1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN 10 IU/ml Synthetic Oxytocin, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Synthetic Oxytocin 10 IU

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Acetic acid	
Sodium chloride	
Sodium acetate	
Disodium edetate	
Chlorobutanol hemihydrate	5 mg
Water for injection	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Sows, Ewes, Cows, Bitches and Queens.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in females with obstructive dystocia, 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product to animals:
Pregnant women and people with known hypersensitivity to oxytocin should avoid 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. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sows, Ewes, Cows, Bitches and Queens: None known

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not administer to pregnant females until parturition.

3.8 Interaction with other medicinal products and other forms of interaction

Calcium and oestrogens enhance the activity of oxytocin, whereas progestogens decrease it.
There may be an increase in the prevalence of uterine inertia in sows treated with prostaglandins prior to administration of oxytocin.
Stimulation of β adrenergic receptors may reduce the effect of oxytocin on the uterus or mammary gland.

3.9 Administration routes and dosage

Intramuscular use:
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).

Intravenous use:
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

If very large doses are given, a marked fall in blood pressure may occur.
Large doses may produce uncoordinated uterine contractions which can interfere with progress of the foetus.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QH01BB02

4.2 Pharmacodynamics

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 progestogens. 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3. Special precautions for storage

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

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL, S.L.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of the first authorisation: {MM/YYYY}

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARCTERISTICS

{MM/YYYY}

10 CLASSIFICATION OF VETERINARY MEDICIANL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX WITH 2 VIALS OF 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Synthetic Oxytocin 10 IU

3. PACKAGE SIZE

2 x 10 ml

4. TARGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use:
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).

Intravenous use:
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.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE

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

BIOGÉNESIS GLOBAL, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX WITH 20 VIALS OF 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Synthetic Oxytocin 10 IU

3. PACKAGE SIZE

20 x 10 ml

4. TARGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use:
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).

Intravenous use:
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.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLEAT BEFORE USE”

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

BIOGÉNESIS GLOBAL, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX WITH 25 VIALS OF 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVTE OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Synthetic Oxytocin 10 IU

3. PACKAGE SIZE

25 x 10 ml

4. TARGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use:
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).

Intravenous use:
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.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 - 8°C).

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

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

BIOGÉNESIS GLOBAL, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX WITH 1 BOTTLE OF 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Synthetic Oxytocin 10 IU

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use:
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).

Intravenous use:
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.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

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

BIOGÉNESIS GLOBAL, S.L.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

LABEL FOR THE 10 ml VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Synthetic Oxytocin 10 IU

3. TARGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

4. ROUTES OF ADMINISTRATION

Intravenous or intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp {mm/yyyy}

7. SPECIAL STORAGE PRECAUTION

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOGÉNESIS GLOBAL, S.L.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

LABEL FOR THE 50 ml BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GESTAVET OXYTOCIN
10 IU/ml Synthetic Oxytocin, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Synthetic Oxytocin 10 IU

3. TAGET SPECIES

Sows, Ewes, Cows, Bitches and Queens.

4. ROUTES OF ADMINISTRATION

Intravenous or intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp {mm/yyyy}

7. SPECIAL STORAGE PRECAUTION

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

GESTAVET OXYTOCIN 10 IU/ml Synthetic Oxytocin, solution for injection

2. Composition

Each ml contains:

Active substance:
Synthetic Oxytocin 10 IU

Excipients:
Chlorobutanol hemihydrate 5 mg

3. Target species

Sows, Ewes, Cows, Bitches and Queens.

4. Indications for use

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.

5. Contraindications

Do not use in females with obstructive dystocia, 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.
Do not administer to pregnant females until parturition.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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 veterinary medicinal product to animals:
Pregnant women and people with known hypersensitivity to oxytocin should avoid 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. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
Do not administer to pregnant females until parturition.

Interaction with other medicinal products and other forms of interaction:
Calcium and oestrogens enhance the activity of oxytocin, whereas progestogens decrease it.
There may be an increase in the prevalence of uterine inertia in sows treated with prostaglandins prior to administration of oxytocin.
Stimulation of β adrenergic receptors may reduce the effect of oxytocin on the uterus or mammary gland.

Overdose:
If very large doses are given, a marked fall in blood pressure may occur.
Large doses may produce uncoordinated uterine contractions which can interfere with progress of the foetus.

< Special restrictions for use and special conditions for use:>

Major incompatibilities:
None known.

7. Adverse events

Sows, Ewes, Cows, Bitches and Queens: None known

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Intramuscular use:
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).

Intravenous use:
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.

9. Advice on correct administration

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.

10. Withdrawal periods

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

11. Special storage precautions

Store in a refrigerator (2 - 8°C).

Protect from light.
Shelf-life after first opening the immediate packaging: 28 days.
Keep out of the sight and reach of children.

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 size

Presentation:
Box with 2 vials of 10 ml.
Pack with 20 vials of 10 ml.
Pack with 25 vials of 10 ml.
Box with 1 bottle of 50 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
BIOGÉNESIS GLOBAL, S.L.
Quintanadueñas, 6, Bloque A, 1ª planta
28050 Madrid- SPAIN
+34 917 467 367

Manufacturer responsible for batch release:
Laboratorios Hipra S.A.
Avda. La Selva 135
17170 - Amer (Girona)
SPAIN

17. Other information