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Vaxchora (*live oral cholera vaccine*)

An overview of Vaxchora and why it is authorised in the EU

What is Vaxchora and what is it used for?

Vaxchora is a vaccine to prevent cholera in adults and children aged from 2 years. Cholera is a disease that is caught from contaminated food or drink and causes severe diarrhoea.

The vaccine contains a weakened form of the cholera bacterium *Vibrio cholerae* (serogroup O1).

How is Vaxchora used?

Vaxchora can only be obtained with a prescription. It should be used according to official recommendations.

The vaccine is made up in water and taken by mouth as a single dose at least 10 days before the person is likely to come into contact with cholera bacteria.

For more information about using Vaxchora, see the package leaflet or contact your doctor or pharmacist.

How does Vaxchora work?

When a person receives Vaxchora, the immune system (the body's defences) recognises the weakened bacteria in the vaccine as foreign and makes antibodies against them. When the person comes into contact with potentially disease-causing cholera bacteria, the immune system will be ready to produce antibodies and in this way remove the bacteria quickly and so prevent cholera disease.

What benefits of Vaxchora have been shown in studies?

A main study involving 197 healthy adults aged 18 to 45 years found that Vaxchora can prevent symptoms of cholera in people coming into contact with cholera bacteria.

In this study, individuals received a single dose of either Vaxchora or placebo (a dummy vaccine) and were then given infectious cholera bacteria (O1 strain). Moderate to severe diarrhoea (a symptom of cholera) occurred in about 6% of those given the cholera bacteria 10 days after Vaxchora and 12% of those given the bacteria 3 months after receiving Vaxchora. By comparison, moderate to severe diarrhoea occurred in 59% of adults who had received placebo.

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Another main study involving 3,022 healthy adults aged 18 to 45 years found that antibodies against cholera bacteria were present after 11 days in 94% of adults who had received Vaxchora compared with 4% in those who received placebo.

Further studies confirmed that giving Vaxchora to adults aged 46 to 64 years or to children and adolescents aged 2 to 18 years was effective at producing antibodies against cholera bacteria.

What are the risks associated with Vaxchora?

The most common side effects with Vaxchora (which may affect more than 1 in 10 people) are tiredness, headache, abdominal (belly) pain, feeling sick, vomiting and loss of appetite.

People who were born with problems with their immune system or are receiving treatment that weakens the immune system must not take Vaxchora.

For the full list of restrictions and side effects of Vaxchora, see the package leaflet.

Why is Vaxchora authorised in the EU?

Vaxchora is effective for protecting vaccinated individuals against moderate and severe cholera disease. Measurement of antibodies after vaccination showed that it is effective in individuals from 2 years of age. The European Medicines Agency noted that evidence from Vaxchora studies is relevant only for travellers visiting areas where cholera is present. It is not known how long the protection lasts. The Agency considered that Vaxchora's side effects are manageable. The Agency therefore decided that Vaxchora's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Vaxchora?

The company that markets Vaxchora will provide a guide for healthcare professionals and a patient guide on how to make up and take the vaccine to avoid medication errors, especially in children aged 2 to 6 years.

Recommendations and precautions to be followed by healthcare professionals and those taking the vaccine for the safe and effective use of Vaxchora have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Vaxchora are continuously monitored. Side effects reported with Vaxchora are carefully evaluated and any necessary action taken to protect those taking the vaccine.

Other information about Vaxchora

Vaxchora received a marketing authorisation valid throughout the EU on 1 April 2020.

Further information on Vaxchora can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vaxchora.

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