# Part VI: Summary of the risk management plan

# Summary of risk management plan for Vaxchora (Cholera Vaccine, Recombinant, Live, Oral)

This is a summary of the risk management plan (RMP) for Vaxchora. The RMP details important risks of Vaxchora, how these risks can be minimised and how more information will be obtained about Vaxchora's risks and uncertainties (missing information).

Vaxchora's summary of product characteristics (SmPC) and its package information leaflet (PIL) give essential information to healthcare professionals and patients on how Vaxchora should be used.

This summary of the RMP for Vaxchora should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Vaxchora's RMP.

## I. The medicine and what it is used for

Vaxchora is authorised for active immunisation against cholera disease in adults and children aged 2 years and older. (see SmPC for the full indication). It contains *V. cholerae* strain CVD 103-HgR as the active substance and it is given by oral administration.

Further information about the evaluation of Vaxchora's benefits can be found in Vaxchora's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/vaxchora.

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Vaxchora, together with measures to minimise such risks and the proposed studies for learning more about Vaxchora's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Vaxchora is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

Important risks of Vaxchora are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Vaxchora. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

| **List of important risks and missing information** | |
|---|---|
| Important identified risks | • None |
| Important potential risks | • Medication errors |
| Missing information | • Use during pregnancy |

## *II.B Summary of important risks*

**Important identified risks:**

None

**Important potential risks:**

| **Medication errors** | |
|---|---|
| Evidence for linking the risk to the medicine | Medication errors have been reported in the post-market period. These concern instances where the subject has eaten/drunk at inappropriate time points, administration of expired product and administration of product without buffer. In addition to the medication errors mentioned above, the following can occur:<br>- Wrong storage of the product (product should be stored in a refrigerator)<br>- Vaccine is not administered within the allotted time after preparation<br>- Eating or drinking less than one hour before and after administration of the vaccine.<br>Additional challenges for children 2 to < 6 years, such as discarding more than half of the buffer solution prior to adding the vaccine sachet, adding more than 1 g of Stevia or 4 g sucrose and challenges in getting the child to ingest the entire vaccine dosage. |
| Risk factors and risk groups | • Patients with inability to read or understand label |

| | |
|---|---|
| | • Patients failure to read package insert, although they possess adequate reading levels<br>• Inadequate instructions given by health care providers<br>• Children 2- < 6years may be at increased risk |
| Risk minimisation measures | **Routine risk minimisation measures:**<br>• SmPC sections 4.2, 6.3, 6.4, 6.6<br>• PL section 2, 3, 5<br>• Medicinal product subject to medical prescription<br>**Additional risk minimisation measures:**<br>Additional risk minimisation measures will include a patient guide containing key messages and administration highlights (especially relating to changes in vaccine preparation and use in children 2 to <6 years). Also, a health care professional's guide (checklist) for assisting the provider with instructing patients will be provided. |

**Missing information**

| **Use during pregnancy** | |
|---|---|
| Risk minimisation measures | **Routine risk minimisation measures:**<br>• SmPC sections 4.6<br>• PL section 2<br>• Medicinal product subject to medical prescription<br>**Additional risk minimisation measures:**<br>No risk minimisation |
| Additional pharmacovigilance activities | None at this time (see III.2) |

## *II.C Post-authorisation development plan*

## II.C.1 Studies which are conditions of the marketing authorisation

None at this time.

## II.C.2 Other studies in post-authorisation development plan

In September 2016, a pregnancy registry was initiated in the US (PXVX-VC-200-PR). The study enrolled one subject; the outcome of that pregnancy was unremarkable. In September 2021, the pregnancy registry was closed and a case report form was submitted to the FDA. The closure of the PAM has been considered acceptable during the assessment of the PSUR EMEA/H/C/PSUSA/00010862/202106 (PRAC Assessment report EMA/PRAC/775310/2021).