1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex 1 mg/ml Suspension for injection for cattle, horses, pigs, cats and dogs. (AT, BG, CZ, DE, EE, EL, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK(NI))
Trovex Suspension for Injection for cattle, horses, pigs, cats and dogs. (FR)
Trovex Vet 1 mg/ml Suspension for Injection for cattle, horses, pigs, cats and dogs. (FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone isonicotinate 1.00 mg
(equivalent to 0.79 mg Dexamethasone)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.35 mg
Propyl parahydroxybenzoate	0.15 mg
Sodium chloride	
Polysorbate 80 (E433)	
Water for injections	

White to yellowish white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, cats and dogs.

3.2 Indications for use for each target species

Cattle, horses, pigs, dogs and cats:
Treatment of inflammatory skin conditions, diseases of the locomotor system and diseases of the respiratory system.
Cattle:
Treatment of ketosis (acetonaemia).

3.3 Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism, or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also section 3.7.
Do not use for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.
Care should be taken not to overdose Channel Island breeds of cattle.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
Because of the pharmacological properties of the active ingredient, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.

Except in cases of ketosis, corticosteroid administration is to induce an improvement in clinical signs rather than a cure.
The underlying disease should be further investigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product contains dexamethasone and parahydroxybenzoates (parabens), which can cause allergic reactions in some people.
People with known hypersensitivity to dexamethasone or to any of the excipients should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Dexamethasone may affect fertility or the unborn child. Pregnant women should not handle this veterinary medicinal product.
The veterinary medicinal product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses, pigs, dogs and cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic reactions[1]
Undetermined frequency (cannot be estimated from the available data):	Cushing's disease[2], Adrenal gland disorder[3] Polyuria[4], polydipsia[4], polyphagia[4] Hypokalaemia[5], Hypernatremia[5] Cutaneous calcinosis, skin atrophy Delayed healing[6] Ulceration[7] Enlarged liver, elevated liver enzymes other abnormal test results[8] Hyperglycaemia[9] Acute pancreatitis[10]

	Laminitis Milk production decrease[11] Behavioural disorder[12]

[1] May be fatal.
[2] Iatrogenic hyperadrenocorticism. Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[3] During therapy effective doses suppress the hypothalamo-pituitary-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening regarding cats) and a gradual reduction of dosage.
[4] Particularly during the early stages of therapy.
[5] Upon long-term use including water retention
[6] Exacerbation of existing infections. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of disease.
[7] Gastrointestinal. May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma.
[8] Changes in the blood biochemical and haematological parameters
[9] Transient.
[10] Increased risk
[11] In cattle only.
[12] Occasional depression in cats and dogs, aggressiveness in dogs.

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

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 its local representative 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:
The use is not recommended during pregnancy. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy may cause early parturition or abortion.

3.8 Interaction with other medicinal products and other forms of interaction

Dexamethasone should not be given together with other anti-inflammatory substances. Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides.
The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.

Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.
Amphotericin B administered concomitantly with glucocorticoids may cause hypokalemia.
Glucocorticoids may also inhibit the hepatic metabolism of cyclophosphamide; dosage adjustments may be required.
Concomitant administration of glucocorticoids and cyclosporine may increase the blood levels of each, by mutually inhibiting the hepatic metabolism of each other; the clinical significance of this interaction is not clear.
Dexamethasone may decrease diazepam levels.
Ephedrine may reduce dexamethasone blood levels and interfere with dexamethasone suppression tests.
Ketoconazole and other azole antifungals may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels; ketoconazole may induce adrenal insufficiency when glucocorticoids are withdrawn by inhibiting adrenal corticosteroid synthesis.
Macrolide antibiotics (erythromycin, clarithromycin) may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels.
Mitotane may alter the metabolism of steroids; higher than usual doses of steroids may be necessary to treat mitotane-induced adrenal insufficiency.

3.9 Administration routes and dosage

Cattle, horses and pigs:
Intramuscular use.
Cattle, calves, horses and foals: 0.02 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2 ml/100 kg bodyweight.
Pigs: 0.02 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2 ml/100 kg bodyweight.
Piglets: 0.1 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight.

