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GUDAIR Emulsion for injection for sheep and goats

Authorised

- Mycobacterium avium, subsp. paratuberculosis, strain 316F, Inactivated

Product identification

Medicine name:
GUDAIR Emulsion for injection for sheep and goats

Active substance:
Mycobacterium avium, subsp. paratuberculosis, strain 316F, Inactivated

Target species:
Sheep
Goat

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Mycobacterium avium, subsp. paratuberculosis, strain 316F, Inactivated
2.00 tuberculin unit(s) / 1.00 millilitre(s)

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Sheep**
  - Meat and offal. 0 day

- **Goat**
  - Meat and offal. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI03AB01

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Iceland

Available in:
Iceland

Package description:
box containing 1 vial of 30 ml (30 doses)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
CZ Vaccines S.A.U.

Marketing authorisation date:
6/08/2013

Manufacturing sites for batch release:
CZ Vaccines S.A.U.

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/13/008/01

Date of authorisation status change:
17/10/2018

Reference member state:
Spain

Procedure number:
ES/V/0210/001

Concerned member states:
France Iceland Norway Portugal

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

English (PDF)
Published on: 13/03/2026
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