



## DUKORAL<sup>®</sup>

Oral, Inactivated Cholera vaccine

**PBS Information:** This product is not listed on the National Immunisation Program (NIP) or the PBS.

Before prescribing, please review Product Information at [www.bioCSL.com/PI](http://www.bioCSL.com/PI)

**MINIMUM PRODUCT INFORMATION. DUKORAL<sup>®</sup>** Oral Inactivated Cholera Vaccine. **INDICATIONS:** Cholera caused by serogroup O1 *Vibrio cholerae*: Active immunisation of adults and children  $\geq 2$  years of age, who will be visiting areas epidemic or endemic for cholera and who are at high risk of infection. **CONTRAINDICATIONS:** Hypersensitivity to active substances, excipients or formaldehyde. Acute gastrointestinal or febrile illness. **PRECAUTIONS:** Does not protect against species other than O1 *V. cholera*; does not necessarily prevent spread of cholera via a vaccinee exposed to *V. cholerae* bacteria; not a sole measure in prevention of cholera outbreaks-clean hygiene practices still required; HIV patients; endogenous or iatrogenic immunosuppression; patients on controlled sodium diet. Pregnancy Category B2. Use in Lactation: Following careful benefit/risk assessment, DUKORAL may be administered to lactating women although no studies conducted. **INTERACTIONS:** Avoid food or drink 1 hour before or after vaccination. Administration of encapsulated oral typhoid vaccine should be separated by  $\geq 8$  hours. Other oral vaccines and medicines avoided 1 hour before or after vaccination. **ADVERSE EFFECTS:** In clinical trials, most frequently reported were abdominal pain, diarrhoea, loose stools, nausea and vomiting, at similar frequencies in vaccine and placebo groups (see full PI). **DOSAGE AND ADMINISTRATION:** Dissolve effervescent granules in 150mL cool water to make buffer solution (pour away 75mL for children 2–6 years). Shake vaccine vial gently and add to buffer solution; mix well and drink. Adults & children  $> 6$  years: 2 doses; Children 2–6 years: 3 doses; administer doses at intervals  $\geq 1$  week. Re-start basic immunisation if  $> 6$  weeks elapse between doses. Booster: Adults and children  $> 6$  years: after 2 years; Children 2–6 years: after 6 months. **PRESENTATION:** Whitish oral liquid suspension (vaccine) in a single dose glass vial with effervescent granules (buffer), in an accompanying sachet. **STORAGE:** Store at 2°C to 8°C. Refrigerate, do not freeze. Based on TGA approved PI dated 9 September 2003, last amended 6 August 2015.

**REFERENCES:** 1. NHMRC, The Australian Immunisation Handbook, 10th Edition, 2013. 2. Jelinek T *et al. Expert Rev. Vaccines* 2008; (7)5:561–567. 3. Zuckerman *et al. Lancet Infect Dis* 2007; 7:521–530. 4. World Health Organisation, Cholera Fact Sheet No. 107, February 2014. Accessed online July 2014. 5. Mattila L *et al. J Travel Med* 1995; 2:77–84. 6. Steffan R *et al. Trav Med Infect Dis* 2003; 1:80–88. Product Information is available from bioCSL (Australia) Pty Ltd. 63 Poplar Road, Parkville, VIC 3052. ABN 66 120 398 067. Medical Information: 1800 642 865. © DUKORAL is a registered trademark of Valneva Sweden AB. © bioCSL is a registered trademark of CSL Limited. Date of preparation: October 2015. DUKO/0915/0034. 12962.

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FACT SHEETS FOR PATIENTS PRESCRIBED DUKORAL<sup>®</sup>



## FACT SHEETS FOR PATIENTS prescribed Dukoral



Information for patients who have been prescribed DUKORAL.  
Not to be left in waiting rooms or public areas.

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Oral, Inactivated Cholera vaccine



## *Are your patients travelling to areas endemic for cholera?*

- ▶ NHMRC recommends cholera vaccination for travellers at increased risk of diarrhoeal disease visiting areas epidemic or endemic for cholera, including:<sup>1</sup>
  - Travellers with inflammatory bowel disease.
  - Travellers with poorly controlled or complicated diabetes.
  - Travellers with impaired immunity.
  - Travellers with significant cardiovascular disease.
  - Travellers with achlorhydria.
- ▶ Additional travellers who may be at risk of exposure to or acquiring cholera include:<sup>2,3</sup>
  - Travellers visiting friends and relatives in an endemic country.
  - Travellers with insufficient access to medical facilities, such as backpackers to remote areas.
  - Long term travellers to endemic areas.
  - Patients taking medication that lowers gastric acidity.
- ▶ WHO estimates that worldwide, there are 3 to 5 million cholera cases and 100,000 to 120,000 deaths due to cholera every year.<sup>4</sup>
- ▶ Whilst careful selection of food and water is key in preventing exposure, travellers may find it difficult to always adhere to this advice.<sup>5</sup>

## *Cholera is likely to be under-reported in travellers<sup>2</sup>*

- ▶ Mild cholera is often clinically indistinguishable from other causes of acute diarrhoea.<sup>3,6</sup>