Dophacyl SB 1000 mg/g, powder for use in drinking water/milk for cattle and pigs

Authorised

- Sodium salicylate

Product identification

Medicine name:
Dophacyl SB 1000 mg/g, powder for use in drinking water/milk for cattle and pigs

Active substance:
Sodium salicylate

Target species:
Cattle (calf)
Pig

Route of administration:
In drinking water/milk use

Product details

Active substance and strength:
Sodium salicylate
1000.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:
Powder for use in drinking water/milk

Withdrawal period by route of administration:
In drinking water/milk use:

- **Cattle (calf)**
  - Meat and offal. no withdrawal period — zero days
- **Pig**
  - Meat and offal. no withdrawal period — zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QN02BA04

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
Bucket: white polypropylene square container provided with a polypropylene lid. The bucket contains 1 kg of product.
- Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene lid. The securitainer contains 500 g of product
Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene lid. The securitainer contains 1 kg of product
Bucket: white polypropylene square container provided with a polypropylene lid. The bucket contains 5 kg of product.
Bucket: white polypropylene square container provided with a polypropylene lid. The bucket contains 2.5 kg of product.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Dopharma Research B.V.

Marketing authorisation date:
17/08/2023

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:
Danish Medicines Agency

Authorisation number:
67568

Date of authorisation status change:
17/08/2023

Reference member state:
Netherlands

Procedure number:
NL/V/0392/001

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

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

Documents

Combined File of all Documents

NLV0392001DC_DophacylSB_RMS PuAR_Final.pdf