[Version 9, 11/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ceftiofur (as hydrochloride) 50.0 mg
Ketoprofen 150.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan oleate
Hydrogenated soya lecithin
Cottonseed oil

Off - white to pinkish suspension for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of bovine respiratory disease (BRD) caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to ceftiofur and the reduction of associated clinical signs of inflammation or pyrexia.

3.3 Contraindications

Do not use in cases of known resistance to other cephalosporins or beta-lactam antibiotics.

Do not use in cases of hypersensitivity to ceftiofur and other β-lactam antibiotics.
Do not use in cases of hypersensitivity to ketoprofen.

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids concurrently or within 24 hours of each other.

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment.
When inflammation or pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing veterinary medicinal product in order to cover 3 to 5 days of continuous antibiotic treatment. Treating for an appropriate length of time is important to limit development of resistance.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used. Increased use, including use of the veterinary medicinal product deviating from the instructions given in the SPC, may increase the prevalence of such resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.
The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

The concomitant use of diuretics or coagulant should be based on a benefit/risk assessment of the responsible veterinarian.

Avoid intra-arterial and intravenous injection.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

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

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Ketoprofen may also cause hypersensitivity. Allergic reactions to these substances may occasionally be serious.

Do not handle this veterinary medicinal product if you know you are sensitised to active substances or to any of excipients, or if you have been advised not to work with such preparations.

Wash hands after use.

Avoid contact with eyes and skin. In case of contact, wash immediately with water.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

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

Cattle:

Common (1 to 10 animals / 100 animals treated):	Injection site inflammation (e.g. Injection site oedema)[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions (e.g. Anaphylaxis, allergic skin reaction)[2] Ruminant stomach disorder[3] Renal disorder[3] Skin discolouration and/or Muscle discolouration.

[1]Mild and without pain in most cases.
[1] Laboratory studies with ceftiofur or ketoprofen have shown occurrence of allergic reaction the treatment should be withdrawn.
[2]Unrelated to dose.
[3]In common with all NSAIDs due to their action of inhibition of prostaglandin synthesis.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies with ceftiofur or ketoprofen have shown no evidence of teratogenesis effects, abortion or influence on reproduction. The safety of the veterinary medicinal product has not been established during pregnancy.
Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Do not use in combination with other NSAIDs or with corticosteroids, diuretics, nephrotoxic drugs or anticoagulants.
The bactericidal properties of beta-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

3.9 Administration routes and dosage

Intramuscular use.

1 mg ceftiofur/kg/day and 3 mg ketoprofen/kg/day by intramuscular injection, *i.e.* 1 ml/50 kg at each injection. The veterinary medicinal product should only be used when the disease is associated with clinical signs of inflammation or pyrexia. The veterinary medicinal product may be administered for 1 to 5 consecutive days depending upon the clinical response on a case by case basis. As the duration

for the antibiotic treatment should not be less than 3 to 5 days, when inflammation and pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing product in order to cover 3 to 5 days of continuous antibiotic treatment. Only few animals are expected to require a fourth or fifth injection with the combined product.

Shake the bottle vigorously for 20 seconds before use to ensure an homogeneous suspension.
Resuspension could be longer after storage at low temperatures.

To ensure correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The user should use the most appropriate vial size according to the number of animals to treat.
The 50 ml and 100 ml vials should not be pierced more than 10 times and the 250 ml not more than 18 times. The use of an aspirating needle may be recommended to avoid excessive broaching of the stopper.

Subsequent intramuscular injections must be given at different sites.
Not more than 16 ml should be administered per injection site.

Use preferably a 14 gauge needle.

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

No signs of systemic toxicity of the veterinary medicinal product have been observed at doses up to 5 times the recommended daily dose for 15 consecutive days.

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

Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

3.12 Withdrawal periods

Meat and offal: 8 days.
Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DD99

4.2 Pharmacodynamics

Ceftiofur is third generation cephalosporin, which is active against many Gram-positive and Gram-negative bacteria. Ceftiofur, as other beta-lactams, inhibits the bacterial cell wall synthesis, thereby exerting bactericidal properties.
Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBPs). Bacteria may develop resistance to cephalosporins by four basic mechanisms: 1) altering or acquiring penicillin binding proteins insensitive to an otherwise effective b -lactam; 2) altering the permeability of the cell to b -lactams; 3) producing b -lactamases that cleave the b -lactam ring of the molecule, or 4) active efflux.
Some beta-lactamases, documented in Gram-negative enteric organisms, may confer elevated MICs to varying degrees to third and fourth generation cephalosporins, as well as penicillins, ampicillin, b -lactam inhibitor combinations, and first and second generation cephalosporins.

