



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals – Part 1

Adopted at the 7-10 June 2021 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals.

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

COVID-19 vaccine (ChAdOx1-S [recombinant]) – Vaxzevria – Capillary leak syndrome (EPITT no 19672)

Summary of product characteristics

4.3. Contraindications

Individuals who have previously experienced episodes of capillary leak syndrome (see also section 4.4)

4.4. Special warnings and precautions for use

Capillary leak syndrome

Very rare cases of capillary leak syndrome (CLS) have been reported in the first days after vaccination with Vaxzevria. A history of CLS was apparent in some of the cases. Fatal outcome has been reported. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Patients with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted. Individuals with a known history of CLS should not be vaccinated with this vaccine. See also section 4.3.

¹ Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



4.8. Undesirable effects

Vascular disorders

Not known: Capillary leak syndrome

Package leaflet

2. What you need to know before you are given Vaxzevria

The vaccine must not be given:

If you have a previous diagnosis of capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

Warnings and precautions

Capillary leak syndrome

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Vaxzevria. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek immediate medical attention if you develop these symptoms in the days following vaccination.

4. Possible side effects

Not known

- Capillary leak syndrome (a condition causing fluid leakage from small blood vessels)