DUKORAL®

Prescribing Information: DUKORAL® suspension and effervescent granules for oral suspension cholera vaccine (inactivated, oral). **Presentation:** Each dose of vaccine suspension (3ml) contains a total of 1.25 x 10^{11} bacteria of the following strains: *Vibrio cholerae* O1 Inaba, classical biotype (heat inactivated) 31.25 x 10^9 bacteria, *Vibrio cholerae* O1 Inaba, El Tor biotype (formalin inactivated) 31.25x 10^9 bacteria, *Vibrio cholerae* O1 Ogawa, classical biotype (heat inactivated) 31.25x 10^9 bacteria, *Vibrio cholerae* O1 Ogawa, classical biotype (formalin inactivated) 31.25x 10^9 bacteria. Recombinant cholera toxin B subunit (rCTB) 1mg. **Indications:** Active immunisation against disease caused by *Vibrio cholerae* serogroup O1 in adults and children from 2 years of age who will be visiting endemic/epidemic areas. **Dosage:** Standard primary course for adults and children aged over 6 years: 2 doses; Children 2 to 6 years of age should receive 3 doses. Doses are to be administered at intervals of at least 1 week but less than 6 weeks apart. If more than 6 weeks have elapsed between doses, the primary immunisation course should be re-started. Immunisation should be completed at least 1 week prior to potential exposure to *Vibrio cholerae* O1. **Administration:** The effervescent granules should be dissolved in approximately 150ml of cool water. The vaccine bottle should be shaken gently and the vaccine suspension should then be added to the buffer solution and mixed well to obtain a colourless slightly opalescent solution. Children 2 to 6 years of age: half of the buffer solution is poured away and the remaining part (approximately 75ml) is mixed with the entire contents of the vaccine bottle. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients or formaldehyde. Administration of DUKORAL® should be postponed for subjects suffering from acute gastrointestinal illness or acute febrile illness. **Warnings and precautions:** DUKORAL® confers protection specific to *Vibrio cholerae* serogroup O1. Immunisation does not protect against V. cholerae serogroup O139 or other species of Vibrio. Administration of DUKORAL® should be postponed for subjects suffering from acute gastrointestinal illness or acute febrile illness. DUKORAL® is not recommended for use in children less than 2 years of age. Formaldehyde is used during the manufacturing process and trace amounts may be present in the final product. Caution should be taken in subjects with known hypersensitivity to formaldehyde. DUKORAL® contains approximately 1.1 g sodium per dose, which should be taken into consideration by patients on a controlled sodium diet. The vaccine does not provide complete protection and it is important to adhere to standard protective measures to avoid cholera. Antibody response in vaccinees with endogenous or iatrogenic immunosuppression may be insufficient. **Interactions:** The vaccine is acid labile. Food and/or drink will increase acid production in the stomach and the effect of the vaccine may be impaired. Consequently, food and drink should be avoided 1 hour before and 1 hour after vaccination. Oral administration of other vaccines and medicinal products should be avoided 1 hour before and 1 hour after vaccination. **Pregnancy and lactation:** No animal data on reproduction toxicity are available. Following careful benefit/risk assessment the vaccine may be administered during pregnancy and to lactating women although no specific clinical studies have been performed to address this issue. **Ability to Drive and Use Machines:** There are no reasons to suspect that DUKORAL® will affect your ability to drive or handle machines. **Undesirable effects:** Uncommon (>1/1,000, <1/100): diarrhoea, abdominal pain, abdominal cramps, stomach/ abdominal gurgling (gas), abdominal discomfort, headache. Rare (>1/10,000, <1/1,000): fever, malaise, nausea, vomiting, loss of /or poor appetite, respiratory symptoms (including rhinitis and cough), dizziness. Very rare (<1/10,000): fatigue/ drowsiness, dyspepsia, shivers, joint pain, sore throat, reduced sense of taste, sweating, insomnia, dehydration, fainting, rash. Prescribers should consult the Summary of Product Characteristics in relation to other side effects reported post marketing (frequency not known). **Special precautions for storage:** Store in refrigerator (2°C – 8°C). Do not freeze. **Package quantities and basic NHS cost:** 2 x 1 dose, basic NHS cost £26.35. **Legal category:** POM. **Marketing authorisation number:** EU/1/03/263/001-003. Marketing authorisation holder: Valneva Sweden AB, S-105 21 Stockholm, Sweden.

For full prescribing information and details of other side effects please refer to the Summary of Product Characteristics which can be found at www.medicines.org.uk/emc

Full prescribing information is available on request from: Medical Information, VALNEVA AUSTRIA GMBH, Campus Vienna Biocenter 3, 1030 Vienna, Vienna, Austria, FB-Nr: FN 389960 x / HG Wien. Telephone: +44 1506 446608. Email: medinfo@valneva.com

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk
Adverse events should also be reported to Valneva via email: safety@valneva.com