13th December 2024

Direct Healthcare Professional Communication (DHPC)

This information is applicable to Healthcare Professionals based in Northern Ireland only

Ocrevus® (ocrelizumab) 920 mg solution for injection: Significant update to premedication administration timing for patients on subcutaneous ocrelizumab in Northern Ireland (NI) to align with the UK Summary of Product Characteristics (SmPC) from 1st January 2025, as a result of the Windsor Framework Agreement.

Dear Healthcare Professional,

Roche Products Ltd, the marketing authorisation holder of **Ocrevus 920 mg solution for injection**, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the updates that will be made to the NI SmPC and Patient Information Leaflet (PIL) to align with the rest of the UK, as a result of the Windsor Framework Agreement.

UPDATE TO OCREVUS SmPC - 4.2 POSOLOGY & METHOD OF ADMINISTRATION

From January 1, 2025, the newly implemented UK-wide licence for **Ocrevus 920 mg solution for injection** will align with the current GB licence. Consequently, the timing of the premedications as set out in section '4.2 Posology and method of administration', will change in NI.

Current wording:
*The following two premedications are to be administered **shortly before** each ocrelizumab injection to reduce the risk of local and systemic injection reactions (IRs).*

- *20 mg oral dexamethasone (or equivalent)*
- *Oral antihistamine (e.g. desloratadine or equivalent)*

Wording from January 1 2025:
*The following two premedications are to be administered **approximately 30 minutes** before each ocrelizumab injection to reduce the risk of local and systemic injection reactions (IRs):*
- *20 mg oral dexamethasone (or equivalent)*
- *Oral antihistamine (e.g. desloratadine or equivalent)*

UPDATE TO OCREVUS PATIENT INFORMATION LEAFLET (PIL) – Section 4 'Possible Side Effects'

In addition, healthcare professionals should be aware of the following change in the PIL for patients located in NI, to align with the GB wording:

In Section 4 'Possible Side Effects', the following symptom has been removed from the list of signs/symptoms of an injection reaction that patients are directed to tell their doctor or nurse about straight away:

- 'Pain or swelling at the injection site'

ACTIONS REQUIRED

From January 1 2025, healthcare professionals are required to adhere to the new licence requirements regarding premedications and adapt their clinical practice accordingly. Responsible healthcare professionals will need to review and update their administration protocols and local guidance in accordance with this change.

Healthcare professionals should also review the change to the PIL and inform their patients of the change as they see fit.

The SmPC can be found at https://www.medicines.org.uk/emc/product/15824/smpc
The PIL can be found at: https://www.medicines.org.uk/emc/product/15824/pil#about-medicine

BACKGROUND

Ocrevus® (ocrelizumab) 920 mg solution for injection is used for treatment of adult patients with:

- relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features
- early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity

As of January 1, 2025, all existing PLGB licences (i.e., product licences that cover Great Britain (GB) only), will automatically cover the entire UK under the Human Medicine Regulations (HMR 2012 as amended). As a result, the Northern Ireland (NI) SmPC and PIL will become redundant. All new medicines licensed in NI, as well as medicines in NI that currently fall under the scope of the EU Centralised Authorisation Procedure, will be authorised on a UK-wide basis by the MHRA for the UK market.

CALL FOR REPORTING

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

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 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates product brand name and batch number.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

Company contact point

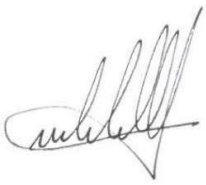
Should you have any questions regarding the use of Ocrevus 920 mg solution for injection, please feel free to contact:

Roche Medical Information by phone on +44(0)800 328 1629 or via e-mail medinfo.uk@roche.com

Thank you in advance for your understanding and cooperation in this additional information.

Yours faithfully,

Roche Products Limited



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