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 dose (1ml) of the 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.

Adjuvant(s):

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

Excipients:

Thiomersal	0.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Milky white homogeneous emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and goats.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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.

4.5 Special precautions for use

Special precautions for use in animals
Use uninterruptedly once the extraction of the content is initiated.
Shake well before use.

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

To the user:
This 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur in rare cases. In this case, administer a suitable antihistamine therapy without delay. The vaccine produces swelling at the injection site which gradually becomes a persistent, fibrous and cold nodule. This event is very common.
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.
In those cases where the vaccine is inoculated to infected animals (secondary antigenic impact), it can be observed a more intense local reaction.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated cases).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

Dosage: 1 mL
Subcutaneous route.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines against paratuberculosis in sheep and goats.

ATCvet code: QI04AB09 and QI03AB01

For stimulating the active immunity against *Mycobacterium paratuberculosis* in sheep and goats

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Marcol oil 52
Montanide 103
Montane 80
Polysorbate 80
Thiomersal
Phosphate buffered saline
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

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

6.4. Special precautions for storage

Store and transport refrigerated between (2º C - 8º C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Type II Glass bottles (according to the Eur. Ph.) 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).

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.
La Relva s/n - Torneiros
36410 Porriño (Pontevedra)
Spain

8. MARKETING AUTHORISATION NUMBER(S)

2792 ESP

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02/02/1994

Date of renewal: November, 2018

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of dispensing: **Medicine subject to veterinary prescription**
Conditions of administration: **Administration under control or supervision of a veterinary surgeon.**

LABELLING AND PACKAGE LEAFLET

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 dose (1ml) of the 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.

Adjuvant(s):

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

Excipients:

Thiomersal	0.1 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

30 mL (30 doses)

5. TARGET SPECIES

Sheep and goats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {Month/Year}
Once open, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Eliminate any residue in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription
Administration under control or supervision of a veterinary surgeon

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CZ Veterinaria, S.A.
36410 Porriño (Pontevedra)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Reg. No.: 2792 ESP

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 30 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUDAIR

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Dosage: 1 mL
30 mL (30 doses)

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous route

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {Month/Year}
Once opened, use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET:
GUDAIR
Emulsion for injection for sheep and goats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible of batch release:
CZ Veterinaria, S.A.
La Relva s/n - Torneiros
36410 Porriño (Pontevedra)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GUDAIR
Emulsion for injection for sheep and goats

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose (1ml) of the 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.

Adjuvant(s):

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

Excipients:

Thiomersal	0.1 mg

Milky white homogeneous emulsion.

4. INDICATION(S)

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. ADVERSE REACTIONS

Hypersensitivity reactions may occur in rare cases. In this case, administer a suitable antihistamine therapy without delay.

The vaccine produces swelling at the injection site which gradually becomes a persistent, fibrous and cold nodule. This event is very common.
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.
Occasionally, 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.
In those cases where the vaccine is inoculated to infected animals (secondary antigenic impact), it can be observed a more intense local reaction.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Sheep and goats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: 1 mL
Subcutaneous route.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid administration in the areas of support and rubbing.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport in fridge between (2º C - 8º C). Protect from light. Do not freeze.
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: immediate use,
Do not use this medicine after the shelf-life indicated in the card box and label after CAD or EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

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.

Special precautions for use in animals:

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 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 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 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.

Use during pregnancy, lactation or lay:

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

Interactions with other medicaments or other interaction forms:

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 (symptoms, emergency procedures, antidotes):

It can't be observed any different adverse reactions produced by a single dose or because of an overdose, than those indicated in point 6.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinarian or pharmacist how to dispose of medicines no longer required.
These measures are designed to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2018.

15. OTHER INFORMATION

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

Conditions of dispensing: **Medicine subject to veterinary prescription**
Conditions of administration: **Administration under control or supervision of a veterinary surgeon.**