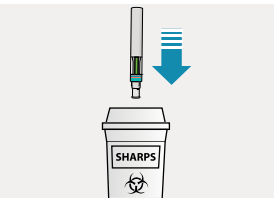
After injection

08 Checking the green indicator fills the window



- This means the medicine has been delivered[2]
- If the green indicator does not fill the window, the full dose has not been administered. The patient should be advised to contact their doctor or pharmacist[2]
- The patient or carer should be advised that there may be a small amount of blood at the injection site. They can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Ensure the patient does not rub the injection site. The site can be covered with a small adhesive plaster, if the bleeding continues[2]

09 Disposing of the KESIMPTA pen



- The patient or carer should be advised to dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar)[2]
- Ensure the patient or carer does not try to reuse the pen[2]
- The sharps container should be kept out of the reach of children

Using and resetting the demonstration device

Please use the enclosed training pen to demonstrate how to use the KESIMPTA pen.
Please remember to reset it before every demonstration.

01

Remove the cap, and keep it close. You'll need it to reset the demonstration pen for the next use.

02

Press down to activate the device. You'll hear the first click and the green indicator will start moving.

03

Hold and watch, on average, 3–4 seconds.

04

Listen for a second click, and check that the green indicator has stopped.

05

Replace the cap to reset the demonstration pen.

Notes

Notes

Some medicines are subject to additional monitoring. KESIMPTA is one of these medicines. This additional monitoring will allow quick identification of new safety information.

References:
1. KESIMPTA (ofatumumab) Summary of Product Characteristics.
2. KESIMPTA (ofatumumab) Patient Information Leaflet. KESIMPTA 20 mg solution for injection in pre-filled pen.

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