

BioBhyo \geq 1 RP - Emulsion for injection

Authorised

- Brachyspira hyodysenteriae, strain AqDysH57, Inactivated

Product identification

Medicine name:

BioBhyo \geq 1 RP - Emulsion for injection

Active substance:

Brachyspira hyodysenteriae, strain AqDysH57, Inactivated

Target species:

Pig

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Brachyspira hyodysenteriae, strain AqDysH57, Inactivated

Presentation_strength:1 RP Reference:HSE Index:0

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:**Intramuscular use:**

-

Pig

- Meat. 0 day
Zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI09AB

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Package description:

Packaging: Bottle (Flexipack HDPE), Package_size: 1 bottle, Content: 250 ml (125 doses)

Packaging: Bottle (Flexipack HDPE), Package_size: 1 bottle, Content: 100 ml (50 doses)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application - new active substance (Article 8 of Regulation (EU) 2019/6)

Marketing authorisation holder:

Aquilon Cyl S.L.

Marketing authorisation date:

30/07/2025

Manufacturing sites for batch release:

CZ Vaccines S.A.U.

Responsible authority:

European Commission

Authorisation number:

This information is not available for this product.

Date of authorisation status change:

30/07/2025

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

English (PDF)

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ema-puar-v6336-biobhyo-initial-en.pdf