The maximal volume to be administered per injection site is 10 ml in cattle and horses and 3 ml in pigs.

Dogs and cats:
Intramuscular or subcutaneous use.
Dogs and cats: 0.1 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight.

The therapeutic effect of the product lasts for approximately 4 days. In horses, cats and dogs, where longer term treatment is necessary, an appropriate corticosteroid preparation should be used.

Shake well before use. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Do not broach the vial more than 25 times.

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

An overdose can induce drowsiness and lethargy in horses. See also section 3.6.

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

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 55 days.
Milk: 60 hours.

Horses:
Meat and offal: 63 days.
Not authorised for use in horses producing milk for human consumption.

Pigs:
Meat and offal: 55 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QH02AB02

4.2 Pharmacodynamics

Dexamethasone is a potent synthetic glucocorticoid with low mineralocorticoid activity. Corticosteroids may decrease the immune response. Indeed, they inhibit capillary dilatation, leukocyte migration and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis. Compared with base dexamethasone, the product has three times the glucogenic effect and seven times the anti-inflammatory effect, and comparatively little effect on milk yield when used in lactating cows.

4.3 Pharmacokinetics

The veterinary medicinal product contains a potent long acting corticosteroid with a therapeutic effect lasting for approximately 4 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Amber, glass (Ph. Eur. Type I or Ph. Eur. siliconized Type II) multidose vial containing 50 ml of product, sealed with a grey siliconized bromobutyl rubber stopper and aluminium cap, in a cardboard box.

Pack sizes:
Cardboard box containing 1 vial of 50 ml.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL 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

Cardboard box with 1 bottle of 50 m**l**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex 1 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Dexamethasone isonicotinate 1.00 mg (equivalent to 0.79 mg Dexamethasone)

3. PACKAGE SIZE

50 ml

4. TARGET SPECIES

Cattle, horses, pigs, cats and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle, horses, pigs: intramuscular use.
Cats, dogs: intramuscular use, subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:
Meat and offal: 55 days.
Milk: 60 hours.

Horses:
Meat and offal: 63 days
Not authorised for use in horses producing milk for human consumption.

Pigs:
Meat and offal: 55 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days, use by: ...

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to 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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trovex

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains: Dexamethasone isonicotinate 1.00 mg (equivalent to 0.79 mg Dexamethasone)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days., use by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Trovex 1 mg/ml Suspension for Injection for cattle, horses, pigs, cats and dogs

2. Composition

Each ml contains:

Active substances:
Dexamethasone isonicotinate 1.00 mg
(equivalent to 0.79 mg Dexamethasone)

Excipients:
Methyl parahydroxybenzoate (E218) 1.35 mg
Propyl parhaydroxybenzoate 0.15 mg
White to yellowish white suspension.

3. Target species

Cattle, horses, pigs, dogs and cats.

4. Indications for use

Cattle, horses, pigs, dogs and cats:
Treatment of inflammatory skin conditions, diseases of the locomotor system and diseases of the respiratory system.
Cattle:
Treatment of ketosis (acetonaemia).

5. Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism, or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not use in cases of hypersensitivity to the active substance, to corticosteroids and to any of the excipients.
See also section Special warnings. Do not use for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition.

6. Special warnings

Special precautions for safe use in the target species:
During a course of treatment the situation should be reviewed frequently by close veterinary supervision.
Care should be taken not to overdose Channel Island breeds.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
Because of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system.

Except in cases of ketosis corticosteroid administration is to induce an improvement in clinical signs rather than a cure.
The underlying disease should be further investigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product contains dexamethasone and parahydroxybenzoates (parabens), which can cause allergic reactions in some people.
People with known hypersensitivity to dexamethasone or to any of the excipients should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Dexamethasone may affect fertility or the unborn child. Pregnant women should not handle this veterinary medicinal product.
The veterinary medicinal product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Pregnancy:
The use is not recommended during pregnancy. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy may cause early parturition or abortion.

