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DOPHEXINE 20 MG/G POWDER FOR USE IN DRINKING WATER/MILK

Authorised

- Bromhexine hydrochloride

Product identification

Medicine name:
DOPHEXINE 20 MG/G POWDER FOR USE IN DRINKING WATER/MILK

Active substance:
Bromhexine hydrochloride

Target species:
Turkey
Pig
Duck
Chicken
Chicken (broiler)
Cattle

Route of administration:
Oral use

Product details

Active substance and strength:
Bromhexine hydrochloride
20.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Powder for use in drinking water/milk

Withdrawal period by route of administration:
Oral use:

- **Turkey**
  - Meat and offal. 0 day
  - Eggs. no withdrawal period

Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

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

- **Duck**
  - Meat and offal. 0 day
  - Eggs. no withdrawal period

Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

- **Chicken**
  - Eggs. no withdrawal period

Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

- **Chicken (broiler)**
  - Meat and offal. 0 day
- **Cattle**
  - Meat and offal. 2 day
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QR05CB02

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

Authorisation status:
Valid

Authorised in:
Sweden

Package description:
Composite can of 1 kg
Bucket of 5 kg
Bucket of 2,5 kg
Bucket of 1 kg
Securitainer of 1 kg

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:
Dopharma Research B.V.

Marketing authorisation date:
17/11/2021

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
62015

Date of authorisation status change:
17/11/2021

Reference member state:
France

Procedure number:
FR/V/0391/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Spain Sweden

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

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

Labelling

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet and Labelling

This document does not exist in this language (English). You can find it in another language below.

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