Ketofen® 10%
Inspuiting/Injection

S3

Veterinary Medicine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
KETOFEN® 10% (Injection)
Strength
Ketoprofen 10 g/ 100 ml [10 % m/v]
Pharmaceutical form
Clear, colourless solution (for injection)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance:
Ketoprofen 10 g/100 ml [10% m/v]
Excipient:
The inactive ingredients include: Benzyl alcohol 1 % m/v (Preservative)
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Clear and colourless solution (for injection).

4. CLINICAL PARTICULARS
4.1. Target species
Horses, Cattle and Pigs
4.2. Indications for use, specifying the target species
Horses
Anti-inflammatory and analgesic treatment of musculo-skeletal disorders.
Symptomatic analgesic treatment of visceral pain.
Cattle
Anti-inflammatory, analgesic and anti-pyretic in cases of musculo-skeletal conditions. Use as an adjunct to the treatment of acute respiratory conditions, mastitis and other inflammatory conditions.
Pigs
Treatment of inflammatory conditions, i.e. mastitis – metritis – agalactia syndrome (MMA) and respiratory infections; Alleviation of fever.
4.3. Contraindications
Do not administer to animals with gastro-duodenal ulcers or hemorrhagic syndromes.
Do not administer to animals with severe renal insufficiency.
Do not administer to animals with a bleeding tendency.
Do not use when previous allergy to ketoprofen has occurred.
Do not administer to horses destined for human consumption.
4.4. Special warnings for each target species
Do not administer by intra-arterial route.
4.5. Special precautions for use
Special precautions for use in animals.
Refer to section 4.3. Contraindications.
4.6. Adverse reactions
Side effects typical of non-steroidal anti-inflammatory agents such as gastro-intestinal ulceration and nephrotoxicity may occur.
4.7. Use during pregnancy, lactation or lay
As the effects of ketoprofen on fertility, pregnancy or foetal health in horses have not been determined, KETOFEN 10% should not be administered to pregnant mares.
KETOFEN 10% may be given to pregnant and lactating cattle and is indicated for use in lactating sows.
The effect of treatment during the parturient period has not been investigated.
Do not use in foals that are less than 15 days old.
Do not administer to horses destined for human consumption.
4.8. Interaction with other medicinal products and other forms of interaction
Do not mix with another substance.
Do not use with other non-steroidal anti-inflammatory drugs, or with diuretics or anticoagulants.
4.9. Amounts to be administered and administration route
Horses
For musculo-skeletal inflammation and pain: 2,2 mg of active ingredient per kg body mass daily for 3 to 5 consecutive days, by intravenous or intramuscular route, i.e. 1 ml per 45 kg.
For visceral pain associated with colic: 2,2 mg of active ingredient per kg. i.e. 1 ml per 45 kg body mass. A single intravenous injection is usually sufficient. Any further injections should be considered after reconsideration of the diagnosis.

Cattle
3 mg of active ingredient per kg body mass, daily for 1 to 3 consecutive days, by intravenous or intramuscular route, i.e. 3 ml per 100 kg.

Pigs
One injection of 3 mg of active ingredient per kg body mass, i.e. 3 ml per 100 kg by intramuscular route.

4.10. Overdose
Gastro-intestinal ulceration and nephrotoxicity is related to duration of treatment.
Treatment is supportive.
4.11. Withdrawal period(s)

Cattle (edible tissues)	1 day intravenous route 4 days intramuscular route
Pigs (edible tissues)	4 days
Cattle (milk)	Milk discard time of nil hours

