

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

Excipient:

Ethanol (96%) 159.8 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses

4.2 Indications for use, specifying the 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 toxæmia (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.

4.3 Contraindications

See also section 4.7.

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 case 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Common adverse reactions include slight transient swelling at the injection site following subcutaneous administration in cattle and pigs. This was observed in less than 10% of the cattle treated in clinical studies.

Uncommon adverse reactions include transient swelling at the injection site in horses, but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), when they occur, they should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle and pigs:

Can be used during pregnancy and lactation.

Horses:

Do not use in pregnant or lactating mares.

See also section 4.3.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

In case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ethanol (96%)
- Poloxamer 188
- Macrogol 400
- Glycine
- Sodium hydroxide
- Hydrochloric acid, concentrated
- Meglumine
- Water for injections

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. 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 |

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06/12/2012.

Date of last renewal: 15/11/2017.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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

Excipient:

Sodium benzoate 5 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

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

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

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

4.3 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 case of hypersensitivity to the active substance or to any of the excipients.

Do not use in horses less than 6 weeks of age.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, 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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible.

In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Meat and offal: 3 days.

Not authorised for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).
ATCvet code: QM01AC06.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium
Carmellose sodium
Silica, colloidal anhydrous
Citric acid monohydrate
Sorbitol, liquid (non-crystallising)
Disodium phosphate dodecahydrate
Sodium benzoate
Honey aroma
Purified water

6.2 Major incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Do not freeze.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBER(S)

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15/02/2014.

Date of last renewal: 15/11/2017.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IRELAND

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Contacera is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) 37/2010:

| Pharmacologically active substance | Marker residue | Animal species | MRL | Target tissues | Other provisions | Therapeutic classification |
|------------------------------------|----------------|--|----------------------------------|---------------------------|------------------|--|
| Meloxicam | Meloxicam | Bovine, caprine, porcine, rabbit, <i>Equidae</i> | 20 µg/kg 65 µg/kg 65 µg/kg | Muscle Liver Kidney | NO ENTRY | Anti-inflammatory agents/Nonsteroidal anti-inflammatory agents |
| | | Bovine, caprine | 15 µg/kg | Milk | | |

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 for cattle, pigs and horses
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

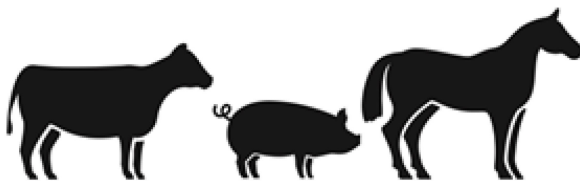
3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

5. TARGET SPECIES



Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:

Single S.C. or I.V. injection.

Pigs:

Single I.M. injection. If required, a second administration can be given after 24 hours.

Horses:

Single I.V. injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf -life after first opening the immediate packaging: 28 days

Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS ‘FOR ANIMAL TREATMENT ONLY’ AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. 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 |

17. MANUFACTURER'S 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 for cattle, pigs and horses
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

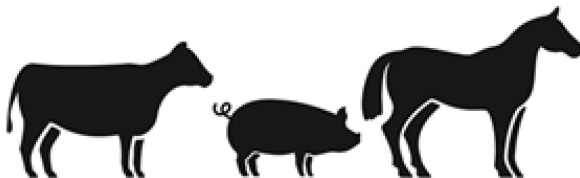
3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES



Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:
SC or IV injection.

Pigs:
IM injection.

Horses:
IV injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf -life after first opening the immediate packaging: 28 days

Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS ‘FOR ANIMAL TREATMENT ONLY’ AND CONDITIONS OF RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/144/003 100 ml
EU/2/12/144/004 250 ml

17. MANUFACTURER'S BATCH NUMBER

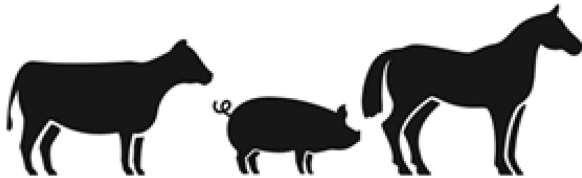
Lot {number}

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



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV.

Pigs: IM.

Horses: IV.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Shelf- life after first opening the immediate packaging: 28 days

Once broached, use by...

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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 for horses
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP {month/year}
Once broached use by.....

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER’S 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 for horses
meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP {month/year}
Once broached use by.....

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IRELAND

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 20 mg
Ethanol (96%) 159.8 mg
Clear, yellow solution.

4. INDICATION(S)

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 toxemia (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 case 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.

6. ADVERSE REACTIONS

Common adverse reactions include slight transient swelling at the injection site following subcutaneous administration in cattle and pigs. This was observed in less than 10% of the cattle treated in clinical studies.

Uncommon adverse reactions include transient swelling at the injection site in horses, but resolves without intervention.

In very rare cases, anaphylactoid reactions, which may be serious (including fatal), when they occur, they should be treated symptomatically.

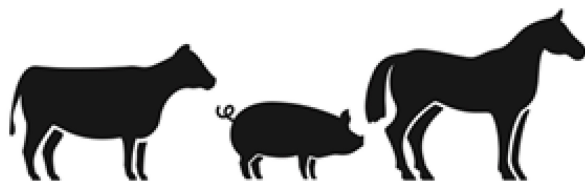
The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses



8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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.

Shelf-life after first opening the container: 28 days.

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.

12. SPECIAL WARNING(S)

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 use in animals:

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.

Interactions 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 (symptoms, emergency procedures, antidotes):

In case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

PACKAGE LEAFLET:
Contacera 15 mg/ml oral suspension for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

Manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
IRELAND

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Contacera 15 mg/ml oral suspension for horses
meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

| | |
|-----------------|-------|
| Meloxicam | 15 mg |
| Sodium benzoate | 5 mg |

4. INDICATION(S)

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 case of hypersensitivity to the active substance or to any of the excipients.

Do not use in horses less than 6 weeks of age.

6. ADVERSE REACTIONS

In very rare cases, adverse reactions typically associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible.

In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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 WARNING(S)

Special precautions for use in animals:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, 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 (symptoms, emergency procedures, antidotes):

In the case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu>).

15. OTHER INFORMATION

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.