ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUDAIR Emulsion for injection for sheep and goats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL dose contains:

Active substance:
Mycobacterium paratuberculosis inactivated, strain 316F ≥ 2 mm ITT avian PPD*

*Increase of the skin thickness in the intradermal tuberculin test in sheep with avian protein derivative and in comparison with bovine protein derivative.

Adjuvants:
Marcol 52_____0,38 mL
Montanide 103_____0,021 mL
Montane 80_____0,021 mL

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition per 1mLdose**
Polysorbate 80	0.014 mL
Thiomersal	0.1 mL
Phosphate buffer saline	
Water for injections	

The appearance GUDAIR is of a milky white homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and goat.

3.2 Indications for use for each target species

Active immunisation of sheep and goats to reduce clinical signs, lesions and mortality caused by *M. paratuberculosis*. It also reduces *M. paratuberculosis* faecal shedding.

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:

Use uninterruptedly once the extraction of the content is initiated.

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

Sheep and goat:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Injection site nodule[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reactions[3]
Undetermined frequency (cannot be estimated from the available data)	Allergic reaction [4]

[1] Gradually evolves into a persistent cold, fibrous nodule.
[2] Nodule can be detected at 1-2 weeks post vaccination with medium size of approximately 2 cm in sheep and goats, reaching a mean maximum size of 3.5 cm in sheep and 4 cm in goats at 2 months post vaccination, decreasing until 1 year after vaccination.
Rarely, the diameter can reach values greater than 5 cm at 2 months after vaccination. Palpable lesions can be observed in the 20-25% of the sheep at 4 years post vaccination.
Nodules disappear normally without treatment.
[3]In case of hypersensitivity administer a suitable antihistamine therapy without delay.
[4]A more intense local reaction is observed when the vaccine is inoculated to infected animals (secondary antigenic impact).

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

The safety of the veterinary medicinal product has not been established during pregnancy or 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

Dosage: 1 mL
Subcutaneous use.
Shake well before use.

Vaccination schedule:
Administer one dose of vaccine to all replacement animals between 2-3 weeks and six months of age, so that it is recommended to vaccinate them as soon as posible. In affected or at risk flocks and herds or groups of animals, the vaccination should be carried out on all individuals, including adult animals.

In general, it is not necessary to revaccinate.

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

It does not provoke adverse reactions different from those produced by the vaccination with a single dose or with an overdose with a double dose and stated in point 3.6.

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

For administration only by a veterinarian.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI04AB09 and QI03AB01

Vaccination sensitises animals against johnin PPD (Purified Protein Derivative of *Mycobacterium avium* subsp. *paratuberculosis*), avian tuberculin PPD (derivative of *Mycobacterium avium*) and to lesser extend bovine tuberculin PPD (derivative of *Mycobacterium bovis*). The reaction against avian tuberculin PPD is more intense than against bovine tuberculin PPD and clearly distinguishable.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 (2º C - 8º C). Protect from light. Do not freeze.

5.4 Nature and composition of immediate packaging

Type II Glass bottles (according to the Ph. Eur.) of 30 mL (30 doses) with rubber-nitrile stopper and aluminium seal.

Package size:
Card box with 1 glass bottle of 30 mL (30 doses).

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

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

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

2792 ESP

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 02/02/1994

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

01/2023

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).

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Card box of 1 glass bottle of 30 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUDAIR Emulsion for injection for sheep and goats.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1mL dose contains:

Active substance:

Mycobacterium paratuberculosis inactivated, strain 316F	≥ 2 mm ITT avian PPD*

*Increase of the skin thickness in the intradermal tuberculin test in sheep with avian protein derivative and in comparison with bovine protein derivative.

Adjuvant(s):

Mineral oil (Marcol 52)	0.38 mL
Montanide 103	0.021 mL
Montane 80	0.021 mL

Excipient(s):

Thiomersal	0.1 mL

3. PACKAGE SIZE

30 mL (30 doses)

4. TARGET SPECIES

Sheep and goat

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.
Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated. Protect from light. Do not freeze.

