

VAXCHORA[®] (*Vibrio cholerae*)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VAXCHORA vaccine?

VAXCHORA vaccine contains the active ingredient of recombinant live attenuated *V. cholerae* strain CVD 103-HgR. VAXCHORA vaccine is used to stimulate the immunological defence in the gut. The vaccine is used for protection from cholera in adults and children aged 2 years and older travelling to cholera affected countries. The vaccine must be taken at least 10 days before travelling to a cholera-affected area.

For more information, see Section [1. Why am I using VAXCHORA vaccine?](#) in the full CMI.

2. What should I know before I use VAXCHORA vaccine?

Do not use if you have ever had an allergic reaction to VAXCHORA vaccine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VAXCHORA vaccine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VAXCHORA vaccine and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VAXCHORA vaccine?

- Always take this vaccine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacists or nurse if you are not sure
- The recommended dose is the contents of both sachets in the carton prepared according to the detailed guide at the end of these instructions. However, for children 2 to 5 years old take note of Step 8 in the instructions on how to prepare the vaccine.

More instructions can be found in Section [4. How do I use VAXCHORA vaccine?](#) in the full CMI.

5. What should I know while using VAXCHORA vaccine?

Things you should do	<ul style="list-style-type: none">• Talk to your doctor, pharmacist, or nurse before taking VAXCHORA vaccine. Especially if:<ul style="list-style-type: none">• you have a weakened immune system or are HIV positive• you are on a controlled sodium diet• you are taking or have recently taken antibiotics, chloroquine for malaria prevention or other vaccines for typhoid fever at the same time as VAXCHORA vaccine• No vaccine is 100% effective. Continue to follow hygiene advice and take special care with food and water in cholera-affected areas. Rehydration measures are strongly recommended in the event of diarrhea.
Things you should not do	<ul style="list-style-type: none">• Do not eat or drink for 60 minutes before and after taking VAXCHORA vaccine. It will affect how the vaccine works
Driving or using machines	<ul style="list-style-type: none">• VAXCHORA vaccine is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell
Drinking alcohol	<ul style="list-style-type: none">• There is insufficient information to know if alcohol affects VAXCHORA effectiveness
Looking after your medicine	<ul style="list-style-type: none">• Refrigerate, do not freeze. Store in the original package. Sachets should not be out of refrigerated storage for more than 12 hours prior to reconstitution. Avoid exposing VAXCHORA vaccine to temperatures above 25°C

For more information, see Section [5. What should I know while using VAXCHORA vaccine?](#) in the full CMI.

6. Are there any side effects?

Very common side effects include headache, stomach pains, feeling unwell, lack of appetite and tiredness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VAXCHORA (*Vibrio cholerae*) cholera vaccine

Active ingredient(s): *live, attenuated, oral cholera bacteria strain CVD 103-HgR*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VAXCHORA vaccine. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VAXCHORA vaccine.**

Where to find information in this leaflet:

- [1. Why am I using VAXCHORA vaccine?](#)
- [2. What should I know before I use VAXCHORA vaccine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VAXCHORA vaccine?](#)
- [5. What should I know while using VAXCHORA vaccine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VAXCHORA vaccine?

VAXCHORA vaccine contains *Vibrio cholerae*, as recombinant live attenuated *V. cholerae* strain CVD 103-HgR. VAXCHORA vaccine is an anti-bacterial vaccine.

VAXCHORA vaccine 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.

VAXCHORA vaccine is used to protect from cholera in adults and children aged 2 years and older travelling to cholera affected countries. VAXCHORA vaccine should be used in accordance with official recommendations.

The vaccine should not replace standard preventive hygiene measures.

This vaccine must be taken at least 10 days before travelling to a cholera-affected area.

2. What should I know before I use VAXCHORA vaccine?

Warnings

Do not use VAXCHORA vaccine if:

- You are allergic to VAXCHORA vaccine, or any of the ingredients listed at the end of these instructions

Check with your doctor if you:

- Have any other medical conditions including HIV or you are on a controlled sodium diet
- 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

Following vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children and Adolescents

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VAXCHORA vaccine and affect how it works.

- Antibiotics – VAXCHORA 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 any antibiotics. Avoid antibiotics for 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 VAXCHORA vaccine at least 10 days before beginning antimalarial prophylaxis with chloroquine
- The typhoid vaccine Ty21a (oral capsules) – VAXCHORA vaccine may not work if it is taken at the same time as Ty21a. You should take VAXCHORA vaccine at least 2 hours before or after taking Ty21a

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VAXCHORA vaccine.

4. How do I use VAXCHORA vaccine?

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.

For children aged 2 to 5 years only, half of the buffer solution should be used (~ 50 mL) and the rest discarded.

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

Detailed instructions for preparing this vaccine for drinking are described in the diagram at the end of this instruction.

5. What should I know while using VAXCHORA vaccine?

Things you should do

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you, or your child:

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

Remind any doctor, dentist, pharmacist or nurse you visit that you have taken VAXCHORA vaccine in the last 14 days.

Continued Hygiene Measures

- Not everyone taking VAXCHORA 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. Rehydration measures are strongly recommended in the event of diarrhea.
- 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 bathroom and before preparing food for at least 14 days after you take

VAXCHORA vaccine. There is potential for transmission of the vaccine to non-vaccinated close contacts (i.e household contacts), including individuals that may be immunocompromised. The safety and effectiveness of VAXCHORA vaccine have not been established in immunocompromised individuals.

- Nappies from children vaccinated with VAXCHORA vaccine should be disposed of in household waste. Wash your hands thoroughly after handling nappies.

