

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VAXCHORA®

Cholera Vaccine, Live Attenuated, Oral

Read this carefully before you start taking **VAXCHORA** vaccine and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VAXCHORA** vaccine.

What is VAXCHORA vaccine used for?

- The vaccine is taken by mouth and is used to help protect people who are travelling to an area where there is a risk of diarrhea caused by cholera. It stimulates the body's natural defense in the gut and mimics the natural infection.
- The vaccine is used for protection from cholera in persons 2 to 64 years of age. The vaccine is effective against the most common serogroup of cholera (O1) but does not work against uncommon serogroups such as O139.

How does VAXCHORA vaccine work?

VAXCHORA vaccine prepares the immune system (the body's defenses) to fight against cholera bacteria if you come in contact with it. When you take the vaccine, the immune system makes proteins called antibodies against the cholera bacterium and its toxin (harmful substance) that causes diarrhea.

What are the ingredients in VAXCHORA vaccine?

Medicinal ingredients: live attenuated *V. cholerae* strain CVD 103-HgR.

Non-medicinal ingredients: ascorbic acid, hydrolysed casein, lactose, sodium bicarbonate, sodium carbonate and sucrose.

VAXCHORA vaccine comes in the following dosage forms:

VAXCHORA vaccine is a white-to-beige powder to be reconstituted into a suspension. Each dose of vaccine contains 4×10^8 to 2×10^9 colony forming units (CFU) of live attenuated *V. cholerae* strain CVD 103-HgR.

Do not use VAXCHORA vaccine if:

- You are allergic to any of the ingredients in the vaccine listed above.
- You had allergic reactions when you previously took a cholera vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VAXCHORA vaccine. Talk about any health conditions or problems you may have, including if you:

- Have a weakened immune system, for example, if you were born with a weakened immune system or if you are having treatments such as high-dose corticosteroid treatment, cancer medicines or radiotherapy that can weaken the immune system.
- Have close contacts who have weakened immunity, as the bacteria from the vaccine may be present in your stool for at least 7 days after you take the vaccine. To prevent any

contamination, wash your hands thoroughly after visiting the toilet and before preparing food for at least 14 days after you take VAXCHORA vaccine.

Other warnings you should know about:

Do not give this vaccine to children younger than 2 years of age because it is not known how well it works in this age group.

Use of VAXCHORA vaccine in pregnant or breastfeeding women has not been studied. If you are considering taking VAXCHORA contact your healthcare professional.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VAXCHORA vaccine:

- Antibiotics: The vaccine may not work if you take it while you are also taking antibiotics. Take VAXCHORA vaccine no earlier than 14 days after the last dose of an antibiotic, or do not take antibiotics for at least 10 days after taking VAXCHORA vaccine.
- Chloroquine for malaria prevention: VAXCHORA vaccine may not work if you take it while you are also taking chloroquine. Take the vaccine at least 10 days before starting chloroquine or 14 days after taking chloroquine.
- Oral Typhoid vaccine Ty21a: VAXCHORA vaccine may not work if it is taken at the same time as Ty21a. You should take it at least 2 hours before or after taking Ty21a.
- Food or drink: You must not eat or drink for one hour before or after taking VAXCHORA vaccine as this may reduce the vaccine's effectiveness.

How to take VAXCHORA vaccine:

Usual dose:

Always take this vaccine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

VAXCHORA vaccine is taken by mouth only.

The recommended dose is the contents of both sachets in the carton.

Protection against cholera is established within 10 days after taking VAXCHORA vaccine. Your healthcare professional will tell you how soon before travelling to take the vaccine.

Avoid eating or drinking one hour before and one hour after taking the vaccine.

Instructions:

PREPARE THIS VACCINE EXACTLY AS DESCRIBED IN THIS LEAFLET

Please read the following before you begin:

VAXCHORA vaccine may not work if the following occurs:

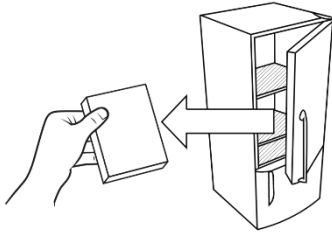

- Incorrect storage; the vaccine must be stored in the refrigerator.
- Using the incorrect amount of water; see step 4 below.

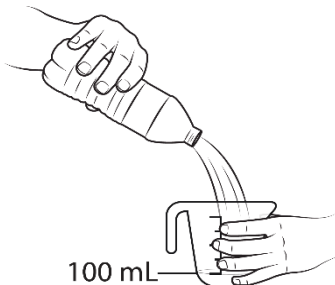
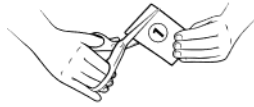


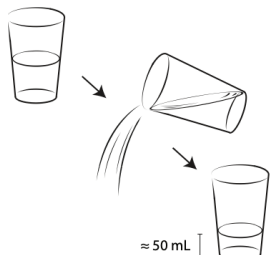
- Using the incorrect type of water; purified, spring or sparkling (carbonated) bottled water that is cold or room temperature must be used.
- Mixing the sachets in the wrong order; sachet 1 (**BUFFER**) must be added to the water first. If the sachets are mixed in the wrong order you must discard the vaccine and request a replacement dose.
- Eating or drinking; must be avoided one hour before and after taking the vaccine, eating or drinking can reduce the effectiveness of the vaccine.





