Labelling -Package leaflet

Exflow 10 mg/g powder for use in drinking water for cattle (calves), pigs, chickens, turkeys and ducks

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:

Laboratoires BIOVE 3 rue de lorraine 62510 Arques France	Ceva Santé Animale Boulevard de la Communication Zone Autoroutière 53950 LOUVERNE France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Exflow 10 mg/g powder for use in drinking water for cattle (calves), pigs, chickens, turkeys and ducks

Bromhexine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:
Active substance:
Bromhexine..... 9.11 mg
(as bromhexine hydrochloride 10.00 mg)

Powder for use in drinking water
White to slightly beige powder

4. INDICATION(S)

Mucolytic treatment of congested respiratory tract.

5. CONTRAINDICATIONS

Do not use in cases of pulmonary oedema.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None known.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (Calves), pigs, chickens, turkeys and ducks.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use in drinking water

0.45 mg of bromhexine per kg bodyweight daily, equivalent to 5 g of product per 100 kg bodyweight per day administered for 3 to 10 consecutive days, in drinking water.

In order to obtain the correct dosage the concentration of bromhexine has to be adjusted accordingly.

The following formula may be used to calculate the required concentration of product (in milligrams of product per litre drinking water):

$$\frac{\text{50.mg of the product per kg body weight and per day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily water intake (l/animal)}} = \text{... mg of the product per litre of drinking water}$$

The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment.

9. ADVICE ON CORRECT ADMINISTRATION

Recommendation for dilution:
Prepare a relevant quantity of water in a container.
Add the product to the water while stirring up the solution.

Prepare the solution with fresh water immediately before use.

When using a water proportionner, adjust the pump between 1% to 5% and adapt the volume of preparation accordingly. Do not set up the dosing pump below 1%.

When using a water tank, it is recommended to prepare a stock solution of at least 1g of product/L and to dilute it to the target final concentration.
The solubility of the product has been tested at the maximum concentration of 100 g/L at 20°C.
Turn off the water supply to the tank until all the medicated solution is consumed.
For example:
Prepare a stock solution at 1 g of product/L, dilute 1/3 to obtain a medicated solution at 0.33g of powder/L eq to 1g of powder/3L.

For pigs, when administered during the meal, first dissolve the product in water and then add feed. Administration during the meal should be restricted to individual treatment or for treatment of a small group of animals. The preparation must be used immediately. Care should be taken that the intended dose will be completely ingested.

The intake of medicated water depends on the clinical condition of the animals.

Any unused medicated water should be discarded after 24 hours.

10. WITHDRAWAL PERIOD

Cattle (calves)
Meat and offal: 2 days
Not permitted for use in cows producing milk for human consumption.

Pigs
Meat and offal: Zero days.

Chickens, turkeys and ducks
Meat and offal: Zero days

Do not use in birds producing eggs for consumption, during and 4 weeks before the laying phase.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution in drinking water according to directions: 24 hours
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
In case of serious lungworm infection, the drug should only be used 3 days after the commencement of the anthelmintic treatment.
In case of primary and/or secondary infection, the combination with antibiotics should be considered. When administered concomitantly with the product, antimicrobial agents should not be underdosed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to bromhexine or any of the excipients should avoid contact with the product.
This product may cause irritation to the skin, eyes and mucous membranes.
During preparation and administration, inhalation of dust particles should be avoided. Wear an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN149) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), when handling the product. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.
Avoid direct contact with the product. Wear gloves and protective glasses during the use of the product. Wash hands and any exposed skin after use. If accidental contact occurs, rinse the affected area with large amounts of clean water.
Do not eat, drink or smoke while handling this product.

Pregnancy and lactation:
Studies in laboratory animals have not produced evidence of foetotoxic effects or effects on fertility at the recommended dose. However this has not been specifically studied in the target species. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators. Bromhexine modifies the distribution of antibiotics in the organism and increases their concentration in the serum especially in the respiratory tract (in bronchial and nasal secretions). Such effect has been observed especially for oxytetracycline, spiramycin, tylosin, erythromycin, ampicillin, doxycycline, amoxicillin and cefuroxime.

Overdose (symptoms, emergency procedures, antidotes:
None known.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Bags of 500 g - 1 kg - 2.5kg - 5kg
Jars of 500 g -1 kg

Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

MA number: Vm 15052/4073

For animal treatment only.

To be supplied only on veterinary prescription

BATCH NUMBER:
EXPIRY DATE:

Approved 28 September 2022