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

CZ Vaccines S.A.U.
36410 O Porriño – Spain

14. MARKETING AUTHORISATION NUMBERS

Reg. No.: 2792 ESP

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 30 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUDAIR

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Mycobacterium paratuberculosis inactivated, strain 316F ≥ 2 mm ITT avian PPD*

*Increase of the skin thickness in the intradermal tuberculin test in sheep with avian protein derivative and in comparison with bovine protein derivative.

Dosage: 1 mL

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

GUDAIR Emulsion for injection for sheep and goats

2. Composition

Each 1mL dose vaccine contains:

Active substance:

Mycobacterium paratuberculosis inactivated, strain 316F	≥ 2 mm ITT avian PPD*

*Increase of the skin thickness in the intradermal tuberculin test in sheep with avian protein derivative and in comparison with bovine protein derivative.

Adjuvants:

Mineral oil (Marcol 52)	0.38 mL
Montanide 103	0.021 mL
Montane 80	0.021 mL

Excipients:

Polysorbate 80
Thiomersal
Phosphate buffered saline
Water for injections

Milky white homogeneous emulsion.

3. Target species

Sheep and goat

4. Indications for use

Active immunisation of sheep and goats to reduce clinical signs, lesions and mortality caused by *M. paratuberculosis*. It also reduces *M. paratuberculosis* faecal shedding.

5. Contraindications

None.

6. Special warnings

Special warnings for each target species:

Vaccinate healthy animals only.

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Special precautions for safe use in the target species

Shake well before use and use uninterruptedly once the extraction of the content is initiated.

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.
Other precautions:
Vaccination sensitises animals against johnin PPD (Purified Protein Derivative of *Mycobacterium avium* subsp. *paratuberculosis*), avian tuberculin PPD (derivative of *Mycobacterium avium*) and to lesser extend bovine tuberculin PPD (derivative of *Mycobacterium bovis*). The reaction against avian tuberculin PPD is more intense than against bovine tuberculin PPD and clearly distinguishable
Pregnancy and lactation:

The safety 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.

Overdose:

It does not provoke adverse reactions different than those produced by the vaccination with a single dose or with a double dose and stated in point 7.

Special precautions for the protection of the environment

Not applicable

Special restrictions for use and special conditions for use

For administration only by a veterinarian.

Major incompatibilities

In the absence of incompatibility studies , this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Sheep and goat:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Injection site nodule[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reactions[3].
Undetermined frequency (cannot be estimated from the available data)	Allergic reaction [4]

[1] Gradually evolves into a persistent cold, fibrous nodule.
[2] Nodule can be detected at 1-2 weeks post vaccination with medium size of approximately 2 cm in sheep and goats, reaching a mean maximum size of 3.5 cm in sheep and 4 cm in goats at 2 months post vaccination, decreasing until 1 year after vaccination.
Rarely, the diameter can reach values greater than 5 cm at 2 months after vaccination. Palpable lesions can be observed in the 20-25% of the sheep at 4 years post vaccination.
Nodules disappear normally without treatment.
[3]In case of hypersensitivity administer a suitable antihistamine therapy without delay.
[4]A more intense local reaction is observed when the vaccine is inoculated to infected animals (secondary antigenic impact).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinarian 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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}*[listed in Appendix I*]*>.

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

Dosage: 1 mL
Subcutaneous use.

9. Advice on correct administration

Avoid administration in the areas of support and rubbing.

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).
Protect from light. Do not freeze.

Shelf-life after first opening the immediate packaging: immediate use,
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.

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 veterinarian 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

Package size:
Card box with 1 glass bottle of 30 mL (30 doses).

15. Date on which the package leaflet was last revised

01/2023

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 and 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 reactions:

Phone number: +34 608 79 45 33
Alternatively: +36 986 33 04 00
e-mail: pharmacovigilance@czvaccines.com

Local representatives and contact details to report suspected adverse reactions:

Phone number: +34 608 79 45 33
Alternatively: +36 986 33 04 00
e-mail: pharmacovigilance@czvaccines.com