

Package leaflet: Information for the user

Vaxchora effervescent powder and powder for oral suspension cholera vaccine (recombinant, live, oral)

Read all of this leaflet carefully before you take this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vaxchora is and what it is used for
2. What you need to know before you take Vaxchora
3. How to take Vaxchora
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1. What Vaxchora is and what it is used for

Vaxchora is an oral vaccine against cholera that stimulates the immunological defence in the gut. The vaccine is used for protection from cholera in adults and children aged 2 years and older. The vaccine must be taken at least 10 days before travelling to a cholera-affected area.

How Vaxchora works

Vaxchora prepares the immune system (the body's defences) to defend itself against cholera. When a person takes the vaccine, the immune system makes proteins called antibodies against the cholera bacterium and its toxin (harmful substance) that causes diarrhoea. In this way the immune system is ready to fight cholera bacteria if the person comes into contact with it.

2. What you need to know before you take Vaxchora

Do not take Vaxchora:

- if you are allergic to any of the ingredients in this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Vaxchora.

Contact a doctor immediately if you get the following serious side effects (see also Section 4):

- serious allergic reactions causing swelling of the face or throat, hives, itchy rash, breathlessness and/or a drop in blood pressure and fainting.

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. Vaccination should be postponed until after recovery because protection against cholera may be diminished.

Not everyone taking this vaccine will be fully protected against cholera. It is important to continue to follow hygiene advice and take special care with food and water in cholera-affected areas.

This vaccine may be less effective if you have HIV.

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, changing nappies and before preparing food for at least 14 days after you take this vaccine.

Children and adolescents

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.

Other medicines and Vaxchora

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines or vaccines. This includes medicines obtained without a prescription, including herbal medicines. This is because this vaccine can affect the way some other medicines and vaccines work.

In particular tell your doctor, pharmacist or nurse if you are taking:

- antibiotics – this vaccine may not work if you take it while you are also taking antibiotics. Take this vaccine no earlier than 14 days after the last dose of an antibiotic. Avoid antibiotics for 10 days after taking this vaccine.
- chloroquine for malaria prevention – this vaccine may not work if you take it while you are also taking chloroquine. Take this vaccine at least 10 days before starting chloroquine or 14 days after taking chloroquine.
- the typhoid vaccine Ty21a – this vaccine may not work if it is taken at the same time as Ty21a. You should take this vaccine at least 2 hours before or after taking Ty21a.

If any of the above apply to you, talk to your doctor, pharmacist or nurse before taking this vaccine.

Vaxchora with food and drink

You must not eat or drink for 60 minutes before and after taking this vaccine as this may reduce the vaccine's effectiveness.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Vaxchora vaccine has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 "Possible side effects" may temporarily affect the ability to drive or use machines. Do not drive or use machines if you are feeling unwell after vaccination.

Vaxchora contains lactose, sucrose, and sodium

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

This vaccine contains 863 mg of sodium (the main component of cooking/table salt) per dose. This is equivalent to 43% of the recommended daily dietary intake of sodium for an adult. Please take this into account if you are on a controlled sodium diet.

3. How to take Vaxchora

Always take this vaccine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is the contents of both sachets in the carton. However for children 2 to less than 6 years old take note of Step 8 in the instructions on how to prepare the vaccine, shown below.

Protection against cholera is established within 10 days after taking Vaxchora. Your doctor, pharmacist or nurse will tell you how soon before travelling to take the vaccine.

Instructions:

PREPARE THIS VACCINE EXACTLY AS DESCRIBED IN THIS LEAFLET

Please read the following before you begin:

Vaxchora may not work if the following occurs:

- Incorrect storage; the vaccine must be stored in the refrigerator (2°C – 8°C).
- Using the incorrect amount of water; 100 mL must be used.
- Using the incorrect type of water; bottled water that is cold or room temperature and non-carbonated or carbonated must be used.
- Mixing the sachets in the wrong order; sachet 1 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 60 minutes 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 spilt, clean the surface with hot water and soap or an antibacterial disinfectant.

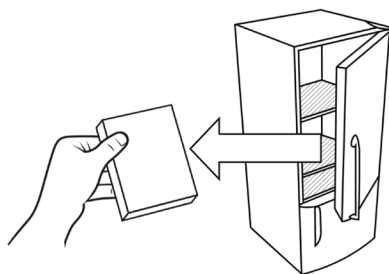
If there is a significant spill (more than a few drops of liquid or grains of powder), dispose of the vaccine and get a new one from your doctor or pharmacist; **DO NOT** take the remaining medication.

