

Vaxchora[®]

Cholera vaccine (recombinant, live, oral)



Patient Guidance

for taking your cholera vaccine

Please read the **Patient Information Leaflet** in the pack for full instructions containing important **information to minimise the risk of medication errors**.

Don't forget to keep your vaccine refrigerated (2°C – 8°C) until you are ready to take it.

You can help by reporting any side effects you may get including any not listed in the package leaflet to your doctor, pharmacist or nurse. You can also report side effects directly to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

Contact a doctor immediately if you experience the following side effects: serious allergic reactions causing swelling of the face or throat, hives, itchy rash, breathlessness and/or a drop in blood pressure and fainting.

Who is this guide for?

Welcome. This guide is for **people who have been prescribed VAXCHORA**, a single dose oral vaccine to help protect against cholera. Since VAXCHORA can be self-administered, it is important that you follow this guide to ensure it is reconstituted and administered correctly. If the vaccine is not prepared and taken properly, it may not work or be less effective.

If you are the **caregiver of a patient who has been prescribed VAXCHORA**, then you will find the following information useful when helping to administer the vaccination.

The guide is comprised of two sections:

- 1 How do I take my vaccine?
- 2 What should I do if I make a mistake?

Please make sure you have read this entire document before you begin.

How do I take my vaccine?

Checklist before you start:

- Do not eat or drink anything for 1 hour before or after taking the vaccine, since that can reduce its effectiveness.
- Keep the vaccine in a refrigerator** until you are ready to take it.
- Inside the pack you will find two numbered sachets:
 - ◆ Sachet 1 contains the buffer (Black and white).
 - ◆ Sachet 2 contains the active ingredient (Blue and white).
- You will also need a clean cup, 100 mL of bottled, non-carbonated or carbonated water that is cold or room temperature, scissors, and a spoon or stirrer for mixing.
- Ensure you follow the step-by-step instructions for preparing VAXCHORA, including dissolving the sachet contents in the correct order.

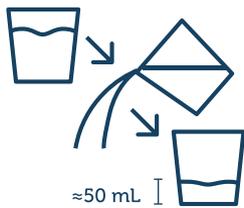
Please read the Patient Leaflet which contains full details about VAXCHORA. You can find the full instructions in section 3 of the VAXCHORA Package Leaflet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you present any of the following or a combination of nausea, vomiting, diarrhoea or abdominal pain, talk to your doctor, pharmacist, or nurse prior to taking the vaccine.



1 Prepare Sachet 1

Pour 100 mL of bottled, non-carbonated or carbonated water that is cold or room temperature into a clean cup. Empty the contents of sachet 1 into the water in the cup and stir until the powder is completely dissolved. Wash your hands if you touch the sachet contents.



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 ¼ 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

Drink the entire mixture within 15 minutes. Some residue may be left behind, which will need to be thrown away. Wash your hands if you touch the sachet contents, in order to reduce the chance of contamination. **Do not eat or drink anything else for the next hour**, as this can reduce the vaccine's effectiveness.

Key information to remember

The checklist below may help you self-administer VAXCHORA.

- VAXCHORA **must be stored in the refrigerator** until the vaccine is reconstituted.
- You 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**, can be added to improve taste. No more than the indicated amounts should be added as this could potentially affect effectiveness 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**.

What should I do if I make a mistake?

You must report the mistake to your healthcare professional:

- Contact your doctor, pharmacist or nurse to explain the mistake, and discuss if a replacement dose is required.



If you find that the vaccine is not intact when you first open it:

- Take it back to your doctor, pharmacist or nurse and ask for a replacement dose.