

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

DUKORAL[®]

Oral, Inactivated Travellers' Diarrhea and Cholera Vaccine

This leaflet is part III of a three-part "Product Monograph" published when DUKORAL[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DUKORAL[®]. Contact your doctor or pharmacist if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is used for:

DUKORAL[®] is an oral vaccine that is used to help prevent travellers' diarrhea caused by enterotoxigenic *E. coli* (or ETEC) and/or cholera. The ETEC bacterium is the most common cause of travellers' diarrhea. DUKORAL[®] is used to help protect people who are travelling to an area where there is a risk of travellers' diarrhea caused by ETEC and/or cholera. This vaccine may be given to adults and children 2 years of age and older.

What the vaccine does:

DUKORAL[®] causes your body to produce its own protection against ETEC and cholera. After getting the vaccine, your body will make substances called antibodies, which fight the ETEC and cholera bacteria and toxins that cause diarrhea. If a vaccinated person comes into contact with ETEC or cholera bacteria the body is usually ready to destroy it.

It usually takes one week after you have completed all doses of the vaccine to be protected against diarrhea due to ETEC or cholera. Most people who take the vaccine will produce enough antibodies to protect them against diarrhea caused by ETEC or cholera. However, as with all vaccines, 100% protection is not guaranteed.

When it should not be used:

Do not use this vaccine in the following cases:

- Do not take DUKORAL[®] if you are allergic to any ingredient of the vaccine or to formaldehyde.

- Do not give DUKORAL[®] to a child who is allergic to any ingredient of the vaccine or to formaldehyde.
- Do not give DUKORAL[®] to a person who has a fever or acute gastrointestinal illness (e.g. diarrhea). Wait until the person is better to give the vaccine. Consult your doctor, nurse or pharmacist for guidance.

Talk to your doctor, nurse or pharmacist if you are not sure whether you or your child should take DUKORAL[®].

What the medicinal ingredient is:

Each single-dose vaccine vial contains:

V. cholera O1 Inaba classic strain, heat inactivated
V. cholera O1 Inaba El Tor strain, formalin inactivated
V. cholerae O1 Ogawa classic strain, heat inactivated
V. cholerae O1 Ogawa classic strain, formalin inactivated
Recombinant cholera toxin B subunit (rCTB)

What the important nonmedicinal ingredients are:

Each Sodium Hydrogen Carbonate sachet contains:

Sodium hydrogen carbonate, saccharin sodium.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

One dose Dukoral contains approximately 1.1 g sodium.

What dosage forms it comes in:

DUKORAL[®] is a liquid vaccine that must be swallowed (taken orally) after adding it to a buffer solution. DUKORAL[®] comes in a carton containing one or two doses.

The vaccine is a small amount of whitish suspension in a single-dose glass vial.

Each dose of vaccine comes with one sachet package that contains white granules of sodium hydrogen carbonate. The granules are to be dissolved in a glass of water – do not use any other liquid. The vaccine is then added and mixed with this buffer solution. The vaccine mixture has a raspberry taste.

WARNINGS AND PRECAUTIONS

If you have any of the following conditions, talk to your doctor, nurse or pharmacist BEFORE you take DUKORAL[®]:

- **Persons who have diseases of the immune system or who take a medical treatment that affects the immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems.
- **Persons who have an allergy to any component of the vaccine or the container or to formaldehyde.**
- **Persons who have acute gastrointestinal illness (e.g. diarrhea) or high temperature.** You may need to postpone taking DUKORAL[®] until the illness has passed. You may take the vaccine if you have a mild illness, such as a cold.
- **Pregnant women.** DUKORAL[®] is not recommended for use in pregnancy. Your doctor will discuss the possible risks and benefits of having DUKORAL[®] during pregnancy.

DUKORAL[®] prevents diarrhea caused by ETEC and cholera. It will not prevent diarrhea caused by other organisms. While travelling, be careful when choosing food and wash, peel or cook it yourself if possible. Drink bottled or boiled water. If possible, wash hands before eating and after using toilet facilities.

As with any vaccine, immunization with DUKORAL[®] may not protect 100% of susceptible persons.

INTERACTIONS WITH THIS VACCINE

Do not eat, drink or take other medicine for 1 hour before and for 1 hour after taking the vaccine. Food and drink taken during this time may prevent the vaccine from working.

PROPER USE OF THIS VACCINE

TO PROTECT AGAINST TRAVELLERS DIARRHEA CAUSED BY ETEC:

Primary vaccination course for adults and children 2 years and older: 2 doses orally (by mouth) at least 1 week (up to 6 weeks) apart. Take the 1st dose no later than 2 weeks before you leave for your trip. Take the 2nd dose at least 1 week after the 1st dose and at least 1 week before your trip. It takes about 1 week after the last dose for protection to begin.

Protection against diarrhea caused by ETEC starts about 1 week after the 2nd dose and lasts for about 3 months. If you wait more than 6 weeks between the 1st and 2nd dose, you will have to start again with the 1st dose.

Booster: If you had your last dose of the vaccine between 3 months and 5 years before, a single dose will renew your protection. If more than 5 years has passed since your last dose, you should have the complete primary vaccination course (2 doses) again.

