SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gudair Emulsion for Injection for Sheep and Goats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

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

*PPD=Purified Protein Derivative

Adjuvants:

Marcol 52
Montanide 103
Montane 80

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Polysorbate 80	
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

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.

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:

For Animal Treatment Only

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):	Hypertermia[3]

[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.
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.
[3] 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.

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 its local representative 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

Subcutaneous route.

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.

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.

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

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

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

For administration only by a veterinarian.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI04AB09 and QI03AB01

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

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.

Do not mix with any other veterinary medicinal product.

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 between +2 º C and +8 ºC.
Protect from light.
Do not freeze.
Keep out of the sight and reach of children.

5.4 Nature and composition of immediate packaging

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

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

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 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

Vm 30824/4002

8. DATE OF FIRST AUTHORISATION

15 April 2013

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

August 2026

LIMITED MARKETS:
Marketing authorisation granted for a limited market and therefore assessment based on customised requirements for documentation.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 18 August 2026