PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gudair Emulsion for Injection for Sheep and Goats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (1ml) of the vaccine contains:

Active substance:
Mycobacterium paratuberculosis inactivated, strain 316F: ≥ 2 mm ITT avian PPD* (2.5 mg)

Mineral oil adjuvant, thiomersal.

**PPD=Purified Protein Derivative*

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

5. TARGET SPECIES

Sheep and goats

6. INDICATION(S)

For the active immunisation of sheep and goats to stimulate cell-mediated and humoral immunity against M. *avium* subsp. *paratuberculosis* infection, as an aid in the control of Johne's disease in those species.

This is a Limited Marketing Authorisation. A full set of supporting efficacy data are not available for this product.

Further information on this product and its supporting data can be found on http://www.vmd.gov.uk/ProductInformationDatabase/

No information on onset of immunity or duration of immunity is available for this product.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route

Read the package leaflet before use.

Shake well before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

Shelf life after first opening the immediate package: 35 days

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2 °C and +8 °C.
Protect from light.
Do not freeze.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

For animal treatment only.

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.
La Relva s/n
36400 Porriño (Pontevedra)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30824/4002

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gudair

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (1ml) of vaccine contains: *Mycobacterium paratuberculosis* inactivated, strain 316F: ≥ 2 mm ITT avian PPD (2.5 mg)

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

30 doses (30 ml)

100 doses (100ml)

250 doses (250 ml)

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

7. EXPIRY DATE

Shelf life after first opening the immediate package: 35 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

This is a limited marketing authorisation

POM – V

Vm 30824/4002

PACKAGE LEAFLET FOR:

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

CZ Veterinaria, S.A.

La Relva s/n

36400 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 INGREDIENTS

Each dose (1ml) of the vaccine contains:

Mycobacterium paratuberculosis inactivated, strain 316F: ≥ 2 mm ITT avian PPD* (2.5 mg)

**PPD=Purified Protein Derivative*

Mineral oil adjuvant.....q.s.
Thiomersal ..... 0.1 mg

4. INDICATION(S)

For the active immunisation of sheep and goats to stimulate cell-mediated and humoral immunity against *M. avium* subsp. paratuberculosis infection, as an aid in the control of Johne's disease in those species.
This is a Limited Marketing Authorisation. A full set of supporting efficacy data are not available for this product.
Further information on this product and its supporting data can be found on http://www.vmd.gov.uk/ProductInformationDatabase/

No information on onset of immunity or duration of immunity is available for this product.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

The vaccine produces swelling at the injection site which gradually becomes a persistent, fibrous and cold nodule that does not affect the general health status of the animal. 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 can rupture and discharge.

An average increase of body temperature in sheep can occasionally be observed varying between 0.5 and 1.0 °C. It lasted no longer than 48-96 hours.

7. TARGET SPECIES

Sheep and goats

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

Subcutaneous route.

Shake well before use.

Sheep and goats:
Administer one dose of 1 ml subcutaneously.

Vaccination schedule
It is recommended that all replacement animals are vaccinated between 4 weeks and six months of age. In affected or at risk flocks and herds or groups of animals, the vaccination should be carried out on all individuals, including adult animals.

Avoid administration in the areas of support and rubbing.

9. ADVICE ON CORRECT ADMINISTRATION

Do not mix with any other veterinary medicinal product.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store and transport between +2 °C and +8 °C.
Protect from light.
Do not freeze.

Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Special warning for each target species

Vaccination sensitises animals against johnin PPD, avian tuberculin PPD and, to a lesser extent, bovine tuberculin PPD. In vaccinated animals, the hypersensitivity reaction against avian tuberculin PPD is normally more intense than against bovine tuberculin PPD and clearly distinguishable. This will require careful interpretation of any tuberculin skin test that may be performed for tuberculosis diagnosis in animals vaccinated with this product.

For Animal Treatment Only

Special precautions for use in animals

None

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 insert 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.

In case of accidental self injection, persons who have been exposed to mycobacteria, either from a previous vaccination, or from environmental exposure may develop a reaction within the following hours. If a strong reaction or systemic symptoms occur seek medical advice immediately. Show the package leaflet or the label to the physician. TB interference test can be observed after accidental self-injection

The use of personal protective equipment consisting of suitable protective clothing, gloves and footwear is recommended when handling the immunological veterinary medicinal product. All practicable measures of cleaning and disinfection of protective clothing, gloves, footwear, hands, and equipment (syringes, etc.) should be undertaken on entry and exit from the holding to minimise the risk of disease transfer.

Use during pregnancy, lactation or lay

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

Interactions

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), if necessary

Overdose produces swelling at the injection site which gradually becomes a persistent, fibrous and cold nodule that does not affect the general health status of the animal. This event is very common.
Nodule can be detected at 1 week post vaccination with medium size of approximately 1.5 cm in sheep and 1.8 cm in goats, reaching a mean maximum size of 3 cm in sheep at 21 days and 4.9 cm in goats at 28 days post vaccination, which decrease quickly in the next days. Uncommonly, the diameter can reach values of 4 cm in sheep and 6 cm in goats.

Nodules can rupture and discharge

An average increase of body temperature in sheep can occasionally be observed varying between 0.5 and 1.0°C. It lasts no longer than 24 hours.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2013

Further information on this product and it's supporting data can be found on:

http://www.vmd.gov.uk/ProductInformationDatabase/

15. OTHER INFORMATION

POM - V

Vm 30824/4002

All suspected adverse reactions and any suspected lack of efficacy should be reported to: CZ Veterinaria, S.A. La relva s/n. P.O. Box 16. 36400 Porriño – Spain

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Gudair is or may at any time be prohibited in certain parts of the United Kingdom territory pursuant to specific animal health policy. Any person intending to import, sell, supply and/or use Gudair must consult the relevant Member State's animal health competent authority on the current importation requirements prior to the import, sale, supply and/or use.

Formats
Card box with 1 glass bottle containing 30 doses (30 ml).
Card box with 1 HDPE bottle containing 100 doses (100 ml)
Card box with 1 HDPE bottle containing 250 doses (250 ml)

Not all pack sizes may be marketed
This is a limited marketing authorisation

IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines against paratuberculosis, ATCvet code: QI04AB (sheep) and AI03AB01 (goats)

GUDAIR stimulates active immunization against *Mycobacterium paratuberculosis* in sheep and goats

Approved: 04/06/2018