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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:

Romania

Available in:

Romania

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:

2/07/2020

Manufacturing sites for batch release:

Dopharma B.V.

Responsible authority:

Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:

250091

Date of authorisation status change:

2/11/2025

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

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Documents

Combined File of all Documents

English (PDF)

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