Do not touch your eyes when you prepare the vaccine to avoid contamination.





If any powder or liquid gets spilled, clean the surface with hot water and soap or an antibacterial disinfectant.

If there is a significant spill (more than a few drops of liquid or grains of powder), dispose of the vaccine and get a new one from your doctor or pharmacist; DO NOT take the remaining medication.

<p>Step 1</p>	<p>Gather materials:</p> <ul style="list-style-type: none"> • Clean cup • Utensil to stir • Bottled water (purified, spring or sparkling [carbonated]), cold or at room temperature, 25°C or less) • Item to measure 100 mL of bottled water (e.g. measuring cup) • Scissors
<p>Step 2</p> 	<p>Remove the vaccine from the refrigerator.</p>
<p>Step 3</p> 	<p>Locate the two sachets: the sachets are labeled 1 and 2.</p> <p>Sachet 1 contains “BUFFER COMPONENT OF VAXCHORA” and is black and white. Sachet 2 contains “ACTIVE COMPONENT OF VAXCHORA” and is blue and white.</p> <p>If a sachet is not intact, do not use either sachet and contact your healthcare professional about acquiring a replacement dose; using a sachet that is not intact can reduce the effectiveness of the vaccine.</p>

<p>Step 4</p> 	<p>Measure 100 mL of cold or room temperature bottled water (purified, spring or sparkling [carbonated]) and pour into a clean cup.</p> <p>Do not use tap/faucet water, or any non purified bottled water, other beverages, or other liquids.</p>
<p>Step 5</p> 	<p>Use scissors to cut off the top of sachet 1.</p> <p>Do not put your fingers into the sachet.</p>
<p>Step 6</p> 	<p>Empty the contents of sachet 1 into the water in the cup. It will fizz.</p>
<p>Step 7</p> 	<p>Stir until the powder completely dissolves.</p>
<p>Step 8</p> 	<p>For children age 2 to 5 years only:</p> <p>Pour out and discard half of the buffer solution</p>

<p>Step 9</p> 	<p>Use scissors to cut off the top of sachet 2.</p> <p>Do not put your fingers into the sachet. Wash your hands if you touch the sachet contents, in order to reduce the chance of contamination.</p>
<p>Step 10</p> 	<p>Empty the contents of sachet 2 into the cup.</p>
<p>Step 11</p> 	<p>Stir for at least 30 seconds. The powder from sachet 2 may not dissolve completely. It will form a slightly cloudy mixture with some white particles.</p> <p>If desired, no more than 4 gram (1 teaspoon) of table sugar or no more than 1 gram of stevia sweetener (1/4 teaspoon) may be added, and then stirred into the suspension.</p>
<p>Step 12</p> 	<p>If you have spilled any material, DO NOT take the remaining dose and contact your healthcare professional about acquiring a replacement dose.</p> <p>Drink the full contents of the cup within 15 minutes of preparing it. Some residue may remain in the cup and must be discarded.</p>

<p>Step 13</p> 	<p>Clean all used items with soap and hot water.</p>
<p>Step 14</p> 	<p>If a spill occurs while stirring or drinking the medication, or there is any residue (powder or liquid left behind from a stirring utensil, cup, or other object) on the mixing surface, clean up spilled material or residue, preferably with a disposable paper towel/cloth using hot water and soap or antibacterial disinfectant. Discard the paper towel together with the sachets (see below).</p>
<p>Step 15</p> 	<p>Discard sachets and any disposable items.</p>
<p>Step 16</p> 	<p>Wash your hands thoroughly with soap and hot water to prevent contamination.</p>

Overdose:

If you take more than the recommended dose, you may have some of the side effects listed below.

If you think you, or a person you are caring for, have taken too much VAXCHORA vaccine, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable as there is only one dose of VAXCHORA vaccine.

Consumption of less than a half dose may result in decreased protection. If you consumed less than half the dose, contact your healthcare professional about acquiring a replacement dose. Consideration may be given to repeating a full dose of VAXCHORA vaccine within 72 hours.

Always make sure you take VAXCHORA vaccine a minimum of 10 days before potential exposure to cholera.

What are possible side effects from using VAXCHORA vaccine?

These are not all the possible side effects you may have when taking VAXCHORA vaccine. If you experience any side effects not listed here, tell your healthcare professional.

Contact a doctor immediately if you get the following serious 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.

The most common side effects of VAXCHORA vaccine were tiredness, headache, nausea/vomiting, abdominal pain and lack of appetite.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Bavarian Nordic A/S cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Also, to report an adverse event related to VAXCHORA® vaccine, please contact Bavarian Nordic A/S at 1-833-203-7933.

Storage:

Store VAXCHORA buffer component and active component sachets refrigerated at 2°C to 8°C. Protect

from light and moisture. Sachets should not be out of refrigerated storage for more than 12 hours prior to reconstitution; when out of refrigerated storage, sachets should not be exposed to temperatures above 25°C.

Keep out of reach and sight of children.

If you want more information about VAXCHORA vaccine:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website bnvaccines.ca , or contact medical.information_NA@bavarian-nordic.com or by calling 1-833-203-7933.

This leaflet was prepared by Bavarian Nordic A/S

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