ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardbox

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reprocine 0.07 mg/ml Solution for Injection for Cattle and Pigs

2. STATEMENT OF ACTIVE SUBSTANCES

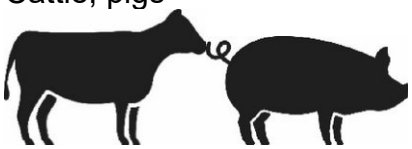
Each ml contains:
Carbetocin 0.07 mg

3. PACKAGE SIZE

6 x 10 mL
1 x 50 mL
12 x 50 mL

4. TARGET SPECIES

Cattle, pigs



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m. or **i.v.** use

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, pigs: meat and offal: Zero days
Cattle: milk: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

For 50 mL vial: Once broached use within 3 weeks.
For 10 mL vial: Once broached use within 2 weeks.

Once broached use by ...

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2°C – 8°C).
Keep the vial in the outer carton in order to protect from light.
When transported in a vehicle by a veterinarian, the product should be kept in a cooler box.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/3005

15. BATCH NUMBER

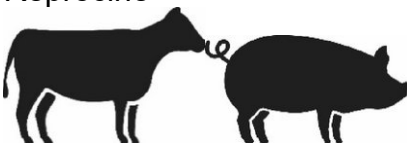
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 10 mL or 50 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reprocine



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Carbetocin 0.07 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

For 50 mL vial: Once broached use within 3 weeks.
For 10 mL vial: Once broached use within 2 weeks.

Once broached use by …

Store in a refrigerator.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Reprocine 0.07 mg/ml Solution for Injection for Cattle and Pigs

2. Composition

Each ml contains:

Active substances:
Carbetocin 0.07 mg

Excipients:
Chlorobutanol hemihydrate 2.00 mg

Clear, colourless solution.

3. Target species

Cattle, pigs

4. Indications for use

Cow:
- Uterine atony during the puerperal period,
- Placental retention as a consequence of uterine atony
- Initiation of milk ejection in stress-induced agalactia or in conditions requiring udder emptying

Sow:
- Uterine atony during the puerperal period
- Supportive therapy of mastitis-metritis-agalactia (MMA-) syndrome
- Initiation of milk ejection
- Shortening of total parturition duration in sows: either after delivery of the first piglet or as a component of synchronisation of parturition in sows, which have not farrowed 24 hours after administration of an appropriate $PGF2_{2\alpha}$ (e.g. cloprostenol) not before day 113 of pregnancy.

5. Contraindications

Do not administer to accelerate parturition if cervix is not opened or if there is a mechanical cause for the delayed parturition such as physical obstruction, positional and postural abnormalities, convulsive labour, threatened rupture of uterus, uterine torsion, relative foetal oversize or deformities of the birth canal.

6. Special warnings

Special precautions for safe use in the target species:

The interval between two injections should not be shorter than 24 hours.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of an accidental self-injection of the veterinary medicinal product in non-pregnant women the following effects may occur: facial flushing and warmth, lower abdominal pain.
These effects usually disappear within a short span of time.
The veterinary medicinal product should not be administered by pregnant women, women post partum and breast-feeding women to avoid accidental exposure. In case of accidental self-injection uterine contractions could be induced in pregnant women.

Lactation:

The veterinary medicinal product is indicated to induce milk ejection.

Interaction with other medicinal products and other forms of interaction:

The administration of oxytocin after the administration of the veterinary medicinal product is unnecessary. Due to a possible intensification of the effect of oxytocin, undesirable uterine spasms may be induced.

Overdose:

Injection of more than twice the recommended dose rate (more than 0.4 mg of carbetocin/animal) could increase the stillbirth rate in older sows if administered during prolonged parturition.

A threefold overdose (0.6 mg of carbetocin/animal) may induce profuse lactation in sows that may result in diarrhoea, reduced weight gain and increased mortality in their piglets.
Carbetocin is considered as moderately irritant. At the injection sites of treated animals, focal lymphocytic infiltration was observed at higher doses (1.0 mg of carbetocin/animal).

Major incompatibilities:

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

7. Adverse events

Cattle, pigs:

None known.
Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at:

E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

Intramuscular or intravenous use.
For single injection.

Cows
For all indications: 3.0 – 5.0 ml/animal, corresponding to 0.21 – 0.35 mg carbetocin/animal

Sows
For uterine atony, MMA and milk ejection:
1.5 – 3.0 ml/animal, corresponding to 0.105 – 0.21 mg carbetocin/animal

For shortening of total parturition duration as a part of the synchronisation of parturition:
1.0 ml/animal, corresponding to 0.07 mg carbetocin/animal

The dosage requirements can be variable within the indicated limits based on the

In case of treatment for milk ejection in the cow and sow or supportive therapy in MMA-syndrome in sows, a repeated administration is possible after 1 to 2 days.

Special information:

The responsiveness to carbetocin of the myometrium is likely to be close to zero from the 5th to the 11th day post partum. Therefore, the administration of the veterinary medicinal product during this period is likely to be inefficient and should be avoided.

If treatment with carbetocin should fail, then it is advisable to reconsider the aetiology of the condition, specifically if hypocalcaemia could be a complicating factor.

In case of severe septic metritis, appropriate concomitant therapy should be instigated when administering the veterinary medicinal product.

9. Advice on correct administration

None.

10. Withdrawal periods

Cattle, pigs:
Meat and offal: Zero days
Cattle:
Milk: Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Keep the vial in the outer carton in order to protect from light.

When transported in a vehicle by a veterinarian, the veterinary medicinal product should be kept in a cooler box.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:
10 ml vial: 2 weeks.
50 ml vial: 3 weeks.
The date of the first opening of the container should be noted in the provided space on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06462/3005

Pack sizes:
1 vial with 50 ml solution for injection in a cardboard box.
12 vials with 50 ml solution for injection in a cardboard box.
6 vials with 10 ml solution for injection in a cardboard box.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Vetoquinol SA
34 Rue de Chene Sainte-Anne
70200 Lure
France

Manufacturer responsible for batch release:

Wirtschaftsgenossenschaft Deutscher Tierarzte eG
Siemensstrasse 14
D-30827 Garbsen
Germany

Gavin Hall
Approved: 21 August 2026