Ceftiofur is active against the following microorganisms which are involved in respiratory diseases in cattle: *Pasteurella multocida*, *Mannheimia haemolytica* (formerly *Pasteurella haemolytica*).

Minimum Inhibitory Concentrations (MICs) have been determined for ceftiofur in European isolates of target bacteria, isolated from diseased animals between 2014 and 2016.

Species (number of isolates)	**MIC range (µg/mL)**	**MIC50 (µg/mL)**	**MIC90 (µg/mL)**
Mannheimia haemolytica (91)	0.002-4	0.015	0.06
Pasteurella multocida (155)	0.008-0.25	0.015	0.03

MICs of respiratory target pathogens showed mono-modal distribution profiles with good susceptibility towards ceftiofur. Clinical breakpoints (CLSI document VET08 (5) and VET06 (6)) for ceftiofur are established for bovine respiratory disease and *M. haemolytica, P. multocida*: susceptible: ≤2 µg/ml; intermediate: 4 µg/ml; resistant: ≥8 µg/ml. According to these breakpoints no clinical resistant strains of respiratory target pathogens were observed.

Ketoprofen is a derivative of phenylpropionic acid, and belongs to the non-steroidal anti-inflammatory group of drugs. The mechanism of action is related to the ability of ketoprofen to interfere with the synthesis of prostaglandins from precursors such as arachidonic acid. Although ketoprofen has no direct effect on endotoxins after they have been produced, it reduces prostaglandin production and hence reduces the many effects of the prostaglandin cascade. Prostaglandins are part of the complex processes involved in the development of endotoxic shock. Like all such substances, its principal pharmacological actions are anti-inflammatory, analgesic and anti-pyretic.

4.3 Pharmacokinetics

After administration, ceftiofur is quickly metabolised to desfuroylceftiofur, the principal active metabolite.

Desfuroylceftiofur has an equivalent anti-microbial activity to ceftiofur against the major target bacteria in animals. The active metabolite is reversibly bound to plasma proteins. Due to transportation with these proteins, the metabolite concentrates at a site of infection, is active and remains active in the presence of necrotic tissue and debris.

Ceftiofur is completely bioavailable following intramuscular administration.

After a single 1 mg/kg dose of ceftiofur (as hydrochloride) given intramuscularly to cattle, maximum ceftiofur and desfuroylceftiofur-related metabolites plasma concentrations of 6.11 ± 1.56 µg/mL (Cmax) are reached within 5 hours (Tmax) after single administration. The apparent terminal elimination half-life (t½) of ceftiofur and desfuroylceftiofur-related metabolites was of 22 hours.
The elimination occurred mainly via the urine (more than 55 %); 31 % of the dose was recovered in the faeces.

Ketoprofen is completely bioavailable following intramuscular administration.

After a single 3 mg/kg dose of ketoprofen given intramuscularly to cattle, maximum ketoprofen plasma concentrations of 5.55 ± 1.58 µg/mL (Cmax) are reached within 4 hours (Tmax) after single administration. The apparent terminal elimination half-life (t½) of ketoprofen was 3.75 hours.

In cattle, ketoprofen is strongly bound to proteins (97%). The elimination occurred mainly via the urine (90 % of the doses), as metabolites.

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Coloured, type II glass vial with bromobutyl rubber stopper and aluminium cap, packed in a cardboard box or Amber coloured, translucent polypropylene (PP) vial containing a stainless steel ball, closed with bromobutyl rubber stopper and aluminium cap, packed in a cardboard box.

Pack sizes:
1 x 50 ml
1 x 100 ml
1 x 250 ml

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. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDECINAL 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 1 vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride)	50.0 mg/ml
Ketoprofen	150.0 mg/ml

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Meat and offal: 8 days.
Milk: zero hours.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the glass 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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass or plastic vial of 50 or 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50.0 mg/ml
150.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass or plastic vials of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride)	50.0 mg/ml
Ketoprofen	150.0 mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 8 days.
Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
For the glass vial only: Keep the glass vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Curacef Duo 50 mg/ml + 150 mg/ml Suspension for injection for cattle

2. Composition

Each ml contains:
Active substances:
Ceftiofur (as hydrochloride) 50.0 mg
Ketoprofen 150.0 mg

Off - white to pinkish suspension for injection.

