PACKAGE LEAFLET: INFORMATION FOR THE USER

DUKORAL suspension and effervescent granules for oral suspension
Cholera vaccine (inactivated, oral)

Read all of this leaflet carefully before you start using 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, nurse or pharmacist.
- 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.
- Make sure to mix the vaccine with buffer solution as described in this leaflet. See Section 3.

What is in this leaflet:

1. What Dukoral is and what it is used for
2. What you need to know before you use Dukoral
3. How to use Dukoral
4. Possible side effects
5 How to store Dukoral
6. Contents of the pack and other information

1. What Dukoral is and what it is used for

Dukoral is an oral vaccine against cholera that stimulates the immunological defence in the gut. The vaccine protects adults and children from 2 years of age against cholera.

Dukoral causes your body to produce its own protection against cholera. After getting the vaccine, your body will make substances called antibodies, which fight the cholera bacteria and toxin that cause diarrhoea.

2. What you need to know before you use Dukoral

Do not use Dukoral
- if you are allergic to any ingredient of the vaccine or to formaldehyde.
- if you have an acute stomach disorder or infection with fever (vaccination should be delayed).

Warnings and precautions
Talk to your doctor before taking Dukoral
- if you take a medical treatment that affects the immune system
- if you have a disease of the immune system (including HIV infection).

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

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

Children
Do not give this vaccine to children younger than 2 years since the protection has not been studied in this group.

Other medicines and Dukoral
Please tell your doctor if you are taking or have recently taken any other medicines.

Do not take other medicine starting 1 hour before until 1 hour after taking the vaccine.

Using Dukoral with food and drink
Avoid food and drink starting 1 hour before until 1 hour after the vaccination.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby or are breast-feeding, ask your doctor before taking the vaccine.

Driving and using machines
There are no reasons to suspect that Dukoral will affect your ability to drive or handle machines.

Dukoral contains sodium
Dukoral contains approximately 1.1 g sodium per dose. Please take this into consideration if you are on a controlled sodium diet.

3. How to use Dukoral

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.
Adults and children from 6 years of age: The primary vaccination is 2 doses taken 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.
For continuous protection, re-vaccination is recommended within 2 years. If you had your last dose of vaccine less than 2 years ago a single dose will renew your protection. If more than 2 years have passed since you had the last vaccine dose, the primary vaccination (2 doses) should be repeated.

Children of 2 to below 6 years of age: The primary vaccination is 3 doses taken orally (by mouth) at least 1 week (up to 6 weeks) apart. Only half of the amount of the buffer solution should be mixed with the vaccine.

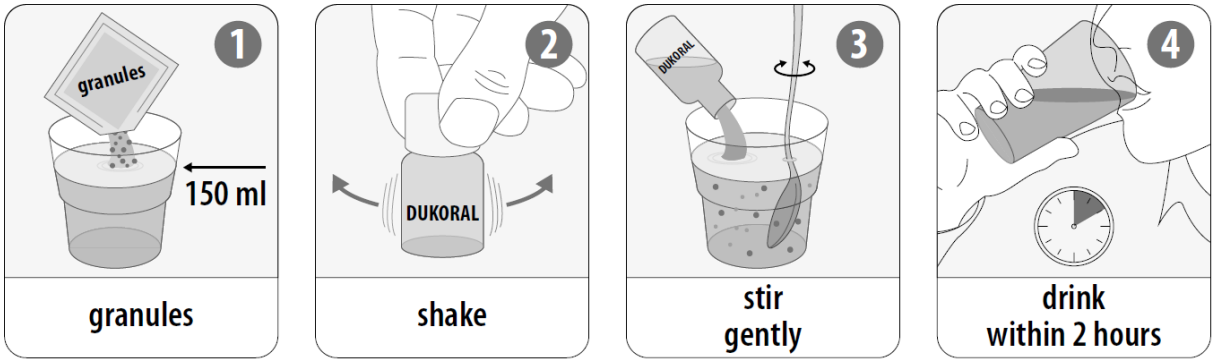
- Give the 1st dose to the child no later than 3 weeks before you leave for your trip.
- Give the 2nd dose to the child at least 1 week after the 1st dose.
- Give the 3rd dose at least one week after the 2nd dose and at least one week before your trip.

It takes about 1 week after the last dose for protection to begin.
For continuous protection, re-vaccination is recommended within 6 months. If less than 6 months have passed since the last vaccination a single dose will renew the protection. If more than 6 months have passed since the last vaccination, the primary vaccination (3 doses) should be repeated.