A4710-01

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Class of medicine:
C3.1 Anti-rheumatics (Anti-inflammatory agents)
Mechanism of action
Ketoprofen is a non-steroidal anti-inflammatory agent with analgesic and antipyretic activity.
It acts by inhibiting prostaglandin synthesis.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
L-arginine
Benzyl alcohol
Citric acid, monohydrate
Water for injections
6.2. Major Incompatibilities
Do not mix with another substance.
Do not use with other non-steroidal anti-inflammatory drugs, or with diuretics or anticoagulants.
See section 4.5
6.3. Shelf life
Shelf-life before opening:
Brown glass vials: 36 months
Amber multilayer plastic vials: 36 months
Shelf-life after opening:
Brown glass vials: 4 weeks
Amber multilayer plastic vials: 4 weeks
6.4. Special precautions for storage
Protect from light and heat.
Store at or below 25 °C
Keep out of reach of children and uninformed persons.
Amber multilayer plastic vials: Keep the vial in the outer carton in order to protect from light.
6.5. Nature and composition of immediate packaging
100 ml multi-dose amber glass bottle with grey chlorobutyl stoppers.
50, 100 or 250 ml amber multilayer plastic vials with grey bromobutyl stoppers.

7. MARKETING AUTHORISATION HOLDER
Ceva Animal Health (Pty) Ltd
P. O. Box 7707
Halfway House
Midrand, 1685
South Africa
Tel: 011 312 4088

8. MARKETING AUTHORISATION NUMBER(S)
94/3.1/11 (Act 101/1965)
Namibia Reg. No.: NS2 V07/3.1.2.1/1059 (Act 13/2003)

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION
27 February 1997

10. DATE OF REVISION OF THE TEXT
May 2021

R0751-01/2022

Veterinêre medisyne

Skeduleringstatus:

S3

1. NAAM VAN DIE VETERINÊRE MEDISYNE

KETOFEN® 10% (Inspuiting)

Sterkte

Ketoprofen 10 g/100 ml [10 % m/v]

Farmaseutiese vorm

Helder, kleurlose oplossing (vir inspuiting)

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddeel

Ketoprofen 10 g/100 ml [10 % m/v]

Bymiddels

Die sluit in: Bensielalkohol 1 % m/v (preserveermiddel)

Vir 'n volledige lys van bymiddels sien afdeling 6.1

3. FARMASEUTIESE VORM

Helder, kleurlose oplossing (vir inspuiting)

4. KLINIESE BESONDERHEDE

4.1 Teiken-spesies

Perde, beeste en varke

4.2 Aanwysings vir gebruik, insluitende die teiken-spesies

Perde

Anti-inflammatoriese en pynstillende behandeling van skeletspiersiekte. Simptomatiese pynstillende behandeling vir ingewandspyn.

Beeste

Anti-inflammatoriese, pynstillend en antipiretiese werking teen skeletspiersiekte. Gebruik as toevoeging by die behandeling van akute respiratoriese infeksies, mastitis en ander inflammatoriese reaksies.

Varke

Behandeling van inflammatoriese toestande, bv. mastitis – metritis – agalaktiese sindroom (MMA) en respiratoriese infeksies; Verligting van koors.

4.3 Kontra-indikasies:

- Moenie aan diere met gastro-duodenale ulkusse of hemorragiese sindroom toedien nie.
- Moenie aan diere met erge renale ontoereikendheid toedien nie.
- Moenie aan diere wat geneig is om te bloei, toedien nie.
- Moenie aan diere waar allergie aan ketoprofen voorheen waargeneem is, toedien nie.
- Moenie aan perde wat vir menslike gebruik bestem is, toedien nie.

4.4 Spesiale waarskuwings vir elke teiken-spesie

Moenie in die slagare toedien nie.

4.5 Spesiale voorsorgmaatreëls vir gebruik

Vir spesiale voorsorgmaatreëls vir gebruik in diere, verwys na afdeling 4.3 Kontra – indikasies.

4.6 Newe-effekte

Newe-effekte kenmerkend aan die toediening van nie-steroïedale anti-inflammatoriese middels soos gastro-intestinale ulkusse en nefrotoksisiteit mag voorkom.