Things you should not do

VAXCHORA vaccine with Food and Drink

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

Driving or using machines

VAXCHORA vaccine is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is insufficient information to know if alcohol affects VAXCHORA effectiveness.

Looking after your medicine

- Do not use VAXCHORA 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
- Sachets should not be out of refrigerated storage for more than 12 hours prior to reconstitution
- Avoid exposing VAXCHORA vaccine to temperatures above 25°C

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

This medicine contains genetically-modified organisms. Ask your doctor, pharmacist or nurse how to throw away medicines you no longer use or waste material.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Very common side effects (may affect more than 1 in 10 people): <ul style="list-style-type: none">• Headache• Stomach pains• Feeling unwell• Lack of appetite• Tiredness Common side effects (may affect up to 1 in 10 people): <ul style="list-style-type: none">• Diarrhoea Uncommon side effects (may affect up to 1 in 100 people): <ul style="list-style-type: none">• Flatulence• Constipation• Bloating (abdominal distention)• Indigestion• Abnormal faeces• Dry mouth• Burping• Fever• Dizziness• Joint pain• Rash Rare side effects (may affect up to 1 in 1,000 people): <ul style="list-style-type: none">• Chills	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Serious allergic reactions: <ul style="list-style-type: none">• Swelling of the face or throat• Hives• Itchy rash• Breathlessness and/or• Drop in blood pressure and fainting	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VAXCHORA vaccine contains

Active ingredient (main ingredient)	Each dose contains 4×10^8 to 2×10^9 viable cells of recombinant live attenuated <i>V. cholerae</i> strain CVD 103-HgR.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sucrose• Hydrolysed casein• Ascorbic acid• Lactose• Sodium bicarbonate• Sodium carbonate
Potential allergens	The <i>Vibrio cholerae</i> bacteria could be a potential allergen.

Do not take this medicine if you are allergic to any of these ingredients.

The vaccine contains lactose as sugars and sucrose. If you have any of these rare hereditary problems: galactose intolerance, congenital lactase deficiency, glucose-galactose malabsorption, fructose intolerance, or sucrose-isomaltase insufficiency, you should not take this vaccine.

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.

The vaccine contains genetically modified organisms (GMOs).

What VAXCHORA vaccine looks like

VAXCHORA vaccine is an antibacterial vaccine (Aust R 389746).

The carton contains 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.

Who distributes VAXCHORA vaccine

Australia
Bioclect Pty Ltd
ABN 88 168 092 171
Suite 405,
Level 4, 51 Rawson Street
Epping NSW 2121 Australia

Customer enquiries and Medical Information:

Telephone: 1300 848 628
Email: info@bioclect.com

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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; 100 mL must be used.
- Using the incorrect type of water; bottled water (non-carbonated or carbonated) that is cold or at room temperature 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.

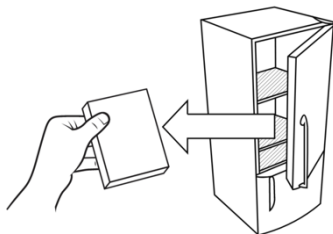
If there is a significant spill (more than a few drops of liquid or grains of powder), dispose of the vaccine and get a new one from your doctor or pharmacist; DO NOT take the remaining medication.

Step 1

Gather materials:

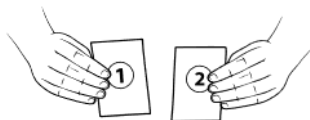
- Clean cup
- Utensil to stir
- Bottled water (non-carbonated or carbonated, cold or at room temperature, 25°C or less)
- Item to measure 100 mL of bottled water (e.g. measuring cup)
- Scissors

Step 2



Remove the vaccine from the refrigerator.





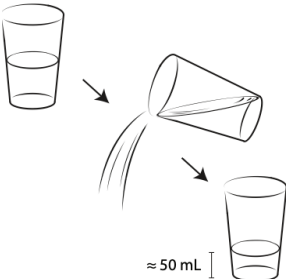

Step 3



Locate the two sachets: the sachets are labelled 1 and 2.

Sachet 1 contains "Sodium hydrogen carbonate effervescent powder" (buffer) and is black and white. Sachet 2 contains "VAXCHORA Active ingredient" and is blue and white.

If a sachet is not intact, or if the vaccine and/or buffer shows signs of yellowing and clumping, 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.

Step 4		<p>Measure 100 mL of bottled cold or room temperature unflavored non-carbonated or carbonated drinking water and pour into a clean cup.</p>
Step 5		<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>Use scissors to cut off the top of sachet 1.</p> <p>Do not put your fingers into the sachet.</p>
Step 6		<p>Empty the contents of sachet 1 into the water in the cup. It will fizz.</p>
Step 7		<p>Stir until the powder completely dissolves.</p>
Step 8		<p>For children age 2 to 5 years only:</p> <p>Pour away and discard half of the buffer solution or buffer with sweetener solution (50 mL). (Note: For children 6 years and older 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



Empty the contents of sachet 2 into the cup.

Step 11



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.

If desired, after stirring in sachet 2, sucrose (table sugar), no more than 4 grams (1 teaspoon), or stevia sweetener (no more than 1 gram or $\frac{1}{4}$ teaspoon) may be added, and then stirred into the suspension. DO NOT add other sweeteners as this may reduce the effectiveness of the vaccine.

Step 12



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.

Step 13



Discard sachets and any disposable items.

Ask your doctor, pharmacist or nurse how to throw away medicine waste material if unsure.

Step 14



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).

Step 15



Wash the cup and spoon or stirrer with soap and hot water.

Step 16



Wash your hands thoroughly with soap and hot water to prevent contamination.

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