IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10846/002/001**
Case No: 7003219

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Laboratorios Hipra S.A.

Avda. La Selva 135, **17170 - Amer (Girona)**, **Spain**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Hipracin 10IU/ml Synthetic Oxytocin, solution for injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **11/09/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRACIN
10 IU/ml Synthetic Oxytocin, solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	
Synthetic Oxytocin	10 IU/ml
Excipients:	
Chlorobutanol hemihydrate	5 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Sows, Ewes, Cows, Bitches, and Queens.

4.2 Indications for use, specifying the target species

In general, for all target species:

Stimulation of uterine contractions to facilitate parturition in the presence of a fully dilated cervix.

To promote involution of the post-parturient uterus and thus aid the passage of retained placenta.

To help control post-partum haemorrhage.

Promotion of milk let-down in cases of agalactia and as a co-adjuvant in antibiotic treatment of mastitis.

4.3 Contraindications

Do not use in females with obstructive dystochia, pelvic-foetal disproportion or with any other mechanical obstruction.

Do not use in animals with cardiovascular problems.

To prevent the risk of foetal death and possible uterine rupture, do not use to induce parturition if cervical dilatation is not confirmed.

Do not use in sows with normal parturition.

4.4 Special warnings for each target species

Adrenaline at physiological levels markedly reduces the effect of oxytocin on the uterus and mammary gland. For this reason the animal should not be stressed when complete oxytocin effect is desired to cause either milk let-down or uterine contractions.

4.5 Special precautions for use

Special Precautions for use in Animals

The intravenous injection must be given by slow intravenous infusion.
A low initial dose is recommended and should only be increased if no effect is observed.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Pregnant women and people with known hypersensitivity to oxytocin should avoid direct contact with the veterinary medicinal product.
In case of skin or eye contact, rinse with plenty of water for several minutes.
Care should be taken to avoid accidental self-injection. Should self-injection occur, medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

At the recommended doses, no side-effects have been described.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant females until parturition.

4.8 Interaction with other medicinal products and other forms of interaction

Calcium and oestrogens enhance the activity of oxytocin, whereas progestagens decrease it.

There may be an increase in the prevalence of uterine inertia in sows treated with prostagladins prior to administration of oxytocin.

Stimulation of β adrenergic receptors may reduce the effect of oxytocin on the uterus or mammary gland.

4.9 Amounts to be administered and administration route

By intramuscular route:
Sows and Ewes: 0.2 to 1 ml/animal (2 to 10 IU/animal).
Cows: 1 to 4 ml/cow (10 to 40 IU/cow).
Bitches: 0.2 to 1 ml/bitch (2 to 10 IU/bitch).
Queens: 0.2 to 0.5 ml/queen (2 to 5 IU/queen).

By intravenous route:
Sows and Ewes: 0.05 to 0.25 ml/animal (0.5 to 2.5 IU/animal).
Cows: 0.25 to 1 ml/cow (2.5 to 10 IU/cow).
Bitches: 0.05 to 0.25 ml/bitch (0.5 to 2.5 IU/bitch).
Queens: 0.05 to 0.125 ml/queen (0.5 to 1.25 IU/queen).

Intravenous injections should be given slowly at a dilution of 1 in 10 using Water for Injection.
A low initial dose is recommended and should only be increased if no effect is observed.
The administration can be repeated every 30 minutes, if it is necessary.

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

If very large doses are given, a marked fall in blood pressure may occur.

Large doses may produce inco-ordinated uterine contractions which can interfere with progress of the foetus.

4.11 Withdrawal Period(s)

Meat and offal: 12 hours.
Milk: 12 hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Oxytocin is a naturally occurring hormone present in females and males of all mammalian species, belonging to the group of posterior pituitary lobe hormones, oxytocin and analogues (ATC Vet Code QH01BB02).

5.1 Pharmacodynamic properties

Oxytocin is a cyclic nonapeptide which has stimulant effects on the smooth muscle of the uterus and on the mammary gland. It stimulates uterine motility increasing contraction and tone. The induction of parturition, promotion of uterine involution after parturition, aid to passage of retained placenta, and control of post-partum haemorrhage are consequences of uterine contraction. It also stimulates contraction of the myoepithelial cells of the mammary acini producing milk let-down.

The uterine response can be modified by sexual hormones, being highly dependent on the presence of oestrogens and progestagens. When oestrogen levels are low, the effect of oxytocin is much reduced whereas when oestrogen levels are high, such as during oestrus, proestrus and late pregnancy, the response of the uterus to oxytocin is greatest. On the other hand, progesterone antagonises the effect of oxytocin, so the excitation of smooth muscle decreases.

5.2 Pharmacokinetic properties

When oxytocin is given orally it is inactivated by chymotrypsin. However, it is effective after administration by any parenteral route. After parenteral administration, oxytocin is rapidly absorbed and it is partially bound by the plasma proteins. It is metabolised in the body by oxytocin kinase.

Oxytocin half-life in plasma is short (2-3 minutes), and its rapid removal from the plasma is accomplished largely by the kidney and the liver where there is a high oxytocin-inactivating activity. Therefore, its effects disappear very quickly.

During pregnancy, a small part of oxytocin inactivation occurs in plasma and there is a high oxytocin kinase activity in the tissue of the pregnant uterus and in the placenta.

Mammary tissue extracts oxytocin from the plasma.

Oxytocin is excreted through the urine though a very small portion of oxytocin reaches the urine in active form. It is also excreted via the mammary gland in lactating animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid
Sodium chloride
Sodium acetate
Disodium edetate
Chlorobutanol hemihydrate
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: 28 days

6.4 Special precautions for storage

Store in a refrigerator (2 - 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is bottled in sterile 10 ml, colourless Type I glass vials or 50 ml colourless Type II glass vials, closed with Type II basic polymeric elastomer closures with anodised aluminium caps. One vial of 50 ml or two 10 ml vials are available in a cardboard box. Also clinical presentations are available: 25 x 10 and 20 x 10.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva
135 17170-Amer (Girona)
SPAIN.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10846/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th September 2002

11th September 2007

10 DATE OF REVISION OF THE TEXT

11th September 2007