Interaction with other medicinal products and other forms of interaction:
Dexamethasone should not be given together with other anti-inflammatory substances.
Gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.
Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides.
The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.
Amphotericin B administered concomitantly with glucocorticoids may cause hypokalemia.
Glucocorticoids may also inhibit the hepatic metabolism of cyclophosphamide; dosage adjustments may be required.
Concomitant administration of glucocorticoids and cyclosporine may increase the blood levels of each, by mutually inhibiting the hepatic metabolism of each other; the clinical significance of this interaction is not clear.
Dexamethasone may decrease diazepam levels.
Ephedrine may reduce dexamethasone blood levels and interfere with dexamethasone suppression tests.
Ketoconazole and other azole antifungals may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels; ketoconazole may induce adrenal insufficiency when glucocorticoids are withdrawn by inhibiting adrenal corticosteroid synthesis.
Macrolide antibiotics (erythromycin, clarithromycin) may decrease the metabolism of glucocorticoids and increase dexamethasone blood levels.
Mitotane may alter the metabolism of steroids; higher than usual doses of steroids may be necessary to treat mitotane-induced adrenal insufficiency.

Overdose:
An overdose can induce drowsiness and lethargy in horses. See also section “Adverse events”.

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

7. Adverse events

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Cattle, horses, pigs, dogs and cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic reactions[1]
Undetermined frequency (cannot be estimated from the available data):	Cushing's disease[2], Adrenal gland disorder[3] Polyuria (increased urination)[4], polydipsia (increased thirst)[4], polyphagia (increased appetite)[4] Hypokalaemia (low blood potassium)[5], Hypernatremia[5] Cutaneous calcinosis (calcium deposit in the skin), skin atrophy Delayed healing[6] Ulceration[7] Enlarged liver, elevated liver enzymes other abnormal test results[8] Hyperglycaemia (high blood sugar)[9] Acute pancreatitis[10] Laminitis Milk production decrease[11] Behavioural disorder[12]

[1] May be fatal.
[2] Iatrogenic hyperadrenocorticism. Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[3] During therapy effective doses suppress the hypothalamo-pituitary-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening regarding cats) and a gradual reduction of dosage.
[4] Particularly during the early stages of therapy.
[5] Upon long-term use including water retention
[6] Exacerbation of existing infections. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of disease.
[7] Gastrointestinal. May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma.
[8] Changes in the blood biochemical and haematological parameters
[9] Transient.
[10] Increased risk
[11] In cattle only.
[12] Occasional depressions in cats and dogs, aggressiveness in dogs.

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 its local representative 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

Cattle, horses and pigs:
Intramuscular use.
Cattle, calves horses and foals: 0.02 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2 ml/100 kg bodyweight.
Pigs: 0.02 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.016 mg of dexamethasone/kg) corresponding to 2 ml/100 kg bodyweight.
Piglets: 0.1 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight.

The maximal volume to be administered per injection site is 10 ml in cattle and horses and 3 mL in pigs.

Dogs and cats:
Intramuscular or subcutaneous use.
Dogs and cats: 0.1 mg of dexamethasone isonicotinate/kg body weight (equivalent to 0.08 mg of dexamethasone/kg) corresponding to 1 ml/10 kg bodyweight

The therapeutic effect of the veterinary medicinal product lasts for approximately 4 days. In horses, cats and dogs, where longer term treatment is necessary, an appropriate corticosteroid preparation should be used.

9. Advice on correct administration

Shake well before use. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Do not broach the vial more than 25 times.

10. Withdrawal periods

Cattle:
Meat and offal: 55 days.
Milk: 60 hours.

Horses:
Meat and offal: 63 days.
Not authorised for use in horses producing milk for human consumption.

Pigs:
Meat and offal: 55 days.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not refrigerate or freeze.
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 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

Cardboard box containing 1 vial of 50 ml.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:
Emdoka, John Lijsenstraat 16, 2321 Hoogstraten, Belgium
Tel. +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:
Divasa Farmavic S.A., Ctra. Sant Hipolit, Km. 71, Gurb Vic, 08503, Barcelona, Spain

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.