SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
LongActon / Reprocine 0.07 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml contains:

Active Substance:
Carbetocin 0.07 mg

Excipients:
Chlorobutanol hemihydrate 2.00 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species
Cattle, pig

4.2 Indications for use, specifying the 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 $PGF_{2\alpha}$ (e.g. cloprostenol) not before day 113 of pregnancy.

4.3 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.

4.4 Special warnings for each target species
None.

4.5 Special precautions for use
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.

4.6 Adverse reactions (frequency and seriousness)
None known.

4.7 Use during pregnancy and lactation or lay
The veterinary medicinal product is indicated to induce milk ejection.
See also 4.3 Contraindications.

4.8 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.

4.9 Amounts to be administered and administration route
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.

For single intramuscular or intravenous injection.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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).

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

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

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.

5.2 Pharmacokinetic Particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol hemihydrate
Acetic acid 99 %
Sodium acetate trihydrate
Water for injection

6.2 Incompatibilities

None known.

6.3 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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Colourless glass injection vial containing 50 ml or 10 ml, respectively, solution for injection closed with a rubber stopper and sealed with an aluminium cap.
1 x 50 ml, 12 x 50 ml or 6 x 10 ml solution for injection, packaged in an outer cardboard box

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

VetCom-pharma GmbH
Seestr. 6
A-6900 Bregenz
Tel: +43 (0) 5574-53214
Fax: +43 (0) 5574-53216
e-mail: vetcom@aon.at

8. MARKETING AUTHORISATION NUMBER(S)

Member State	**Marketing Authorisation No.**
Germany	400323.00.00
Austria	8-00543
UK	Vm 20870/4000
Ireland	VPA 10811/1/1
France	FR/V/2864058 3/2002
Spain	1595 ESP
Belgium	3569 IE 1 F 12
Netherlands	REG NL 10205
Luxemburg	V 880/02/11/0745

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation:

Member State	**Date of first Authorisation**
Germany	February 22, 2000
Austria	October 22, 2002
UK	October 21, 2004
Ireland	05 November 2004
France	December 09, 2002
Spain	October 20, 2004
Belgium	March 31, 2003
Netherlands	November 03, 2004
Luxemburg	December 18, 2002

Date of renewal:
February 23, 2005
March 17, 2010

10. DATE OF REVISION OF THE TEXT

Date of revision of the text: March 15, 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

CONDITIONS OF SUPPLY

On veterinarian's prescription