3. Target species

Cattle.

4. Indications for use

For the treatment of bovine respiratory disease (BRD) caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to ceftiofur and the reduction of associated clinical signs of inflammation or pyrexia.

5. Contraindications

Do not use in cases of hypersensitivity to ceftiofur and other β-lactam antibiotics.
Do not use in cases of hypersensitivity to ketoprofen.
Do not use in cases of known resistance to other cephalosporins or beta-lactam antibiotics.
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids concurrently or within 24 hours of each other.
Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.

6. Special warnings

Special precautions for safe use in the target species:

The veterinary medicinal product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the veterinary medicinal product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment.
When inflammation or pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing product in order to cover 3 to 5 days of continuous antibiotic treatment. Treating for an appropriate length of time is important to limit development of resistance.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used. Increased use, including use of the product deviating from the instructions

given in the SPC, may increase the prevalence of such resistance. Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.
The veterinary medicinal product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

The concomitant use of diuretics or coagulant should be based on a benefit/risk assessment of the responsible veterinarian.

Avoid intra-arterial and intravenous injection.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Ketoprofen may also cause hypersensitivity. Allergic reactions to these substances may occasionally be serious.
Do not handle this veterinary medicinal product if you know you are sensitised to active substances or to any of the ingredients, or if you have been advised not to work with such preparations.
Wash hands after use.
Avoid contact with eyes and skin. In case of contact, wash immediately with water.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.
Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Laboratory studies with ceftiofur or ketoprofen have shown no evidence of teratogenesis effects, abortion or influence on reproduction. The safety of the veterinary medicinal product has not been established during pregnancy.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Do not use in combination with other NSAIDs or with corticosteroids, diuretics, nephrotoxic drugs or anticoagulants.
The bactericidal properties of beta-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

Overdose:
No signs of systemic toxicity of the veterinary medicinal product have been observed at doses up to 5 times the recommended daily dose for 15 consecutive days.

Special restrictions for use and special conditions for use:
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

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

7. Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated)
Injection site inflammation (e.g. Injection site oedema (injection site swelling))[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports)
Hypersensitivity reactions (e.g. Anaphylaxis (severe allergic reaction), allergic skin reaction)[2] Ruminant stomach disorder[3] Renal disorder[3] Skin discolouration and/or Muscle discolouration.

[1]Mild and without pain in most cases.
[1]In case of the occurrence of allergic reaction the treatment should be withdrawn.
[2]Unrelated to dose.
[3]In common with all NSAIDs due to their action of inhibition of prostaglandin synthesis.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 the local representative of 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.

1 mg ceftiofur /kg /day and 3 mg ketoprofen /kg /day by intramuscular injection, i.e. 1 ml/50 kg at each injection. The veterinary medicinal product should only be used when the disease is associated with clinical signs of inflammation or pyrexia. The veterinary medicinal product may be administered for 1 to 5 consecutive days depending upon the clinical response on a case by case basis. As the duration for the antibiotic treatment should not be less than 3 to 5 days, when inflammation and pyrexia have subsided, the veterinarian should switch to a ceftiofur only-containing product in order to cover 3 to 5 days of continuous antibiotic treatment. Only few animals are expected to require a fourth or fifth injection with the combined product.

9. Advice on correct administration

Shake the bottle vigorously for 20 seconds before use to ensure an homogeneous suspension.
Resuspension could be longer after storage at low temperatures.
To ensure correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The user should use the most appropriate vial size according to the number of animals to treat. 50 ml and 100 ml vials should not be pierced more than 10 times and the 250 ml not more than 18 times.
The use of an aspirating needle may be recommended to avoid excessive broaching of the stopper
Subsequent intramuscular injections must be given at different sites.
Not more than 16 ml should be administered per injection site.
Use preferably a 14 gauge needle.

10. Withdrawal periods

Meat and offal: 8 days.
Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not freeze.
Keep the glass 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 or carton after Exp.

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

1 x 50 ml, 1 x 100 ml and 1 x 250 ml (glass vials or polypropylene vials).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
FRANCE

Local representatives and contact details to report suspected adverse reactions:

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