ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBhyo emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Brachyspira hyodysenteriae, strain AqDysH57, inactivated RP* ≥ 1

*RP: relative potency determined by ELISA in rabbit serum.

Adjuvants:
Montanide IMS 251 C VG 0.4 ml

Excipients:

Qualitative composition of excipients and other constituents
Sodium acetate 0.1 M
Water for injections

Whitish emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening)

3.2 Indications for use for each target species

For the active immunisation of pigs for fattening to reduce the occurrence of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae.*

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 18 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature [1] Injection site erythema [2], injection site swelling [2] Injection site nodule [3]
Common (1 to 10 animals / 100 animals treated):	Loss of condition score [4], depression [4] Lameness [5]

1 Up to 2.8°C (mean increase 0.7°C), within 4 hours after administration, for up to 24 hours.
2 Mild, resolves within 2-4 days.
3 Up to 10 cm in diameter, resolves within 1-4 days.
4 Mild or moderate, up to 14 days.
5 Up to 14 days after inoculations, resolves within 7 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Safety during pregnancy and lactation has been demonstrated.
The efficacy of the veterinary medicinal product has not been established during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Intramuscular use.

Administer the first dose of 2 ml to pigs from 5 weeks of age onwards and a second dose 2 weeks later.
Administer in the deep neck muscles. Preferably administer each dose on different side of the neck.

Before use, allow the vaccine to reach room temperature.
Shake well before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB

For active immunisation against genetically diverse virulent strains of *Brachyspira hyodysenteriae* in pigs.

The efficacy of the vaccine is based on studies performed in fattening pigs under field conditions. The data have shown a reduction of cases of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae* in vaccinated fattening pigs when compared with non-vaccinated fattening pigs at the end of the fattening period.

The fact that vaccinated animals had higher antibody levels and a lower frequency of disease than unvaccinated animals suggest a relationship between high antibody levels and the (lower) likelihood of developing a clinical disease. The onset of immunity was defined based on these serological data.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) nitril bottle closed with nitrile rubber stopper and aluminium seal.

Pack sizes:
Cardboard box with 1 bottle of 50 doses (100 ml).
Cardboard box with 1 bottle of 125 doses (250 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Aquilón CyL S.L.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/348/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/07/2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

100 ml or 250 ml CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBhyo emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Brachyspira hyodysenteriae strain AqDysH57, Inactivated RP* ≥ 1
*RP: relative potency determined by ELISA in rabbit serum

3. PACKAGE SIZE

100 ml (50 doses)
250 ml (125 doses)

4. TARGET SPECIES

Pigs (for fattening)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Aquilón CyL S.L.

14. MARKETING AUTHORISATION NUMBERS

EU/2/25/348/001-002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml or 250 ml BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioBhyo emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
Brachyspira hyodysenteriae strain AqDysH57, inactivated RP* ≥ 1
*RP: relative potency determined by ELISA in rabbit serum

3. TARGET SPECIES

Pigs (for fattening)

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Aquilón CyL S.L.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BioBhyo emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:
Brachyspira hyodysenteriae strain AqDysH57, inactivated RP*≥1
*RP: relative potency determined by ELISA in rabbit serum.

Adjuvants: Montanide IMS 251 C VG 0.4 ml

Excipients:

Qualitative composition of excipients and other constituents
Sodium acetate 0.1 M
Water for injections

Whitish emulsion.

3. Target species

Pigs (for fattening)

4. Indications for use

For the active immunisation of pigs for fattening to reduce the occurrence of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae.*

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 18 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
Safety during pregnancy and lactation has been demonstrated.
The efficacy of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Elevated temperature [1] Injection site erythema [2], injection site swelling [2] Injection site nodule [3]
Common (1 to 10 animals / 100 animals treated):	Loss of condition score [4], depression [4] Lameness [5]

1 Up to 2.8°C (mean increase 0.7°C), within 4 hours after administration, for up to 24 hours.
2 Mild, resolves within 2-4 days.
3 Up to 10 cm in diameter, resolves within 1-4 days.
4 Mild or moderate, up to 14 days.
5 Up to 14 days after inoculations, resolves within 7 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramuscular use.

Administer the first dose of 2 ml to pigs from 5 weeks of age onwards and a second dose 2 weeks later.
Administer in the deep neck muscles. Preferably administer each dose on different side of the neck.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature.
Shake well before use.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/348/001-002

Pack sizes:
Cardboard box with 1 bottle of 50 doses (100 ml).
Cardboard box with 1 bottle of 125 doses (250 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Aquilón CyL S.L.
Facultad de Veterinaria
Campus de Vegazana s/n
24007 León
Spain

Manufacturer responsible for batch release:

CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain

Contact details to report suspected adverse events:

AEGISANA S.L.
Carretera de Fuencarral 22
28108 Alcobendas
Madrid
Spain
Tel: +34 610 01 64 03
E-mail: pharmacovigilance@aegisana.com

17. Other information

After intramuscular vaccination of pigs, this vaccine stimulates a protective response against genetically diverse virulent strains of *Brachyspira hyodysenteriae.*

The efficacy of the vaccine is based on studies performed in fattening pigs under field conditions. The data have shown a reduction of cases of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae* in vaccinated fattening pigs when compared with non-vaccinated fattening pigs at the end of the fattening period.

The fact that vaccinated animals had higher antibody levels and a lower frequency of disease than unvaccinated animals suggest a relationship between high antibody levels and the (lower) likelihood of developing a clinical disease. The onset of immunity was defined based on these serological data.