The suspension supplied in a single-dose glass vial is a whitish suspension. Each vial comes with one sachet package that contains white effervescent granules of sodium hydrogen carbonate. The effervescent granules should be dissolved in a glass of cool water, and the resulting buffer solution should be mixed with the suspension. It is important to use the buffer solution, as it protects the vaccine from the gastric acid.

Drink the entire mixture within 2 hours after mixing with the buffer solution.

Instructions for use:



1. To prepare the buffer solution, dissolve the effervescent granules in a glass of cool water (approx. 150 ml) by gently stirring.
   Do not use any other liquid.
   For children of 2 to below 6 years: pour away half of the buffer solution.

2. Shake the Dukoral® suspension vial (1 vial = 1 dose).

3. Pour the content of the Dukoral® suspension vial into the glass of buffer solution (see 1).
   Mix by gently stirring.

4. Drink the entire mixture within 2 hours. Avoid food and drink starting 1 hour before until 1 hour after drinking the mixture.

If you take more Dukoral than you should
If you take the doses less than one week apart, contact your doctor, pharmacist or nurse.
Because each vial of Dukoral contains only one dose, overdosage is unlikely.
If you have taken more than one dose at one time, please contact your doctor, pharmacist or nurse.

If you forget to take Dukoral.
You can take the 2nd dose of Dukoral up to 6 weeks after the 1st dose (children of 2 to below 6 years have to take 3 doses). If more than 6 weeks have passed, contact your doctor, pharmacist or nurse.

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

4. Possible side effects

Like all medicines, Dukoral can cause side effects, although not everybody gets them.
Contact a doctor immediately if you experience the following serious side effects:
- severe diarrhoea with loss of water from the body
- serious allergic reactions causing swelling of the face or throat and breathlessness

Other side effects:
Uncommon side effects (may affect up to 1 in a 100 people)
- Diarrhoea, stomach pain, stomach cramps, gurgling stomach, bloated stomach, stomach gas and general stomach discomfort
- Headache

Rare side effects (may affect up to 1 in a 1,000 people)
- Fever
- Generally feeling unwell, feeling dizzy
- Nausea (feeling sick), vomiting, loss of /or poor appetite
- Swelling irritation inside the nose, and cough

Very rare side effects (may affect up to 1 in a 10,000 people)
- Rash
- Sore throat, reduced sense of taste
- Fatigue/feeling tired
- Sweating, shivering
- Joint pain
- Difficulty in sleeping

Other side effects (frequency cannot be estimated from the available data)
- Flu -like symptoms, chestiness, chills, general pain, weakness
- Hives, itching
- Swelling of the lymph glands
- Numbness or pins and needles
- High blood pressure

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or
Apple App Store.
Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
Malta
ADR Reporting
www.medicinesauthority.gov.mt/adrportal

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

5. How to store Dukoral

Keep this medicine out of the sight and reach of children.
Do not use Dukoral after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C – 8°C). Do not freeze.

Product in the unopened vial and sachet, stored in the outer carton, is stable at temperatures up to 25ºC for a period of 14 days. At the end of this period the product should be used or discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dukoral contains

- The active substances are:
  $31.25x10^9$ bacteria* of each of the following *V. cholerae* O1 strains: Inaba classical biotype (heat inactivated), Inaba El Tor biotype (formalin inactivated), Ogawa classical biotype (heat inactivated), Ogawa classical biotype (formalin inactivated).
  Recombinant cholera toxin B subunit (rCTB) 1 mg.
  *bacterial content prior to inactivation

- The other ingredients in the vaccine suspension are sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride and water for injections.

- The effervescent granules contain sodium hydrogen carbonate, citric acid, sodium carbonate, saccharin sodium, sodium citrate and raspberry flavour.

What Dukoral looks like and contents of the pack
Dukoral is presented as a suspension and effervescent granules for oral suspension. The suspension is a whitish suspension supplied in a vial. The effervescent granules are white with a raspberry flavour and are supplied in a sachet.

Dukoral is available in packs of 1, 2 and 20 doses. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Valneva Sweden AB, 105 21 Stockholm, Sweden.
infodukoral@valneva.com

This leaflet was last revised in 07/2018.

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu
This leaflet is available in all EU/EEA languages on the European Medicines Agency website.