1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Reprocine 0.07 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Carbetocin ..... 0.07 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorobutanol hemihydrate	2.00 mg
Acetic acid 99 %	
Sodium acetate trihydrate	
Water for injection	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Lactation:

The veterinary medicinal product is indicated to induce milk ejection.

3.8 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.

3.9 Administration routes and dosage

Intramuscular or intravenous use.
For single injection.

Cow:
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 assessment of the veterinarian.

In case of treatment for milk ejection in the cow and sow or supportive therapy in MMA-syndrome in sow, 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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QH01BB03

4.2 Pharmacodynamics

Carbetocin is a synthetic analogue of the posterior pituitary lobe hormone oxytocin and has its physiological and pharmacological main effects at the smooth muscle (induction and increase of contractions) of reproductive organs.

Carbetocin has the same effect as natural oxytocin: at the oestrogen stimulated uterus it causes a change from weak, spontaneous and irregular to synchronised, regular, increased and directed contractions. Moreover, in the mammary gland it produces physiological contractions of the myoepithelial cells in the alveolae and small lactiferous ducts as well as a simultaneous relaxation of the teat sphincter.

The action of carbetocin is prolonged and it causes an intensification of the physiological effect.

4.3 Pharmacokinetics

Carbetocin is, due to its strongly developed peptidase-resistance, much more slowly degraded in vivo and distinguishes itself by a prolonged efficacy. Carbetocin is much more lipophilic than exogenously applied oxytocin and therefore, a better distribution and a longer effect on the receptors occur. Beside the stability against proteases, this may also contribute to the prolonged increase of uterine tone activity. After administration of 0.6 mg of carbetocin, in sows a bicompartimental kinetic was observed. The elimination half-life is approximately 85 - 100 min. There are no essential differences between intramuscular and intravenous administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging:
10 ml vial: 2 weeks.
50 ml vial: 3 weeks.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Colourless glass vial containing 50 ml or 10 ml, respectively, solution for injection closed with a rubber stopper and sealed with an aluminium cap.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/002/001

8. DATE OF FIRST AUTHORISATION

05/11/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).