Outer Cardbox

6 x 10 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

1 ml contains:
Carbetocin 0.07 mg
Chlorobutanol hemihydrate 2.00 mg

3. PHARMACEUTICAL FORM

Solution for injection (does not appear on the final printed materials)
Clear colourless solution

4. PACKAGE SIZE

6 x 10 ml

5. TARGET SPECIES

Cattle, pig

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For im. or iv. injection

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle, pig: meat and offal: Zero days
Cattle: milk: Zero days

9. SPECIAL WARNING(S) IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once a vial has been broached the product must be used within 2 weeks (store in a refrigerator).

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

(Any unused product or waste material should be disposed of in accordance with national requirements.)

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinarian prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADRESS OF THE MARKETING AUTHORIZATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

16. MARKETING AUTHORIZATION NUMBER

Vm 08007/4151

17. MANUFACTURER'S BATCH NUMBER

Batch-no.:

50 ml and 12 x 50 ml

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

1 ml contains:

Carbetocin	0.07 mg
chlorobutanol hemihydrate	2.00 mg

3. PHARMACEUTICAL FORM

Solution for injection (does not appear on the final printed materials)
Clear colourless solution

4. PACKAGE SIZE

1 x 50 ml or 12 x 50 ml, respectively

5. TARGET SPECIES

Cattle, pig

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For im. or iv. injection

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S) IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once a vial has been broached the product must be used within 3 weeks (store in a refrigerator).

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

(Any unused product or waste material should be disposed of in accordance with national requirements.)

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinarian prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADRESS OF THE MARKETING AUTHORIZATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

16. MARKETING AUTHORIZATION NUMBER

Vm 08007/4151

17. MANUFACTURER'S BATCH NUMBER

Batch-no.:

Label

10 ml

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:
Carbetocin 0.07 mg

3. CONTENTS BY WEIGHT, VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

For im. or iv. injection

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle, pig: meat and offal: Zero days
Cattle: milk: Zero days

6. BATCH NUMBER

Batch-no.:

7. EXPIRY DATE

EXP
Once broached, use by ……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

50 ml

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

1 ml contains:
Carbetocin 0.07 mg
chlorobutanol hemihydrate 2.00 mg

3. PHARMACEUTICAL FORM

Solution for injection (does not appear on the final printed materials)

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle, pig

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For im. or iv. injection

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle, pig: meat and offal: Zero days
Cattle: milk: Zero days

9. SPECIAL WARNING(S) IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once broached, use by ……

11. SPECIAL STORAGE CONDITIONS

Store at 2 - 8 °C. Keep container in the outer carton. When transported in a vehicle by a veterinarian, the product should be kept in a cooler box.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS; IF ANY

(Any unused product or waste material should be disposed of in accordance with national requirements.)

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADRESS OF THE MARKETING AUTHORIZATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

16. MARKETING AUTHORIZATION NUMBER

Vm 08007/4151

17. MANUFACTURER'S BATCH NUMBER

Batch-no.:

PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder:
Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr Alderton, Towcester, Northamptonshire, NN12 7LS, United Kingdom

Manufacturing authorisation holder:
Wirtschaftsgenossenschaft deutscher Tierärzte (WdT) eG – Siemensstr. 14 – 30827 Garbsen

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 ml contains:
Carbetocin 0.07 mg
Chlorobutanol hemihydrate 2.00 mg

4. INDICATION(S)

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 $PGF_{2\alpha}$ (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. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pig

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

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 assessment of the veterinarian.

Method of administration
To be administered as a single dose by intramuscular or intravenous injection.
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 LongActon / Reprocine 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 LongActon / Reprocine.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (2 - 8 °C). Keep container in the outer carton. When transported in a vehicle by a veterinarian, the product should be kept in a cooler box.

Do not use after the expiry date stated on the container and carton. Do not use, if you notice any apparent growth or discolouration.

Shelf-life after first opening the container
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 WARNING(S)

Special precautions for use in animals
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.
Pregnant women, women post partum and breast-feeding women should not use this product, in order to avoid an accidental exposure. In case of accidental self-injection uterine contractions could be induced in pregnant women.

Use during pregnancy and 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 (symptoms, emergency procedures, 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).

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 products should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmacological properties
Pharmacotherapeutic group: Systemic hormonal preparations, excl. sex hormones
ATCvet code: QH01BB03

Mode of action
Carbetocin is a synthetic analogue of the endogenous peptide hormone oxytocin. Due to changes in the chemical structure it is much more slowly degraded in vivo than the native hormone and thus is distinguished by prolonged efficacy.
The pharmacological effects of carbetocin are similar to oxytocin and consist of stimulation of milk ejection as well as the uterine muscular activity on the oestrogen-stimulated uterus.
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.

Packaging sizes:
6 x 10 ml
1 x 50 ml
12 x 50 ml

Not all pack sizes may be marketed.

Approved: 31 August 2018