TO PROTECT AGAINST CHOLERA:

Primary vaccination course for adults and children

6 years and older: Take 2 doses orally (by mouth) at least 1 week (up to 6 weeks) apart. Take the 2nd dose at least 1 week after the first dose and at least 1 week before your trip. It takes about 1 week after the last dose for protection to begin. Protection against cholera lasts for about 2 years. If you wait more than 6 weeks between the 1st and 2nd dose, you will have to start again with the 1st dose.

Booster for adults and children over 6 years: If you had your last dose of the vaccine between 2 and 5 years before, a single dose will renew your protection. If more than 5 years has passed since your last dose, you should have the complete primary vaccination course (2 doses) again.

Primary vaccination course for children 2 to 6

years: Give 3 doses orally (by mouth) at least 1 week (up to 6 weeks) apart and finishing at least 1 week before the trip.

Give the 1st dose at least 3 weeks before the trip, the 2nd dose at least 1 week after the 1st dose, and the 3rd dose at least 1 week after the 2nd dose. It takes about 1 week after the last dose for protection to begin. Protection against cholera will last for about 6 months. If more than 6 weeks elapse between any of the doses, the child will have to start again with the 1st dose.

Booster for children 2 to 6 years: If the child had the last dose of the vaccine between 6 months and 5 years before, a single dose will renew protection. If more than 5 years has passed since the last dose, complete primary vaccination course (3 doses) is recommended.

Important Information about Taking DUKORAL[®]:

The vaccine has to be taken mixed with a buffer solution to protect it from the stomach acid. Use only cool water to prepare the buffer solution. Do not use any other liquid.

Do not eat or drink for 1 hour before and for 1 hour after taking the vaccine.

Do not take any other medicine orally (by mouth) for 1 hour before and 1 hour after taking the vaccine.

Follow the directions for proper mixing as shown below. It is important to follow these instructions to make sure the vaccine works.

How to take DUKORAL®:



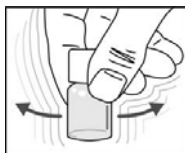
Step 1: Prepare the buffer solution:

Open the buffer sachet and dissolve the granules in 5 oz (150 mL) of cool water.

Do not use any other liquid.

For adults and children 6 years and older - proceed to Step 2.

For children 2 to 6 years - pour away half of the solution before proceeding to Step 2.



Step 2: Shake the vaccine vial

Shake the small glass vial that contains the vaccine to mix it well.



Step 3: Mix the vaccine with the buffer solution

Open one vial and add the vaccine to the buffer solution (water and granule mixture) in the glass. Stir well and drink this mixture immediately.

If the mixture is not drunk immediately, it should be consumed within 2 hours of mixing. Keep it at room temperature.

Your doctor or pharmacist will tell you how to take this vaccine. **Follow their directions carefully. If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.**

When to take DUKORAL®:

It is important to take DUKORAL® at the right time to make sure you will be protected against travellers' diarrhea and cholera.

Make sure that you take each of the doses at least 1 week (up to 6 weeks) apart.

Make sure that you take the last dose of vaccine at least 1 week before leaving on your trip.

Missed Dose

You can take the 2nd dose of DUKORAL® up to 6 weeks after the 1st dose (children 2 to 6 years have to take 3 doses to protect against cholera).

If the 2nd (or 3rd) dose is missed, it can be taken at any time within 6 weeks of the previous dose. Food and drink must be avoided for 1 hour before and for 1 hour after taking the vaccine.

Overdose

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

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of DUKORAL® causing serious harm is extremely small. The small risks associated with DUKORAL® are much less than the risks associated with getting the diseases.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving DUKORAL®.

The side effects of DUKORAL® are usually mild. The most common side effects are gastrointestinal upsets, such as abdominal pain, diarrhea, nausea or vomiting. Some people who receive DUKORAL® may feel feverish. Potentially serious side effects (e.g., dehydration, shortness of breath) are extremely rare.

This is not a complete list of side effects. For any unexpected effects while taking DUKORAL®, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **DO NOT FREEZE DUKORAL®.** Freezing destroys the vaccine.

The vaccine can be stored at room temperature (up to 25°C) for up to two weeks on one occasion only.

After mixing with the buffer solution, the vaccine should be taken within 2 hours.

Do not use after expiration date. **Do not take DUKORAL® after the expiry date printed on the carton.**

to Friday.

This leaflet was prepared by Crucell Sweden AB.

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REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in **your province/territory**.

For the General Public:

Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada

By toll-free telephone: 866-844-0018

By toll-free fax: 866-844-5931

Email: caefi@phac-aspc.gc.ca

Web: <http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

Mail:

The Public Health Agency of Canada

Vaccine Safety Section

130 Colonnade Road, A/L 6502A

Ottawa, ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health-care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

The full product monograph, prepared for health professionals can be found at <http://www.janssen.ca> or by contacting the Canadian vaccine distributor, Crucell Vaccines Canada, a division of Janssen Inc. at 1-800-567-3331 or 1-800-387-8781. Business hours: 8:30 a.m. to 4:30 p.m. Eastern Time, Monday