

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**for 10 ml / 20 ml / 50 ml / 100 ml vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hypophysin LA 35 µg/ml solution for injection for cattle and pigs  
Carbetocin

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml solution for injection contains:

*Active substance:*

Carbetocin 35.00 µg

*Excipients:*

Chlorocresol 1.00 mg

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

1 x 10 ml

1 x 20 ml

1 x 50 ml

1 x 100 ml

**5. TARGET SPECIES**

Cattle, pigs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular or intravenous use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period

Cattle, pigs Meat and offal: Zero days

Cattle Milk: Zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

Pregnant and breast feeding women should avoid handling this product.  
Read the package leaflet before use.

**10. EXPIRY DATE**

Expiry date: month/year  
Once broached, use by:  
Shelf life after first broaching the vial: 28 days

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2 - 8 °C). Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet

**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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Veyx-Pharma GmbH  
Söhreweg 6  
34639 Schwarzenborn  
Germany

**16. MARKETING AUTHORISATION NUMBER**

Vm 27569/4003

**17. MANUFACTURER’S BATCH NUMBER**

Batch number:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**20 ml / 50 ml / 100 ml vials**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hypophysin LA 35 µg/ml solution for injection for cattle and pigs  
Carbetocin

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml solution for injection contains:

*Active substance:*

Carbetocin 35.00 µg

*Excipients:*

Chlorocresol 1.00 mg

**3. PHARMACEUTICAL FORM**

**4. PACKAGE SIZE**

20 ml  
50 ml  
100 ml

**5. TARGET SPECIES**

Cattle, pigs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intramuscular or intravenous use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period

Cattle, pigs Meat and offal: Zero days

Cattle Milk: Zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

Expiry date: month/year  
Once broached, use by:  
Shelf life after first broaching the vial: 28 days

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator (2 - 8 °C). Keep the vial in the outer carton in order to protect from light.

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

**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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Veyx-Pharma GmbH  
Söhreweg 6  
34639 Schwarzenborn  
Germany

**16. MARKETING AUTHORISATION NUMBER**

Vm 27569/4003

**17. MANUFACTURER'S BATCH NUMBER**

Batch number:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

10 ml vials

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hypophysin LA 35 µg/ml solution for injection for cattle and pigs  
Carbetocin

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

35 µg/ml

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

10 ml

**4. ROUTE(S) OF ADMINISTRATION**

For intramuscular or intravenous use.

**5. WITHDRAWAL PERIOD**

Withdrawal period  
Cattle, pigs                      Meat and offal: Zero days  
Cattle                      Milk:                      Zero hours

**6. BATCH NUMBER**

Batch number:

**7. EXPIRY DATE**

Expiry date: month/year  
Once broached, use by:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**

Hypophysin LA 35 µg/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**

Veyx-Pharma GmbH  
Söhreweg 6  
34639 Schwarzenborn  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hypophysin LA 35 µg/ml solution for injection for cattle and pigs  
Carbetocin

**3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS**

Hypophysin LA is a clear colourless solution for injection containing:

*Active substance:*

Carbetocin 35.00 µg/ml

*Excipients:*

Chlorocresol 1.00 mg/ml

**4. INDICATION(S)**

Cows:

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

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<sub>2α</sub> or PGF<sub>2α</sub> analogue (e.g. cloprostenol) not prior to day 114 of pregnancy and have not started farrowing within 24 hours after the PGF<sub>2α</sub> or PGF<sub>2α</sub> 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. ADVERSE REACTIONS

In very rare cases carbetocin may have a uterotonic effect in the late pregnancy.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle, pigs

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

For intramuscular or intravenous use.

### Cows

For all indications:

6.0 – 10.0 ml/animal, corresponding to 210 – 350 µg carbetocin/animal

### 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] the product should be administered once.

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 and 100 ml vials to avoid excessive puncturing of the closure.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

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 - 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 carton and vial label after "EXP". The expiry date refers to the last day of that month. Shelf life after first opening the immediate packaging: 28 days

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

## 12. SPECIAL WARNING(S)

### Special warnings for each target species:

The responsiveness to carbetocin of the myometrium is likely to be close to zero from the 5<sup>th</sup> to the 11<sup>th</sup> 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 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 product with special caution.

Use during pregnancy, lactation or lay:

The veterinary medicinal product is indicated to induce milk ejection. See also 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 (symptoms, emergency procedures, antidotes):

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).

Incompatibilities:

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

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.

Revised: July 2019  
AN: 01071/2018

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves upwards at the end.

Approved 30 July 2019