

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.

Keep this leaflet. You may need to read it again.

What DUKORAL[®] is used for

DUKORAL[®] is a vaccine used to help prevent cholera and travellers' diarrhoea caused by heat-labile toxin-producing enterotoxigenic *Escherichia coli* (ETEC).

Travellers' diarrhoea can have many causes. ETEC is only one cause.

DUKORAL[®] will only prevent travellers' diarrhoea due to ETEC.

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

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 produces a toxin, which is almost identical to the cholera toxin, and the antibodies also protect against this toxin. If a vaccinated person comes into contact with cholera

bacteria or cholera toxin, the body is usually ready to destroy it.

Your body usually takes two weeks after vaccination to develop protection against diarrhoea due to cholera or ETEC.

Most people will produce enough antibodies to protect against diarrhoea due to cholera or ETEC. 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. This decreases to 52% at the end of the second year, when a booster should be given.

60% of people who take the vaccine properly will be protected against ETEC 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

Avoid food or drink for 2 hours before vaccination. Food and drink taken during this time may inactivate the vaccine.

Do not take DUKORAL[®] if you have an allergy to DUKORAL[®] or any of the ingredients listed at the end of this leaflet.

Do not take DUKORAL[®] if you have a high temperature.

Do not give DUKORAL[®] to a child under 2 years. There is not enough experience with the use of DUKORAL[®] in children under 2 years.

Do not take DUKORAL[®] after the expiry date printed on the pack. Do not take DUKORAL[®] if the packaging is torn or shows signs of tampering. If it has expired or 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 start to take it

Tell your doctor if you have an infection or high temperature. 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 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.

DUKORAL[®] is not expected to cause any problems for breast-fed babies.

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 on the box, ask your doctor or pharmacist for help.

How much to take

Cholera: the course of primary vaccination is 2 doses for adults and children over the age of 6. Children from 2 to 6 years of age should receive three doses. Doses are to be administered with an interval of 1 to 6 weeks between them. Adults and children over 6 years should receive a booster dose after 2 years and children 2-6 years should receive a booster dose after 6 months.

ETEC: the course of primary vaccination for adults and children is 2 doses with an interval of 1 to 6 weeks between doses.

How to take it

Please see the diagram on the carton.

1. Dissolve the effervescent granules from the buffer sachet in a glass of cool water (approx. 150 mL). *Children 2-6 years: pour away half of the solution.*
2. Shake the vaccine vial (1 vial = 1 dose)
3. Add the vaccine to the effervescent (bubbly) solution. Mix well and drink mixture.

The vaccine must not be injected.

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

When to take it

For best protection against cholera the last dose of vaccine should be taken 2 weeks before arrival at your destination. Satisfactory protection against cholera and ETEC can be obtained one week after the last dose.

If you forget to take it

For optimum protection you should take two doses 1-6 weeks apart. If more than 6 weeks have elapsed between doses you need to re-start the primary course.

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

If you are given too much (overdose)

Because each vial of DUKORAL[®] contains only one dose, overdosage is unlikely.

If you think you or anyone else may have been given too much of this medicine

- consult your doctor immediately or
- telephone the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 POISON (0800 764 766) in New Zealand) for advice, or
- go to Accident and Emergency at your nearest hospital.

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

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 to be careful of

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

Side effects

The side effects of Dukoral[®] are usually mild and limited to gastrointestinal upsets due to the buffer used with this vaccine. Rarely severe abdominal cramping occurs.

Tell your doctor or pharmacist as soon as possible if you or your child does not feel well after having DUKORAL[®].

Storing DUKORAL[®]

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

Product description

What it looks like

DUKORAL[®] is supplied as a glass vial, containing one dose of the vaccine, together with a sachet, containing the buffer, in a carton. The buffer is a dry granular powder. The vaccine is a small amount of whitish liquid.

Ingredients

The vaccine vial contains:

Active ingredients:

- 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

Other ingredients:

- Sodium phosphate, monobasic monohydrate
- 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.

Other information

Manufacturer:

Crucell Sweden AB, 105 21 Stockholm, Sweden

DUKORAL[®] is distributed in Australia by:

CSL Biotherapies
45 Poplar Road
Parkville Victoria
3052, Australia

DUKORAL[®] is distributed in New Zealand by:

CSL Biotherapies (New Zealand) Limited
666 Great South Road
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