ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 20 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

meloxicam 20 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96%)	159.8 mg
Poloxamer 188	
Macrogol 400	
Glycine	
Sodium hydroxide	
Hydrochloric acid, concentrated	
Meglumine	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses.

3.2 Indications for use for each target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

3.3 Contraindications

See also section 3.7.
Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

3.4 Special warnings

Treatment of calves with Contacera 20 minutes before dehorning reduces post-operative pain. Contacera alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

3.5 Special precautions for use

Special precautions for safe use in the target species:

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

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

Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs and horses:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site swelling[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[3]

[1]Slight transient swelling following subcutaneous administration in cattle and pigs.
[2]Transient swelling in horses but resolves without intervention.
[3]May be serious (including fatal), if such reaction occurs, it should be treated symptomatically.

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 and lactation:

Cattle and pigs:

Can be used during pregnancy and lactation.

Horses:

Do not use in pregnant or lactating mares.
See also section 3.3.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other Non-Steroidal Anti-Inflammatory Drugs or with anticoagulant agents.

3.9 Administration routes and dosage

Maximum number of piercings is 14 for the 20 ml, 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo - skeletal disorders, oral suspensions of meloxicam may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Avoid introduction of contamination during use.

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

In case of overdose, symptomatic treatment should be initiated.

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: 15 days.
Milk: 5 days.

Pigs:

Meat and offal: 5 days.

Horses:

Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a NSAID of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.
After two intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.9 µg/ml was reached after 1 hour in pigs.

Distribution
More than 98% of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. The metabolism in horses has not been investigated.

Elimination
Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.
In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.
In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.
Approximately 50% of the administered dose is eliminated via urine and the remainder via faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless glass vial containing 20 ml, 50 ml, 100 ml or 250 ml. Each vial is closed with a rubber stopper and sealed with an aluminium cap.

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/144/001 20 ml
EU/2/12/144/002 50 ml
EU/2/12/144/003 100 ml
EU/2/12/144/004 250 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/12/2012.

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

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).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

meloxicam 15 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	5 mg
Saccharin sodium	
Carmellose sodium	
Silica, colloidal anhydrous	
Citric acid monohydrate	
Sorbitol, liquid (non-crystallising)	
Disodium phosphate dodecahydrate	
Honey aroma	
Purified water	

Honey flavoured, off-white to yellow viscous oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

3.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

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

People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, 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

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Abdominal pain, Colitis, Diarrhoea[1], Anaphylactoid reaction[2], Urticaria[1], Appetite loss, Lethargy

[1]Reversible.
[2]May be serious (including fatal); if such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued, and the advice of a veterinarian should be sought.

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

Laboratory studies in cattle have not produced any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticoids, other Non-Steroidal Anti-Inflammatory Drugs or with anti-coagulant agents.

3.9 Administration routes and dosage

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

Shake well before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

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

Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a Non-Steroidal Anti-Inflammatory Drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98%. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98% of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs, although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

Cardboard box containing one HDPE bottle of 100 or 250 ml with a tamper proof child resistant closure and a polypropylene measuring syringe.

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/144/005 100 ml
EU/2/12/144/006 250 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/12/2012.

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

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 20 ml, 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

meloxicam 20 mg/ml

3. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle:
Single subcutaneous or intravenous injection.

Pigs:
Single intramuscular injection. If required, a second administration can be given after 24 hours.

Horses:
Single intravenous injection.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/12/144/001 20 ml
EU/2/12/144/002 50 ml
EU/2/12/144/003 100 ml
EU/2/12/144/004 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 100 ml, and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

meloxicam 20 mg/ml

100 ml
250 ml

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle:
SC or IV injection.

Pigs:
IM injection.

Horses:
IV injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for 20 ml and 50 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

meloxicam 20 mg/ml

20 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days
Once broached use by…

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 100 ml or 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

meloxicam 15 mg/ml

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/12/144/005 100 ml
EU/2/12/144/006 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label for 100 ml and 250 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

meloxicam 15 mg/ml

100 ml
250 ml

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Contacera 20 mg/ml solution for injection for cattle, pigs and horses

2. Composition

One ml contains:

Active substance:

meloxicam 20 mg

Excipient:

Ethanol (96%) 159.8 mg

Clear, yellow solution.

3. Target species

Cattle, pigs and horses.

4. Indications for use

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

5. Contraindications

Do not use in horses less than 6 weeks of age.
Do not use in pregnant or lactating mares.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. Special warnings

Special warnings:
Treatment of calves with Contacera 20 minutes before dehorning reduces post-operative pain. Contacera alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Special precautions for safe use in the target species:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other Non-Steroidal Anti-Inflammatory Drugs or with anticoagulant agents.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

7. Adverse events

Cattle, pigs and horses:

Common (1 to 10 animals / 100 animals treated):
Injection site swelling[1]
Uncommon (1 to 10 animals / 1,000 animals treated):
Injection site swelling[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[3]

[1]Slight transient swelling following subcutaneous administration in cattle and pigs.
[2]Transient swelling in horses but resolves without intervention.
[3]May be serious (including fatal), if such reaction occurs, it should be treated symptomatically.

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

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculoskeletal disorders, oral suspensions of meloxicam may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. Advice on correct administration

Avoid introduction of contamination during use.
Maximum number of piercings is 14 for the 20 ml, 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

10. Withdrawal periods

Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 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 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

EU/2/12/144/001-004

Cardboard box containing one colourless glass vial of 20 ml, 50 ml, 100 ml or 250 ml.

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 contact details to report suspected adverse reactions:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

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Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

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Manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Limited
Ida Industrial Estate
Dublin Road
Loughrea
Co. Galway
H62 FH90
Ireland

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Contacera 15 mg/ml oral suspension for horses

2. Composition

One ml contains:

Active substance:

meloxicam 15 mg

Excipient:

Sodium benzoate 5 mg

3. Target species

Horses.

4. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in horses.

5. Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).
Do not use in horses less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive horse, 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:
People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, other Non-Steroidal Anti-Inflammatory Drugs or with anti-coagulant agents.

Overdose:
In the case of overdose symptomatic treatment should be initiated.

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Abdominal pain, Colitis, Diarrhoea[1], Anaphylactoid reaction[2], Urticaria[1], Appetite loss, Lethargy

[1]Reversible.
[2]May be serious (including fatal), if such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued, and the advice of a veterinarian should be sought.

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

Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. This is equivalent to 1 ml of Contacera per 25 kg body weight of horse. For example, a horse weighing 400 kg will receive 16 ml of Contacera, a horse weighing 500 kg will receive 20 ml of Contacera, and a horse weighing 600 kg will receive 24 ml of Contacera.

Shake well before use. To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

9. Advice on correct administration

Avoid introduction of contamination during use.

10. Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 3 months.

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 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

EU/2/12/144/005-006

Cardboard box containing one HDPE bottle of 100 or 250 ml with a tamper proof child resistant closure and a polypropylene measuring syringe.

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 contact details to report suspected adverse reactions:

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