



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Vaxchora: avoiding errors when making up and using the vaccine

Vaxchora, an oral cholera vaccine, is authorised for use in the EU. The vaccine is supplied as a powder and the person taking it needs to make it up in water before taking it. The vaccine's effectiveness may be affected if the instructions in the package leaflet on preparing the vaccine are not followed correctly. Therefore, together with the summary of product characteristics for healthcare professionals and the package leaflet for the person taking Vaxchora, additional information will be provided to doctors and those taking the vaccine on the correct way to make up the vaccine and take it.

Each pack of the vaccine includes two sachets: one, labelled '1', containing a powder to make up a buffer solution and the other, labelled '2', containing a powder of the vaccine.

Information for people taking Vaxchora

- Store Vaxchora in the refrigerator until you are ready to take it.
- Follow the step-by-step instructions given to you for making up Vaxchora, particularly on the order in which you use the sachets to make up the vaccine.
- To make up the vaccine, you must use 100 ml of non-carbonated ('still') bottled water (either out of the refrigerator or at room temperature). Do not use tap water.
- Do not let the powder or the vaccine liquid come into contact with your skin or eyes. If you touch the vaccine wash the area with soap and hot water.
- If any liquid or powder is spilled do not take the vaccine and get a replacement dose. Clean the spillage with soap (or an antibacterial disinfectant) and hot water.
- Do not eat or drink anything 1 hour before and 1 hour after you take the vaccine.
- Drink all the vaccine liquid within 15 minutes of preparing it. Some solids may get left behind, which must be thrown away.
- Throw away the empty sachets and waste material according to local biosafety guidelines. Ask your doctor, pharmacist or nurse how to throw away medicine waste material. Wash your hands with soap and water after you have taken the vaccine.
- Speak with your doctor, pharmacist or nurse if you have any questions or need more advice on making up and taking Vaxchora.

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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Information for healthcare professionals

- There is a risk of errors with the reconstitution and use of Vaxchora. People taking the vaccine must follow carefully the instruction in the package leaflet.
- Healthcare professionals should make sure that people taking the vaccine receive the package leaflet (with detailed instructions on reconstituting the vaccine) and a patient/carer guide.
- Healthcare professionals should counsel people taking the vaccine (or carers) on how to reconstitute and take Vaxchora. In particular, those taking the vaccine should understand the need for:
 - correct storage until the vaccine is reconstituted and taking it promptly after reconstitution;
 - using the sachets in the correct order for reconstitution;
 - taking the vaccine dose at least an hour away from food and drink;
 - correct cleansing or disposal of materials used to reconstitute and take the vaccine according to local biosafety guidelines.
- Healthcare professionals should report any medication errors through the national reporting system.

More about the medicine

Vaxchora is a vaccine for immunisation against disease caused by *Vibrio cholerae* serogroup O1. It contains a weakened form of the cholera bacterium *Vibrio cholerae* (serogroup O1) and is given as a single dose at least 10 days before potential exposure to cholera bacteria.

More information on Vaxchora can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/vaxchora