

Registration No.1C 31/58 (NB)

Importer / Manufacturer: Biogenetech Co., Ltd. / Valneva Sweden AB

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

DUKORAL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

I Vaccine, one dose (3 ml) contains:

Vibrio cholerae O1 Inaba and Ogawa, classic and El Tor strains, approximately 1.25×10^{11} bacteria (heat/formalin inactivated), cholera toxin B subunit 1 mg, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride, sterile water.

II Sodium hydrogen carbonate, one sachet (5.6 g) contains:

Sodium hydrogen carbonate, citric acid, sodium carbonate, saccharin sodium, sodium citrate, raspberry flavour.

The vaccine is a beige opalescent suspension in a single-dose glass bottle. The sodium hydrogen carbonate is supplied as white effervescent granules with a raspberry flavour, which should be dissolved in a glass of water.

Each dose of vaccine is supplied with one sachet of sodium hydrogen carbonate.

3. PHARMACEUTICAL FORM

Oral suspension (vaccine) and effervescent granules (buffer).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Protection against cholera and ETEC-diarrhoea.

Cholera: The vaccine is recommended for adults and children from 2 years of age who will be visiting areas with an ongoing or anticipated epidemic or who will be spending an extended period of time in areas in which cholera infection is a risk.

ETEC: The vaccine is recommended for adults and children from 2 years of age who will be visiting areas posing a great risk of diarrhoeal illness caused by enterotoxigenic *Escherichia coli* (ETEC).

4.2 Posology and method of administration

Cholera:

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 at least 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 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 at least 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.

ETEC:

Adults and children:

The primary vaccination is 2 doses taken orally (by mouth) at least 1 week (up to 6 weeks) apart.

- Take the 1st dose at least 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.

4.3 Contraindication

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).

4.4 Special warnings and precautions for use

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 AIDS). 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.

4.5 Interaction with other medical products and forms of interaction

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.

4.6 Pregnancy and lactation

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.

4.7 Effects on the ability to drive and use machines

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

4.8 Undesirable 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

4.9 Overdose

If you take the doses less than one week apart, contact your doctor, pharmacist or nurse.

Because each bottle 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The vaccine stimulates the immunological defence in the intestinal tract and gives protection against cholera and ETEC-diarrhoea. The ETEC-bacterium is one of the most common causes of “travellers’ diarrhoea”. The occurrence of ETEC varies a lot between different geographical areas. Satisfactory protection against cholera and ETEC diarrhoea can be expected about one week after basic immunisation is concluded.

5.2 Pharmacokinetic properties

N/A

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride, sterile water, Sodium hydrogen carbonate, citric acid, sodium carbonate, saccharin sodium, sodium citrate, raspberry flavour.

6.2 Incompatibilities

N/A

6.3 Shelf life

12 months

6.4 Special precautions for storage

Store at 2°C – 8°C (in a refrigerator). Do not freeze.

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

After reconstitution the vaccine should be drunk within 2 hours.

Keep out of the reach and sight of children.

Do not use Dukoral after the expiry date which is stated on the carton.

6.5 Nature and contents of container

N/A

6.6 Special precautions for disposal and other handling

N/A

7. MARKETING AUTHORISATION HOLDER

Biogenetech Co., Ltd.

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8. MARKETING AUTHORISATION NUMBER(S)

1C 31/58 (NB)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

November 10, 2015

10. DATE OF REVISION OF THE TEXT

June 1, 2016