



### Millions have safely taken oral cholera vaccines

Killed oral cholera vaccines (OCVs) have been widely used and found to be safe. As per the Global Task Force on Cholera Control, in 2013–2018, a total of 83,509,941 OCV doses have been requested by 24 countries, of which 55,409,160 were approved and 36,066,010 eventually shipped in 83 deployments, resulting in 104 vaccination campaigns in 22 countries. OCVs have had high uptake and no serious adverse events have been reported. OCV Campaigns have been organized quickly (five days median duration). In emergency settings, the longest delay was from the occurrence of the emergency to requesting OCV (median: 26 days). The mean cost of administering one dose of vaccine was 2.98 USD. <sup>1</sup>

### Killed bacterial oral vaccines are generally known to be safe

OCVs consist of killed bacterial cells. There are no living bacteria in the vaccine and thus there is no chance that the bacteria in the vaccine could somehow revert to becoming virulent and cause cholera.

Many years ago, killed whole-cell cholera vaccines were given by injection. These older versions caused muscle soreness and fever. Since the new vaccines are given by mouth, they do not cause these side effects and are inherently safer.

### OCV has been acceptable to people who have taken it

OCV consists of two doses, given about two weeks apart. In vaccine campaigns, most people (70% - 85%) return for the second dose, although some complain about the bad taste. The high rate of return for a second dose indicates that people generally find the vaccine acceptable.

### Use in small children

Shanchol, Euvichol and Euvichol Plus are approved for all persons aged one year and older, while Dukoral can be given starting at age two.

### Use during Pregnancy

As described in Cholera and the Use of OCV in Pregnant Women, oral cholera vaccine can be given to women

who are pregnant when a vaccine campaign is being organized. It is not necessary to exclude pregnant women during a campaign, and there is no need to ascertain the pregnancy status of women being offered vaccine.

Risks for pregnant women who develop cholera include severe dehydration which frequently causes miscarriage, premature delivery and stillbirth.<sup>3,4</sup> Because of the benefits from the vaccine and safety of the vaccine, the World Health Organization recommends that the vaccine be given to pregnant women who are at risk of cholera.<sup>5</sup>

#### Excerpt: Shanchol package insert (2015)

*"No specific clinical studies have been performed to evaluate the safety and immunogenicity of Shanchol in pregnant women and for the fetus. **The vaccine is therefore not recommended for use in pregnancy.** However Shanchol is a killed vaccine that does not replicate, is given orally and acts locally in the intestine. Therefore, in theory, Shanchol should not pose any risk to the human fetus. Administration of Shanchol to pregnant or lactating women may be considered after careful evaluation of the benefits and risk in case of a medical emergency or an epidemic."*

## References

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2. Hashim, R., et. al. Safety of the Recombinant Cholera Toxin B Subunit, Killed Whole-Cell (rBS-WC) Oral Cholera Vaccine in Pregnancy. *PLoS Negl Trop Dis* 2012; 6:e1743.
3. Ciglencecki I, Bichet M, Tena J, Mondesir E, Bastard M, Tran NT et al. Cholera in pregnancy: outcomes from a specialized cholera treatment unit for pregnant women in Léogâne, Haiti. *PLoS Neglected Tropical Diseases* 2013/August; 7(8):e2368.
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