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Fatroseal 2.6 g intramammary suspension for dry cows

Authorised

- Bismuth subnitrate, heavy

Product identification

Medicine name:
Fatroseal 2.6 g intramammary suspension for dry cows

Active substance:
Bismuth subnitrate, heavy

Target species:
Cattle (dairy cow at drying-off)

Route of administration:
Intramammary use

Product details

Active substance and strength:
Bismuth subnitrate, heavy
26.00 gram(s) / 4.00 gram(s)

Pharmaceutical form:
Intramammary suspension

Withdrawal period by route of administration:

Intramammary use:

- **Cattle (dairy cow at drying-off)**
  - Meat and offal. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QG52X

Legal status of supply:
Veterinary medicinal product not subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Ireland

Available in:
Ireland

Package description:
Cardboard box with 24 syringes of 4 g
Cardboard box with 60 syringes
Cardboard box with 120 syringes
Cardboard box with 24 syringes of 4 g + 24 cleaning wipes
Cardboard box with 60 syringes of 4 g + 60 cleaning wipes
Cardboard box with 120 syringes of 4 g + 120 cleaning wipes

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Fatro S.p.A.

Marketing authorisation date:
1/04/2022

Manufacturing sites for batch release:
Fatro S.p.A.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10836/012/001

Date of authorisation status change:
1/04/2022

Reference member state:
Spain

Procedure number:
ES/V/0407/001

Concerned member states:
Austria Belgium Czechia Denmark Estonia France Germany Greece Hungary Ireland Luxembourg Netherlands Poland Portugal Slovakia United Kingdom (Northern Ireland)

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

Documents

Package Leaflet

eu-PUAR-esv0407001-dcp-fatroseal-2.6-g-en.pdf