4.7 Gebruik gedurende dragtigheis en laktasie

- Aangesien die effek van ketoprofen op vrugbaarheid, dragtigheid en foetale gesondheid in perde nie vasgestel is nie, moet Ketofen 10 % nie aan dragtige merries toegedien word nie.
- Ketofen 10 % mag aan dragtige en lakterende beeste toegedien word en is aanbeveel vir gebruik by lakterende sôe. Die uitwerking van behandeling tydens partus is nie ondersoek nie.
- Moenie aan vullens jonger as 15 dae, toedien nie.

4.8 Interaksies met ander medisinale produkte en ander soorte van interaksies

- Moenie met ander middels meng nie.
- Moenie met ander nie-steroïedale anti-inflammatoriese middels, diuretikums of anti-koagulante meng nie.

4.9 Dosis en gebruiksaanwysings

Perde

Vir skeletspierinflammasie en pyn: 2,2 mg aktiewe bestanddeel per kg liggaamsmassa binneaars of binnespiers daagliks vir 3 tot 5 agtereenvolgende dae, bv. 1 ml per 45 kg.

Vir ingewandspyn geassosieer met koliek: 2,2 mg aktiewe bestanddeel per kg, bv. 1 ml per 45 kg liggaamsmassa. Een binneaarse inspuiting is normaalweg voldoende. Verdere inspuitings moet eers na deeglike heroorweging toegedien word.

Beeste

3 mg aktiewe bestanddeel per kg liggaamsmassa, daagliks vir 1 tot 3 agtereenvolgende dae, binneaars of binnespiers, bv. 3 ml per 100 kg.

Varke

Een inspuiting van 3 mg aktiewe bestanddeel per kg liggaamsmassa, bv. 3 ml per 100 kg, binnespiers.

4.10 Oordosering en die behandeling daarvan

Gastro-intestinale newe-effekte en nefrotoksisiteit hou verband met die duur van behandeling. Behandeling is ondersteunend.

4.11 Onttrekkingsperiode

Beeste (eetbare weefsels)	1 dag binneaarse roete 4 dae binnespierse roete
Varke (eetbare weefsels)	4 dae
Beeste (melk)	Melk onttrekkingsperiode van nul ure

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

Farmakologiese klassifikasie

C3.1 Anti-rumatiese middels (Anti-inflammatoriese middels)

Farmakologiese werking

Ketoprofen is 'n nie-steroïedale anti-inflammatories middel met pynstillende en anti-piretiese eienskappe. Ketoprofen inhibeer prostaglandien sintese.

6. FARMASEUTIESE EIENSKAPPE

6.1 Lys van bymiddels

L-arganien
Bensielalkohol
Sitroensuur, monohidraat
Water vir inspuiting

6.2 Onvereningbaarhede

Moenie met ander middels meng nie.
Moenie met ander nie-steroïedale anti-inflammatoriese middels, diuretikums of anti-koagulante meng nie.

6.3 Rakleeftyd

Rakleeftyd voor oopmaak
Amber glasfles: 36 maande
Amber multi-laag plastiekfles: 36 maande
Rakleeftyd na oopmaak
Amber glasfles: 4 weke
Amber multi-laag plastiekfles: 4 weke

6.4 Spesiale voorsorgmaatreëls vir berging

Beskerm teen lig en hitte.
Bewaar teen of onder 25 °C
Hou buite bereik van kinders en oningeligte persone.
Die amber multi-laag plastiekfles: Berg die fles in die karton-dosie om teen lig te beskerm.

6.5 Samestelling van primêre verpakking

100 ml multi-dosis amber glasfles met grys chlorobutiel prop.
50 ml, 100 ml en 250 ml amber multi-laag plastiekfles met grys bromobutiel prop.

