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* (2.5 mg)

Adjuvant(s):
Mineral oil adjuvant.....q.s.

Excipients:
Thiomersal ..... 0.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Milky-white emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and goats

4.2 Indications for use, specifying the target species

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 is 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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Gudair vaccine should be exclusively administered subcutaneously using a 6 mm (18 Gauge) needle on a 45º degree angle on the side of the neck midway between the ear and the front of the shoulder. Do not inject at any other site.

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.

4.5 Special precautions for use

Special precautions for use in animals

Gudair vaccine should be exclusively administered subcutaneously using a 6 mm (18 Gauge) needle on a 45º degree angle on the side of the neck midway between the ear and the front of the shoulder. Do not inject at any other site.

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.

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 symptons 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.

4.6 Adverse reactions (frequency and seriousness)

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.

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

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.

4.10 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.

4.11 Withdrawal period(s)

Zero days

5. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Marcol 52
Montanide 103
Montane 80
Polysorbate 80
Thiomersal
Phosphate buffered saline (sodium chloride, disodium phosphate and potassium phosphate, water for injections)

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
HDPE bottle: 2 years
Glass bottle: 3 years

Shelf-life after first opening the immediate packaging: 35 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type II Glass bottles of 30 ml with rubber-nitrile stopper and aluminium seal.
High density polyethylene (HDPE) bottles with rubber-nitrile stopper and aluminium seal.

Package size:
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)

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

8. MARKETING AUTHORISATION NUMBER

Vm 30824/4002

9. DATE OF FIRST AUTHORISATION

15 April 2013

10. DATE OF REVISION OF THE TEXT

November 2023

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.

Approved 05 December 2023