PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX/100 ML}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclofin 300 mg/ml + 20 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Oxytetracycline (as oxytetracycline dihydrate) 300 mg
Flunixin (as flunixin meglumine) 20 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Solution for injection

7. WITHDRAWAL PERIODS

Meat and offal: 35 days.
Not authorised for use in cattle producing milk for human consumption.

8. EXPIRY DATE

EXP {month/year}

Shelf life after first opening: 28 days
Once opened use by __/__

9. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.
Keep the container in the outer carton.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW

14. MARKETING AUTHORISATION NUMBERS

Vm 10434/5004

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (To be supplied only on veterinary prescription)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL/100 ML}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclofin 300 mg/ml + 20 mg/ml solution for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Oxytetracycline (as oxytetracycline dihydrate) 300 mg
Flunixin (as flunixin meglumine) 20 mg

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Solution for injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 35 days.
Not authorised for use in cattle producing milk for human consumption.

6. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.
Keep the container in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW

9. BATCH NUMBER

Lot

10. PACKAGE SIZE

100 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

For animal treatment only.
POM-V (To be supplied only on veterinary prescription)

15. MARKETING AUTHORISATION NUMBER

Vm 10434/5004

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclofin 300 mg/ml + 20 mg/ml solution for injection for cattle

2. COMPOSITION

Each ml contains:

Active substances:

Oxytetracycline (as oxytetracycline dihydrate)	300 mg
Flunixin (as flunixin meglumine)	20 mg

Excipient:

Sodium Formaldehyde Sulphoxylate	2.0 mg

A clear, orange to reddish-brown solution, practically free from visible particles.

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

For the treatment of bovine respiratory disease caused by *Mannheimia (Pasteurella) haemolytica* where an anti-inflammatory and anti-pyretic effect is required.

In addition, a wide range of organisms are known to be sensitive in vitro to oxytetracycline, including *Pasteurella spp*, *Arcanobacterium pyogenes*, *Staphylococcus aureus* and certain mycoplasmas. The product may therefore be of use in the treatment of disease in cattle caused by such organisms where an anti-inflammatory and antipyretic effect is required.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding.
Do not use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use the veterinary medicinal product where there are signs of blood dyscrasias or haemostasis alteration.

6. SPECIAL WARNING(S)

Cross-resistance has been shown between oxytetracycline and other antimicrobials belonging to the tetracyclines class in *Mannheimia (Pasteurella) haemolytica*. When susceptibility testing has shown resistance to other tetracycline antimicrobials the use of oxytetracycline should be carefully considered because its effectiveness may be reduced.

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national, and regional antimicrobial policies.

Use in any animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
It is preferable that prostaglandin inhibiting drugs are not administered to animals undergoing general anaesthesia until fully recovered.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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

This veterinary medicinal product may be harmful after accidental self-injection. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may be irritating to the skin and/or eye. Avoid skin and/or eye contact. Latex or nitrile gloves should be worn during application. In case of accidental contact with skin or eyes, rinse with copious amounts of water. If irritation persists, seek medical advice.

This veterinary medicinal product may cause hypersensitivity reactions due to the presence of oxytetracycline, flunixin, polyethylene glycol or ethanolamine. People with known hypersensitivity to tetracyclines, NSAIDs or one of the excipients should avoid contact with the veterinary medicinal product. If allergic symptoms develop, such as a skin rash, swelling of the face, lips or eyes or difficulty in breathing, you should seek medical attention immediately and show the package leaflet or label to the doctor.

Daily exposure of laboratory animals (rats) to glycerol formal results in teratogenic and foetotoxic effects. Pregnant women and women of child-bearing age should take particular caution to avoid exposure when administering the veterinary medicinal product.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Studies in laboratory animals have shown evidence of foetotoxicity after oral (rabbit and rat) and intramuscular (rat) administration of flunixin at maternotoxic doses, and a lengthening of the duration of gestation (rat).
Use is not recommended during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:

Concurrent use of potentially nephrotoxic drugs should be avoided (e.g. aminoglycosides). Flunixin may reduce the renal excretion of certain veterinary medicinal products and increase their toxicity, such as for aminoglycosides.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Additional therapy with an NSAID may be administered after 24 hours if required.
Concurrent use of corticosteroids should be avoided.
Flunixin may reduce the effect of some anti-hypertensive medicinal products, such as diuretics and beta blockers, by inhibition of prostaglandin synthesis.

Overdose:

Following administration at twice the recommended treatment dose (4 mg/kg flunixin and 60 mg/kg oxytetracycline) the veterinary medicinal product is expected to be well tolerated. At this 2x dose level transient dysentery with or without apathy may occur; symptoms resolving without treatment within 48-72 hours.

Studies in cattle at twice the normal dose rate have shown transient and dose dependent reactions at the injection site.

At higher dose levels, above 3x the recommended treatment dose, there is an increased risk of renal toxicity. This may manifest as elevated plasma urea and creatinine levels and pathological changes to the kidneys (cortical tubular necrosis).

Management of overdose should be symptomatic, ensuring adequate hydration is maintained.

Major incompatibilities:

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

7. ADVERSE EVENTS

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions[a]
Undetermined frequency (cannot be estimated from the available data)	Injection site reaction[b], Mild increase in body temperature[c], Dental discoloration[d], Bone discoloration[d]

[a] May occur, which can be fatal.
[b] A usually mild reaction at the injection site may be observed following intramuscular administration and may persist for up to 30 days. Studies in cattle at the normal dose rate have shown transient and dose dependent reactions at the injection site.
[c] Any increase is transient and will be unlikely to occur in animals already suffering from pyrexia.
[d] The use of tetracyclines during the period of tooth and bone development may lead to discoloration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Indicated for deep intramuscular administration to cattle.
The recommended dosage is 1 ml per 10 kg bodyweight (equivalent to 2 mg/kg flunixin and 30 mg/kg oxytetracycline).
To ensure a correct dosage, body weight should be determined as accurately as possible.

Dosing guide:

Body weight (kg)	Dosage in ml single intramuscular administration.:	Treatable animals per 100 ml bottle
50	5	20
70	7	14
90	9	11
100	10	10
110	11	9
130	13	7
150	15	6
200	20*	5
250	25*	4

* maximum volume per injection site: 15 ml, 2 injection sites per animal required

If concurrent treatment is administered use a separate injection site.
This product is recommended for administration on a single occasion only.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Meat and offal: 35 days.
Not authorised for use in cattle 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 label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V (To be supplied only on veterinary prescription).

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 10434/5004

100 ml vial, closed with stopper and cap, in a cardboard box.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

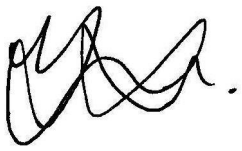
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW

Manufacturer responsible for batch release:

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

17. OTHER INFORMATION **Environmental properties:**

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.



Approved: 05 September 2023