7. REGISTRASIEHOUER:

Ceva Animal Health (Pty) Ltd.
Mpy. Reg. Nr.: 1973/016009/07
Posbus 7707
Halfway House
Midrand
1685
Suid Afrika
Tel. Nr.: 011 312 4088

8. REGISTRASIENOMMER:

94/3.1/11 (Wet 101/1965)

Namibië Reg. Nr.: NS2 V07/3.1.2/1059 (Wet 13/2003)

9. PUBLIKASIEDATUM VAN DIE VOUBILJET:

27 Februarie 1997

10. DATUM VAN HERSIENING VAN TEKS

Mei 2021

R0751-01/2022

NOT KETOFEN INJ 10% CLAS ZA 680x160/FP35,5x160 CODE ARTICLE : A4710-01 RECTO-VERSO BLACK	KETOFEN INJ 10% 100ML CLAS AFRIQUE DU SUD ID : 80106- 81461 CORPS : 11 pts

LOUIS 24/08/23

NOTICE **FT0481V2**
680x160 > Pliée 35.5x160

FOURNISSEUR	FACEDIM

INDUSTRIEL	LIBOURNE : Usine

Désignation	Fabricant	Référence
OP POLAR BRIGHT 37 GRAMMES	Delfort group	NA
PRIMABRITE ULTRA 37 GRAMMES	PDL	NA

Référence Fournisseur : 160x680_160x35,5_ceva

Ceva Santé Animale

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SA au capital de 40 331 892 Euros - RCS Libourne B 301 763 405

NOTICE **FT0481V2**
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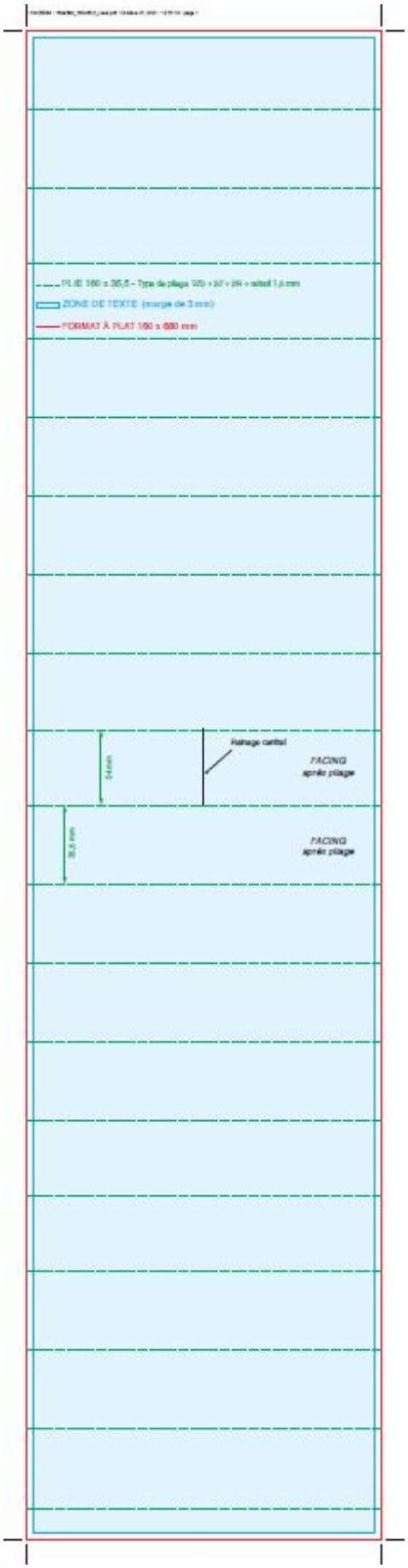

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Les codes datamatrix doivent être visibles après pliage

Point de colle : Non

Pliage : Plié

Méthode de pliage : 1//D + 2// + 2R + retrait 1,5 mm

Conditionnement transport 690 notices /carton et 230 notices/couche

Validation PACKAGING	Validation FOURNISSEUR	Validation LIBOURNE
Andrea FOLLY 23/11/2022	Jean-Marc BUTTON 30/11/2022	Anne DORTHE 01/12/2022

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