PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Carton box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Hypophysin LA 35 µg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES
Each ml contains:
Carbetocin 35 µg

3. PACKAGE SIZE
10 ml
20 ml
50 ml
100 ml

4. TARGET SPECIES
Cattle (cows), pigs (sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION
Intramuscular use. Intravenous use.

7. WITHDRAWAL PERIODS
Withdrawal periods:

Cattle, pigs:
Meat and offal: Zero days

Cattle:
Milk: Zero hours

8. EXPIRY DATE
Exp. {mm/yyyy}

Once broached use within 28 days.
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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"
Pregnant and breast feeding women should avoid handling this veterinary medicinal product.
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
Veyx-Pharma GmbH

14. MARKETING AUTHORISATION NUMBERS
Vm 27569/4003

15. BATCH NUMBER
Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
(Glass vial 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Hypophysin LA 35 µg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES
Each ml contains:
Carbetocin 35 µg

3. TARGET SPECIES
Cattle (cows), pigs (sows).

4. ROUTES OF ADMINISTRATION
Intramuscular use. Intravenous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS
Withdrawal periods:

Cattle, pigs:
Meat and offal: Zero days

Cattle:
Milk: Zero hours

6. EXPIRY DATE
Exp. {mm/yyyy}

Once broached use within 28 days.
Use by: …

7. SPECIAL STORAGE PRECAUTIONS
Store in a refrigerator (2 °C – 8 °C).
Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER
Veyx-Pharma GmbH

9. BATCH NUMBER
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Glass vial (10 ml, 20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Hypophysin LA

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES
Each ml contains:
Carbetocin 35 µg

3. BATCH NUMBER
Lot {number}

4. EXPIRY DATE
Exp. {mm/yyyy}

Once broached use within 28 days.
Use by: …

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product
Hypophysin LA 35 µg/ml solution for injection for cattle and pigs

2. Composition
Each ml contains:

Active substance:
Carbetocin 35 µg

Excipients:
Chlorocresol 1.0 mg

Clear, colourless solution.

3. Target species
Cattle (cows), pigs (sows).

4. Indications for use
Cattle (cows):
- 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

Pigs (sows):
- Acceleration or restart of parturition after disruption of uterine contractions (uterine atony or inertia) following the expulsion of at least one piglet
- Supportive therapy of mastitis-metritis-agalactia (MMA-) syndrome
- Initiation of milk ejection
- Shortening of total parturition duration as a component of synchronisation of parturition in sows The product may be applied to sows which have previously been administered an appropriate $PGF_{2\alpha}$ or $PGF_{2\alpha}$ analogue (e.g. cloprostenol) not prior to day 114 of pregnancy and have not started farrowing within 24 hours after the $PGF_{2\alpha}$ or $PGF_{2\alpha}$ analogue injection (day 1 of pregnancy is the last day of insemination)

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

6. Special warnings

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection uterine contractions could be induced in pregnant women.
Pregnant women, women post-partum and breast-feeding women should not administer this veterinary medicinal product, in order to avoid an accidental exposure.
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.

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Personal protective equipment consisting of disposable gloves should be worn when handling the veterinary medicinal product.
Carbetocin may be absorbed through the skin. In case of accidental contact with the skin, the corresponding area should be thoroughly cleaned with soap and water.
In case of contact with the eyes, they should be thoroughly rinsed with water.
People with known hypersensitivity to carbetocin or any of the excipients should avoid contact with the veterinary medicinal product.
Women of childbearing age should administer the veterinary medicinal product with special caution.

Pregnancy and lactation:
The veterinary medicinal product is indicated to induce milk ejection.
See also section 5. “Contraindications”.

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:
An overdosing of more than 400 µg of carbetocin/animal could increase the stillbirth rate in older sows if administered during prolonged parturition.

An overdosing of 600 µg 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 (1000 µg 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 (cows), pigs (sows):

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Uterotonic effect[1]

[1] In late pregnancy

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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Intramuscular use. Intravenous use.

Cattle (cows):
For all indications:
6.0 – 10.0 ml/animal, corresponding to 210 – 350 µg carbetocin/animal
Pigs (sows):
For shortening of total parturition duration as a part of the synchronisation of parturition:
1.0 ml/animal, corresponding to 35 µg carbetocin/animal
For acceleration or restart of parturition after disruption of uterine contractions (uterine atony or inertia) following the expulsion of at least one piglet:
1.0 -2.0 ml/animal, corresponding to 35 - 70 µg carbetocin/animal
For MMA and milk ejection:
3.0 – 6.0 ml/animal, corresponding to 105 – 210 µg 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. The interval between two injections should not be shorter than 24 hours.

For all other indications stated in section 4. “Indications for use” the product should be administered once.

9. Advice on correct administration

The rubber stopper of the vial may be safely punctured up to 25 times. Otherwise, automatic syringe equipment, or a suitable draw-off needle, should be used for the 50 ml and 100 ml vials to avoid excessive puncturing of the closure.

10. Withdrawal periods

Cattle, pigs:
Meat and offal: Zero days

Cattle:
Milk: Zero hours

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.

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: 28 days.

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 27569/4003

Pack sizes:
1 vial (10 ml) in a cardboard box.
1 vial (20 ml) in a cardboard box.
1 vial (50 ml) in a cardboard box.
1 vial (100 ml) 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, manufacturer responsible for batch release and contact details to report suspected adverse events:
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany
Tel: +49 5686 9986 62
E-mail: pharmacovigilance@veyx.de

Manufacturer responsible for batch release:
Veyx Pharma BV
Forellenweg 16
NL-4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse events:

GB:
Anupco Ltd T/A Kela Animal Health UK
Office 39
Lodge House, Lodge Park, Lodge Lane
Langham, Colchester
Essex, CO4 5NE
England
Tel: +44 1206 233528

NI:
Kela Veterinaria nv
Nieuwe Steenweg 62
9140 Elversele
Belgium
Tel.: +32 (0)3 780 63 90
E-mail: info.vet@kela.health

17. Other information

POM-V

Gavin Hall

Approved: 02 October 2026