

DUKORAL[®]

Oral inactivated cholera and ETEC vaccine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dukoral[®].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child taking Dukoral[®] against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Please read this leaflet carefully and keep it in a safe place. You may need to read it again.

What DUKORAL[®] is used for

Dukoral[®] is a vaccine used to help prevent:

1. Cholera which is caused by bacteria called *Vibrio cholerae*
2. travellers' diarrhoea caused by a type of bacteria called enterotoxigenic *Escherichia coli* (ETEC) bacteria.

Dukoral[®] is used to protect people who are travelling to an area where there is a risk of cholera or diarrhoea due to ETEC bacteria.

Travellers' diarrhoea can have many causes. ETEC is only one cause. Dukoral[®] will only prevent travellers' diarrhoea due to ETEC.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How it works

Dukoral[®] works by causing your body to produce its own protection against cholera and ETEC diarrhoea. It does this by making substances called antibodies in the intestine wall, which fight the cholera bacteria (*Vibrio cholerae*) and the cholera toxin. Cholera toxin causes diarrhoea and is produced by the cholera bacteria. ETEC bacteria also produce a toxin, which is almost identical to the cholera toxin. The

antibodies your body makes to fight the cholera toxin also fight the ETEC toxin. If a vaccinated person comes into contact with cholera bacteria, cholera toxin or ETEC toxin, the body is usually ready to destroy it.

Your body usually takes one week after vaccination to develop protection against diarrhoea due to cholera or ETEC bacteria.

Most people will produce enough antibodies to protect against diarrhoea due to cholera or ETEC bacteria. However, as with all vaccines, 100% protection cannot be guaranteed.

About 85% of people can expect to be protected against cholera in the 6 months following initial vaccination.

About 60% of people will be protected against ETEC diarrhoea for 3 months after the second vaccine dose.

The vaccine will not give you or your child cholera or ETEC diarrhoea.

The chance of a severe reaction from Dukoral® is very small, but the risks from not being vaccinated against cholera may be very serious.

Before you take DUKORAL®

When you or your child must not take it

Do not take Dukoral® if you have an allergy to:

- Dukoral® or any of the ingredients listed at the end of this leaflet
- formaldehyde.

Do not take Dukoral® if you have:

- a high temperature
- symptoms such as vomiting, nausea, cramps or diarrhoea.

Do not give Dukoral® to a child under 2 years of age.

There is not enough information to recommend the use of Dukoral® in children under 2 years of age.

Do not take Dukoral® after the expiry date printed on the pack.

If it has expired, return it to your pharmacist for disposal.

Do not take Dukoral® if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

Talk to your doctor or pharmacist if you are not sure whether you or your child should take Dukoral®.

Before you or your child take it

Tell your doctor if you, or your child, have an infection or have been unwell.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

Tell your doctor if you or your child have, or have had, any medical conditions, especially the following:

- a disease that weakens your immune system (e.g. HIV/AIDS)
- low/weak immunity due to treatment with medicines that affect the immune system

The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.

Tell your doctor if you are on a controlled sodium (low salt) diet.

Dukoral[®] contains approximately 1.1 g sodium per dose.

Tell your doctor if you, or your child, have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having Dukoral[®] during pregnancy.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Your doctor will discuss the possible risks and benefits of having Dukoral[®] while you are breast-feeding.

Avoid food and drink for 1 hour before and 1 hour after vaccination.

Food and drink taken during this time may inactivate the vaccine.

Taking other medicines

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

Do not take any other oral medicines at the same time as Dukoral[®].

Other oral medicines should not be taken for at least 1 hour before and 1 hour after you take Dukoral[®].

Having other vaccines

Your doctor will tell you if you can have Dukoral[®] at the same time as another vaccine.

How to take DUKORAL[®]

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor or pharmacist will tell you how to take this vaccine.

If you do not understand the instructions in this leaflet or on the box, ask your doctor or pharmacist for help.

How much to take

To help prevent Cholera:

Primary Course

Adults and children over 6 years of age:

A total of two (2) doses: The second dose should be taken at least 1 week (and no more than 6 weeks) after the first dose.

Children 2 to 6 years of age:

A total of three (3) doses: Each dose should be taken at least 1 week (and no more than 6 weeks) apart.

Booster Dose:

If there is an ongoing risk of cholera or in the case of repeated travel an extra (booster dose) is recommended:

Adults:

One (1) booster dose is recommended 2 years after the primary course.

Children 2 to 6 years of age:

One (1) booster dose is recommended 6 months after the primary course.

To help prevent ETEC:

Primary Course

Adults and children over 2 years of age:

A total of two (2) doses:

The second dose should be taken at least 1 week (and no more than 6 weeks) after the first dose.

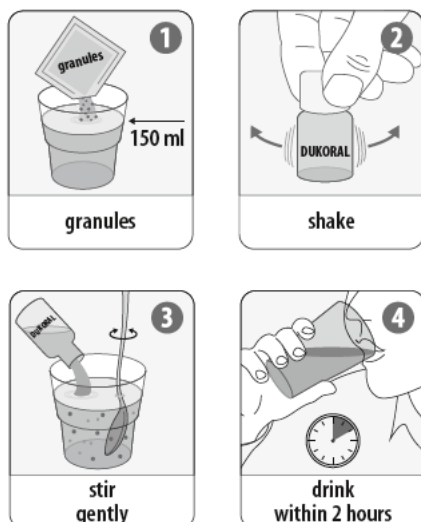
Booster dose:

No specific interval can be recommended for booster doses for protection against ETEC, due to the lack of clinical data on booster dosing.

