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Direct HealthCare Professional Communication

Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]): supply of Great Britain-labelled stock in Northern Ireland

09 May 2022

Summary: Supply of Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]) to Northern Ireland

To ensure continuity in supply during the vaccination programme, AstraZeneca UK Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA), to supply Great Britain (GB)-labelled stock of 'Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant])' to Northern Ireland.

Please note the following:

- Currently Northern Ireland is supplied with UK-wide packs under 'Covid-19 Vaccine AstraZeneca' temporary Regulation 174 authorisation (Reg 174).
- To ensure continuity in supply, AstraZeneca will supply GB-labelled stock of Vaxzevria to UK (NI) for a period of 6 months.
- The GB-labelled stock has the same formulation as the current Reg 174 product.
- There are minor differences between the Reg 174 and the GB-labelled product information including the carton, label and Patient Information Leaflet - see page 2 for a full comparison.
- The currently approved Patient Information Leaflet (leaflet) and Summary of Product Characteristics (SmPC) can be searched electronically at https://www.medicines.org.uk/emc

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

GB-36289
Date of Preparation: May 2022

Registered Office:
1 Francis Crick Avenue, Cambridge Biomedical Campus
Cambridge, CB2 0AA
Registered Number: 03674842

Please note that some minor differences do exist between the UK wide Reg 174 leaflet and the GB Vaxzevria leaflet that will be supplied with the pack. The differences are detailed as follows:

Reg 174 (UK wide) Leaflet	**GB Vaxzevria Leaflet**
Name: Covid-19 Vaccine AstraZeneca	Name: Vaxzevria
Dose given in viral particles (vp)	Dose given in infectious units (Inf.U)
Solution for injection	Suspension for injection
Additional wording in Warnings and Precautions for 3rd dosing in immunocompromised individuals	N/A
N/A	Addition of Marketing Authorisation Holder
N/A	Addition of information for the Royal National Institute of the Blind (RNIB) service which provides an alternative version of the statutory information for patients in Great Britain. The RNIB service is available to all UK patients.

There are also minor differences between the GB Vaxzevria and Reg 174 carton and label. The key differences are as follows:

Reg 174 Carton	**GB Vaxzevria Carton**
Branding logo differs	Branding logo differs
Colour scheme differs	Colour scheme differs
Name: Covid-19 Vaccine AstraZeneca	Name: Vaxzevria
N/A	Addition of infection units dosing information
Solution for injection	Suspension for injection
Marketing Authorisation Holder address	Marketing Authorisation Holder address
N/A	Addition of Marketing Authorisation Number
N/A	Addition of Barcode

Reg 174 Label	**GB Vaxzevria Label**
Name: Covid-19 Vaccine AstraZeneca	Name: Vaxzevria
Colour scheme differs	Colour scheme differs

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Call for reporting adverse events

Report suspected side effects to medicines, vaccines, medical device and test kit incidents used in coronavirus (COVID-19) testing and treatment using the dedicated Coronavirus Yellow Card reporting site at https://coronavirus-yellowcard.mhra.gov.uk or via the Yellow Card app.

As these products are under additional monitoring, this includes all suspected adverse reactions associated with these vaccines. This will allow quick identification of new safety information.

Alternatively, adverse events of concern in association with COVID-19 Vaccine AstraZeneca can be reported to AstraZeneca on 08000 541 028 or via www.azcovid-19.com.

Please do not report the same adverse event(s) to both systems as all reports will be shared between AstraZeneca and MHRA (in an anonymised form) and dual reporting will create unnecessary duplicates.

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

Company contact point

If you have any queries regarding this product or information in this letter, please contact AstraZeneca Medical Information on 0800 783 0033.

Yours sincerely,

Dr Edward Piper

UK Medical & Scientific Affairs Director

AstraZeneca UK

GB-35987
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