

Annex A

<u>MA (EU) number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EU/1/03/263/001	Dukoral	-- ¹	Suspension and effervescent powder for oral suspension	Oral use	vaccine: vial (glass); powder: sachet (PE/alu)	vaccine: 3 ml; sachet: 5.6 g	1 vial + 1 sachet
EU/1/03/263/002	Dukoral	-- ¹	Suspension and effervescent powder for oral suspension	Oral use	vaccine: vial (glass); powder: sachet (PE/alu)	vaccine: 3 ml; sachet: 5.6 g	2 vials + 2 sachets
EU/1/03/263/003	Dukoral	-- ¹	Suspension and effervescent powder for oral suspension	Oral use	vaccine: vial (glass); powder: sachet (PE/alu)	vaccine: 3 ml; sachet: 5.6 g	20 vials + 20 sachets

--¹ Each dose of vaccine suspension (3 ml) contains:

- A total of 1.25×10^{11} bacteria of the following strains:

Vibrio cholerae O1 Inaba, classical biotype (heat inactivated) 31.25x10⁹ bacteria

Vibrio cholerae O1 Inaba, El Tor biotype (formalin inactivated) 31.25x10⁹ bacteria

Vibrio cholerae O1 Ogawa, classical biotype (heat inactivated) 31.25x10⁹ bacteria

Vibrio cholerae O1 Ogawa, classical biotype (formalin inactivated) 31.25x10⁹ bacteria

- Recombinant cholera toxin B subunit (rCTB) 1 mg