Bristol Myers Squibb™

IMPORTANT INFORMATION

FOR HEALTHCARE PROFESSIONALS AND PATIENTS

December 2021

Orencia® (abatacept) 125 mg/mL ClickJect Pen: Supply Issue

Dear Healthcare Professional,

Bristol Myers-Squibb (BMS) in agreement with the Medicines & Healthcare products Regulatory Agency (MHRA) would like to inform you of the following. The recommendations have been agreed with the Department of Health & Social Care (DHSC).

Summary

- We are currently experiencing a shortage of Orencia® (abatacept) 125 mg/mL ClickJect Pens in the UK. The constrained supply situation only applies to the ClickJect Pen formulation and does not affect the supply of the 125 mg/mL Pre-Filled Subcutaneous (SC) Syringes or the 250 mg Powder for intravenous (IV) Infusion.

- All new adult patients should be prescribed the 125 mg/mL Pre-Filled Subcutaneous Syringe formulation until advised otherwise.

- Although the IV Infusion formulation is also an alternative, it requires specialist administration once a month.

- Existing patients using ClickJect Pen should be reviewed and switched to the 125 mg/mL Pre-Filled Subcutaneous Syringe formulation unless they are deemed unsuitable. Training materials are provided below for patients administering at home.

- We anticipate stock levels of the ClickJect Pens to return to normal levels by March 2022.

Management of the Supply Shortage

If actions below are taken immediately, this will reduce the supply shortage impact

1. All **new** patients are prescribed the 125 mg/mL Pre-Filled Subcutaneous Syringe formulation until advised otherwise.

Bristol-Myers Squibb Pharmaceuticals Limited
Uxbridge Business Park
Sanderson Road
Uxbridge, Middlesex
UB8 1DH United Kingdom
bms.com/gb
Office +44 (0)1895 523000
Fax +44 (0)1895 523010
Medical Information 0800 731 1736
medical.information@bms.com

2. All **existing** ClickJect Pen patients are reviewed & switched to the 125 mg/mL Pre-Filled Subcutaneous Syringe formulation unless they are deemed unsuitable.
3. If patients are receiving their ClickJect Pens via a BMS Funded Homecare Service, a **new prescription** for the Pre-Filled Subcutaneous Syringe (PFS) formulation should be sent to their Homecare provider.
    a. We would like to request that the new prescription be **3 months** in validity with patients being switched back to the Clickject presentation from-March 2022.
    b. Homecare providers will monitor the proportion of patient switches and report these to Commercial Medicines Unit, DHSC and BMS on a regular basis.
    c. Patients will be informed about the change of presentation by the Homecare provider before their next delivery. Patient administration training materials will also be provided to patients before their next delivery.
    d. Current valid prescriptions for Orencia® ClickJect on the Homecare provider systems will be cancelled when a new prescription for the PFS is received.
    e. Patients will continue to receive Orencia® ClickJect until a new prescription is received.

We anticipate stock levels of the ClickJect Pens to return to normal levels by March 2022.

Please do not delay reviewing all patients to identify who are able to switch with immediate effect.

BMS is working to manage existing stocks of the ClickJect Pens to minimise the effects of this situation. There is sufficient supply of the SC Pre-Filled Syringes and IV formulations to allow for new patient initiations and continued therapy for ongoing patients.

Important Instructions for Use

ORENCIA® Pre-Filled SC Syringes still allow patients to self-inject at home once they are trained. BMS have produced a patient information video (link below), which instructs patients on how to use the Pre-Filled Syringe. This will help to reassure any patient that is affected, as they change to the Pre-Filled Syringe.

Link to training video - www.bms-optimal.co.uk

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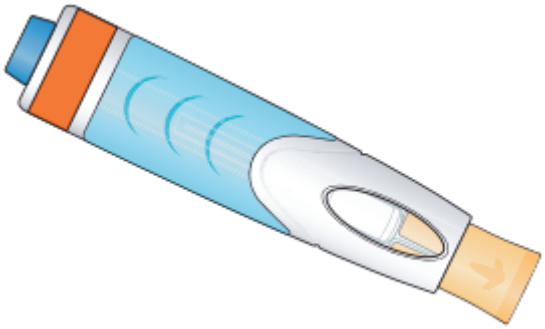
Images of (United Kingdom) Orencia® 125 mg/mL ClickJect and 125 mg/mL Pre-Filled SC Syringe:

Orencia® 125 mg/mL ClickJect



Orencia® 125 mg/mL Pre-Filled SC Syringe

ORENCIA® Powder for IV Infusion formulation is also an alternative, however it requires specialist administration. This would require patients to be infused once a month.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Supply cannot be guaranteed until March 2022. We will inform healthcare professionals of further developments.

Further Information

For further information on abatacept, please refer to the approved product information available at:

Great Britain
https://www.medicines.org.uk/emc/search?q=orencia

Northern Ireland
https://www.emcmedicines.com/en-gb/northernireland/medicines?search=orencia

Call for Reporting

Reporting suspected adverse reactions after authorisation of a medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

Please report suspected adverse drug reactions (ADRs) or suspected defective medicines to the MHRA through the Yellow Card Scheme.

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You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9 am and 5 pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Company Contact Point

If you have any medical questions in relation to abatacept, please contact the BMS Medical Information department at 0800 731 1736 or via email at medical.information@bms.com.

Yours Sincerely,

Dr H Fathi

Dr Hosnieh Fathi – MD, EMBA, FFPM
UK/IE Disease Area Head for Innovative Medicines

Job Code: 427-GB-2100118
DOP: 13/12/21

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