

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

16. MARKETING AUTHORISATION NUMBER(S)

Reg. No.: 2792 ESP

17. MANUFACTURER'S BATCH NUMBER
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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

