Oral inactivated cholera vaccine (Dukoral)

Summary

<table>
<thead>
<tr>
<th>PBS listing:</th>
<th>Dukoral is not PBS-listed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason for listing:</td>
<td>Dukoral is not PBS-listed.</td>
</tr>
<tr>
<td>Place in therapy:</td>
<td>Vaccination is not necessary for most travellers because the risk of cholera infection is very low. Avoiding infection by carefully selecting food and drink is most important.</td>
</tr>
<tr>
<td>Safety issues:</td>
<td>Mild and transient gastrointestinal adverse effects are most common.</td>
</tr>
<tr>
<td>Dosing issues:</td>
<td>Basic immunisation in adults and children 6 years and over requires 2 doses given at least one week apart. Protection against cholera develops by 2 weeks after the second dose.</td>
</tr>
</tbody>
</table>

PBS listing

Dukoral is not PBS-listed.

Reason for PBS listing

Dukoral is not PBS-listed.

Place in therapy

Dukoral is an oral cholera vaccine consisting of whole killed *Vibrio cholerae* cells and recombinant cholera toxin B subunit. It has been available in Latin America and some European countries for a number of years, but has only recently been registered in Australia.

Dukoral provides protective efficacy of approximately 85% in the first 6 months after vaccination. In adults and children aged 6 years and over, protective efficacy remains relatively stable for the first 2 years. In children aged 2–5 years, protective efficacy declines markedly after 6 months. Protective efficacy in children under 2 years is unknown.
Cholera vaccination is not necessary for most travellers

Routine cholera vaccination is not necessary, because the risk to most travellers is very low and cholera vaccination is not an official requirement for entry into any country. Vaccination is suggested for people at risk of cholera, such as those visiting rural areas of countries with endemic cholera, or humanitarian relief workers in disaster areas and refugee camps.

Avoiding sources of cholera infection is more important than vaccination. Advise travellers to avoid contact with potentially contaminated food and water (see Information for patients). Infection is also possible through contact with the faeces and vomitus of infected people during the illness and for several days after it has ceased. Steps to avoid cholera infection are still necessary in people who have been vaccinated.

Safety issues

Dukoral is generally well tolerated. Mild and transient gastrointestinal side-effects, such as abdominal cramping and loose stools, are most common.

Refer to the approved product information for information about administering Dukoral at the same time as other vaccines.

Dosing issues

Basic immunisation in adults and children over 6 years requires 2 doses given at least one week apart. Satisfactory protection against cholera develops by 2 weeks after the second dose. Where there is ongoing risk, adults and children over 6 years require a booster dose after 2 years.

For children aged 2-6 years, basic immunisation consists of 3 doses, and a booster is required after 6 months.

Dukoral is not recommended for children under 2 years because its protective efficacy in this population is unknown.

Refer to the approved product information for detailed dosage and administration instructions.

Information for patients

For more detailed information, suggest or provide the Dukoral Consumer Medicine Information (CMI).

Instruct consumers to be aware of steps to avoid cholera infection and manage diarrhoea. Information for consumers about avoiding and treating cholera infection is available on the following websites:

- The Gastroenterological Society of Australia  
- The World Health Organization Department of Communicable Diseases  
  http://w3.who.sea.org/cholera/
- The Australian Government Department of Health and Ageing  
References


Prepared March 2004

The information contained in this material is derived from a critical analysis of a wide range of authoritative evidence. Any treatment decisions based on this information should be made in the context of the individual clinical circumstances of each patient.

NPS is an independent, Australian organisation for Quality Use of Medicines
National Prescribing Service Limited ACN 082 034 393 Level 7 418A Elizabeth Street Surry Hills NSW 2010
Phone: 02 8217 8700 Fax: 02 9211 7578 email: info@nps.org.au web: http://www.npsradar.org.au