Step 1


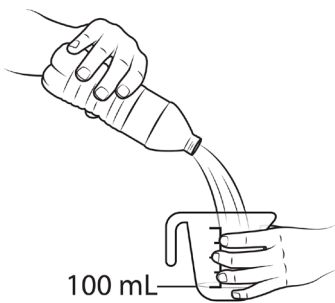



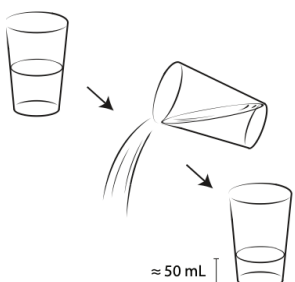
Gather materials:






- Clean cup
- Utensil to stir
- Bottled water (non-carbonated or carbonated, cold or room temperature, 25°C or less)
- Item to measure 100 mL of bottled water (e.g. measuring jug)
- Scissors




Step 2



Remove the vaccine from the refrigerator.

<p>Step 3</p> 	<p>Locate the two sachets: the sachets are labelled 1 and 2.</p> <p>Sachet 1 contains “Vaxchora Buffer” and is black and white. Sachet 2 contains “Vaxchora Active ingredient” and is blue and white.</p> <p>If a sachet is not intact, do not use either sachet and contact your doctor, pharmacist or nurse 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 bottled cold or room temperature non-carbonated or carbonated water and pour into a clean cup.</p> <p>Using bottled water is necessary for the vaccine to be effective – using non-bottled (e.g. tap water) may render the vaccine ineffective.</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. Wash your hands if you touch the sachet contents, in order to reduce the chance of contamination.</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 <6 years only: Pour away and discard half of the buffer solution. (Note: For children over 6 years and adults this step is NOT required)</p>

Step 9		<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>
Step 10		<p>Empty the contents of sachet 2 into the cup.</p>
Step 11		<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, after stirring in sachet 2 for at least 30 seconds, stevia sweetener (no more than 1 gram or ¼ teaspoon) or sugar (sucrose, not 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.</p>
Step 12		<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. If you or your child take less than half of the dose, contact your doctor, pharmacist, or nurse right away about the need for a repeat dose.</p>
Step 13		<p>Dispose of the empty sachets according to local biosafety guidelines. Ask your doctor, pharmacist or nurse how to throw away medicine waste material.</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 above).</p>
<p>Step 15</p>		<p>Wash the cup and spoon or stirrer with soap and hot water.</p>
<p>Step 16</p>		<p>Wash your hands thoroughly with soap and hot water to prevent contamination.</p>

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

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.

Other side effects:

Very common side effects (may affect more than 1 in 10 people)

- tiredness,
- headache,
- stomach pains,
- feeling or being sick,
- decreased appetite.

Common side effects (may affect up to 1 in 10 people)

- diarrhoea.

Uncommon side effects (may affect up to 1 in 100 people)

- fever,

- joint pain,
- dizziness,
- bloating (abdominal distension),
- rash,
- dry mouth,
- constipation,
- flatulence,
- burping,
- indigestion,
- abnormal faeces.

Rare side effects (may affect up to 1 in 1 000 people):

- chills.

Additional side effects in children and adolescents

Based on clinical trials the type of adverse reactions in children are expected to be similar to those in adults. Some adverse reactions were more common in children than adults such as tiredness, stomach pain, vomiting, decreased appetite and fever.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vaxchora

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Store in the original package in order to protect from light and moisture.

The vaccine in the original package is stable for up to 12 hours at 25°C. At the end of this period the vaccine should be used immediately or discarded. Avoid exposing Vaxchora to temperatures above 25°C.

Do not use this vaccine if you notice the sachets are damaged and contact your doctor, pharmacist, or nurse for a replacement dose.

This medicine contains genetically-modified organisms. Local biosafety guidelines should be followed for unused medicine or waste material. Ask your doctor, pharmacist or nurse how to throw away medicines you no longer use or waste material.

6. Contents of the pack and other information

What Vaxchora contains

- Each dose contains 4×10^8 to 2×10^9 viable cells of *Vibrio cholerae* strain CVD 103-HgR¹.
- The other ingredients are sucrose, hydrolysed casein, ascorbic acid, lactose, sodium bicarbonate, and sodium carbonate (see Section 2. Vaxchora contains lactose, sucrose and sodium).
- This vaccine contains genetically modified organisms (GMOs).

¹ Produced by recombinant DNA technology.

What Vaxchora looks like and contents of the pack

One dose of Vaxchora effervescent powder and powder for oral suspension is provided in a carton containing two sachets. One sachet contains white-to-off-white buffer sodium hydrogen carbonate effervescent powder. The other sachet contains white-to-beige active ingredient vaccine powder for oral suspension.

Marketing Authorisation Holder

Bavarian Nordic A/S, Philip Heymans Alle 3, DK-2900 Hellerup, Denmark

Manufacturer

Smiro Qualitas Limited
4 Flatford Road
Haverhill, CB9 7WW
United Kingdom

This leaflet was last revised in 11/2024.

Other sources of information

Detailed information on this medicine is available on the MHRA website: <http://www.mhra.gov.uk>.