

Vaxchora® ▼

Cholera vaccine (recombinant, live, oral)

# Guide for Healthcare Professionals

Important information about reconstitution and administration of VAXCHORA for healthcare professionals, their patients or their caregivers.

VAXCHORA is a single oral dose cholera vaccine that can be self-administered by your patients. It is indicated for active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children aged 2 years and older. This vaccine should be used in accordance with official recommendations.

- ▼ This medical product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions or medication errors. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse reactions and medication errors should also be reported to Bavarian Nordic at [drug.safety@bavarian-nordic.com](mailto:drug.safety@bavarian-nordic.com)



## What is the purpose of this guide?

This guide is to provide healthcare professionals with detailed information about the **reconstitution and administration procedures for VAXCHORA** to minimise important potential risks of medication errors that could occur during patient self-administration. This guide also provides you with information when counselling your patients or their caregivers on how to reconstitute and administer the vaccine.

This guide contains two sections:

- ◆ Patient counselling points.
- ◆ VAXCHORA administration instructions.

At the end of this educational material, you will find a checklist that may be used to remind you of the key discussion points with your patients or their caregivers that will administer VAXCHORA.

## Patient counselling points:

**Explain to your patient or their caregiver that VAXCHORA consists of two sachets:**

- ◆ Sachet 1 is black and white and contains the buffer powder
- ◆ Sachet 2 is blue and white and contains the active ingredient

**Inform you patient about the Package Leaflet (included in the VAXCHORA carton) and the Patient Guide (available at [bnpatientguides.co.uk](http://bnpatientguides.co.uk))**

Here they will find detailed information on the step-by-step procedure, created to minimise the risk of medication errors.

**Talk your patient or their caregiver through the instructions, and ensure they fully understand each step. For children between 2 to <6 years of age please advise the caregiver of the special instruction regarding the preparation of the buffer solution as indicated in the illustration on page 3.**

End the discussion by asking them if they have any further questions about how to properly prepare and take their vaccine.



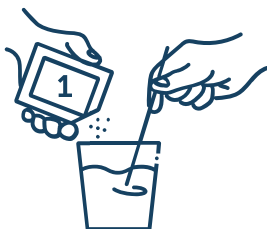
### IMPORTANT:

VAXCHORA should be stored in its original package in a refrigerator between 2°C – 8°C.

# VAXCHORA administration instructions:

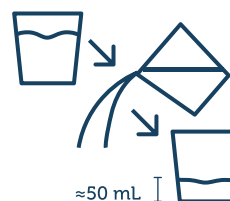
Patients should not eat or drink for 1 hour before or after ingesting VAXCHORA.

## 1 Prepare Sachet 1



Pour **100 ml** of bottled, non-carbonated or carbonated water, that is cold or room temperature, into a clean empty cup. **Empty the contents of sachet 1 into the water** in the cup and stir until the powder is completely dissolved.

## 2 For children age 2 to <6 years only:



Pour away and discard half of the buffer solution, 50 ml will remain in the cup.

Note: For over 6 years 100 ml to be used

## 3 Prepare Sachet 2

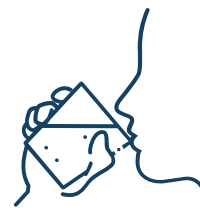


**Empty the contents of sachet 2** into the same solution and **stir for at least 30 seconds**.

A slightly cloudy colour with some white particles is normal. Wash your hands if you touch the sachet contents.

If desired, after stirring in sachet 2 for at least 30 seconds, **stevia sweetener (no more than 1 gram or 1/4 teaspoon)** or **sugar (no more than 4 grams or 1 teaspoon)** may be added, and then stirred into the suspension. **DO NOT add other sweeteners as this may reduce the effectiveness of the vaccine.**

## 4 Drink Mixture



**Consume within 15 minutes** of mixing.

Read the VAXCHORA Summary of Product Characteristics for detailed instructions. Advise patients or their caregivers to carefully read the VAXCHORA Package Leaflet instructions.

**REMEMBER!** Patients should not eat or drink for 1 hour before or after ingesting VAXCHORA.

# Key information to remember

The checklist below may help guide your discussion with your patient or their caregiver that self-administer VAXCHORA.

- VAXCHORA **must be stored in the refrigerator** until the vaccine is reconstituted.
- Patients should **not eat or drink for 1 hour before or after ingesting VAXCHORA.**
- VAXCHORA contains **2 sachets** that must be **added in the correct order** during reconstitution.
- VAXCHORA must be **reconstituted using bottled, non-carbonated or carbonated water** that is **cold** or **room temperature.**
- When using VAXCHORA in children aged 2-6 years old, initially, the full buffer solution (100 mL) is made up but then half (50 mL) of it is discarded **BEFORE** adding the contents of sachet 2 (active ingredient)
- The addition of a sweetener, **either 1 g of stevia or 4 g of sucrose only**, may be added for palatability. No more than the indicated amounts should be added as this could potentially affect efficacy of the vaccine.
- Additionally, it is important to get the child (children aged 2 to 6 years old) to ingest the entirety of the 50 ml volume of vaccine.
- VAXCHORA must be **consumed** within **15 minutes of reconstitution.**
- Remind your patient or their caregiver to **contact you** regarding any **medication errors.**

This guide and the Patient Guide can be found at [bnhpcguides.co.uk](https://bnhpcguides.co.uk)

Reference: VAXCHORA SmPC. 31Jan2024

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