PACKAGE LEAFLET FOR:

Hypophysin LA 70 µg/ml solution for injection for cattle and pigs
Depotocin 70 µg/ml solution for injection for cattle and pigs (AT/DE)
Hypophysin LA 70 microgram/ml solution for injection for cattle and pigs (IE/UK)
Hypophysin 70 µg/ml solution for injection for cattle and pigs (EE)

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 70 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 70.00 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-induced agalactia 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 $PGF_{2\alpha}$ 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. 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:
3.0 – 5.0 ml/animal, corresponding to 210 – 350 µg carbetocin/animal
Sows
For shortening of total parturition duration as a part of the synchronisation of parturition:
0.5 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:
0.5 -1.0 ml/animal, corresponding to 35 - 70 µg carbetocin/animal
For MMA and milk ejection:
1.5 – 3.0 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 20 and 50 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 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 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

Not all pack sizes may be marketed.