B. PACKAGE LEAFLET

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 for batch release:
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O 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(S)

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.

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

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.**