How to take it

Please follow the instructions and diagrams below:

Avoid food and drink for 1 hour before and 1 hour after vaccination. Food and drink taken during this time may inactivate the vaccine.



1. **Dissolve the effervescent granules from the buffer sachet in a glass of cool water** (approx. 150 mL). This is the buffer solution.
If you are preparing the vaccine for a child 2–6 years of age: pour away (discard) half of the buffer solution.
2. Shake the vaccine vial (1 vial = 1 dose)
3. Add the entire contents of the vaccine vial to the buffer solution. Mix well.
4. The mixture should be drunk within 2 hours.

The vaccine must not be injected.

Avoid food and drink for 1 hour after vaccination. Food and drink taken during this time may inactivate the vaccine.

Do not use any liquid except water to make the buffer solution.

It is important to follow these instructions otherwise the vaccine will not work.

When to take it

For best protection against cholera and ETEC diarrhoea the last dose of vaccine should be taken at least 1 week before arrival at your destination.

If you forget to take it

For optimum protection each dose should be taken at least 1 week (and no more than 6 weeks) apart.

If more than 6 weeks have elapsed between doses you should consult your doctor or pharmacist about the need to repeat the primary course.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

If you think you or anyone else may have taken too much of this medicine immediately telephone your doctor or the New Zealand Poisons Information Centre 0800 POISON [0800 764 766], or go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

As each vial of Dukoral® contains only one dose, overdose is unlikely.

After taking DUKORAL®

Things you or your child must do

Keep an updated record of your vaccinations.

Keep follow-up appointments with your doctor or clinic. It is important to take your follow-up doses of Dukoral® at the appropriate times to make sure the vaccine has the best chance of providing protection against cholera and ETEC diarrhoea.

Things you or your child must not do

Do not have food or drink for 1 hour before and 1 hour after taking Dukoral®. Food and drink taken during this time may inactivate the vaccine.

Do not have any other oral medicines for 1 hour after taking Dukoral®.

Things to be careful of

Dukoral® does not provide complete protection and it is important to adhere to dietary and hygiene advice to avoid diarrhoeal diseases.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you, or your child, do not feel well after having Dukoral®.

Tell your doctor, nurse or pharmacist if you or your child, notice any of the following and they worry you:

- diarrhoea, stomach symptoms such as pain, cramps, gurgling or bloating, gas or general stomach discomfort
- headache
- nausea, vomiting, or indigestion
- loss of appetite
- reduced sense of taste
- fever, dizziness
- difficulty sleeping or sleepiness
- generally feeling unwell or tired

- shortness of breath
- flu-like symptoms such as sweating, shivering, or feeling tired
- runny or blocked nose, sneezing, cough, sore throat
- high blood pressure
- joint pain
- swelling of the lymph glands
- numbness or pins and needles
- rash.

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital if any of the following happen to you, or your child:

- severe diarrhoea
- an allergic reaction: typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body.

Other side effects not listed above may also occur in some people.

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storing DUKORAL[®]

Store Dukoral[®] in a refrigerator, between 2°C and 8°C. Do not freeze Dukoral[®]. Freezing destroys the vaccine.

Keep out of the reach and sight of children.

Do not take Dukoral[®] after the expiry date printed on the pack. If it has expired return it to your pharmacist for disposal.

Product description

What it looks like

Dukoral[®] is supplied as a small amount of whitish liquid in a glass vial. The vial is closed with a rubber stopper and a screw cap. Each vial contains one dose of the vaccine.

Each dose of vaccine is also supplied with one sachet of buffer. The buffer is a dry granular powder which is whitish in colour.

Dukoral[®] is supplied in a carton that contains one dose (1 vaccine vial and 1 sachet of buffer).

Ingredients

The vaccine vial contains:

Active ingredients:

- Bacteria from the following strains:
 - *Vibrio cholerae* O1 Inaba classic strain, heat-inactivated
 - *Vibrio cholerae* O1 Inaba El Tor strain, formalin-inactivated
 - *Vibrio cholerae* O1 Ogawa classic strain, formalin-inactivated
 - *Vibrio cholerae* O1 Ogawa classic strain, heat-inactivated
- Recombinant cholera toxin B subunit

Inactive ingredients:

- Sodium phosphate, monobasic dihydrate
- Sodium phosphate, dibasic dihydrate
- Sodium chloride
- Water for injections.

The buffer sachet contains:

- Sodium bicarbonate
- Citric acid anhydrous
- Raspberry flavour
- Sodium carbonate — anhydrous
- Sodium citrate
- Saccharin sodium.

Dukoral[®] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer:

Dukoral[®] is made by Valneva Sweden AB, 105 21 Stockholm, Sweden

Dukoral[®] is distributed in New Zealand by:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane
Auckland 1546
New Zealand

Telephone: 0800 502 757

Date of preparation

13 March 2020

Dukoral[®] is a registered trademark of Valneva Sweden AB.