PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains sodium cephalexin equivalent to 180 mg/ml cephalexin

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Target species: as per product name.

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Dosage and administration:

Cattle: 1 ml / 25 kg	I.M.
Dogs: 1 ml / 18 kg	S.C. or I.M.
Cats: 0.25 ml (up to 4.5 kg)	S.C. or I.M.

Swab the septum before removing each dose.

Use a dry, sterile needle and syringe.
Shake well before use.

8. WITHDRAWAL PERIOD

Withdrawal periods for cattle:
Meat: 19 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warning.
After withdrawal of the first dose, use the product within 28 days. Discard unused material.
This product does not contain an antimicrobial preservative.

10. EXPIRY DATE

BN: / EXP end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Protect from light.
Keep the container in the outer carton.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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

[Distribution category]

For animal treatment only

POM-V

To be supplied only on veterinary prescription.

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business Park,
Citywest Road,
Dublin 24, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4590

17. MANUFACTURER’S BATCH NUMBER

BN: / EXP end of:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains sodium cephalexin equivalent to 180 mg/ml cephalexin

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Target species: as per product name.

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:

Cattle: 1 ml / 25 kg	I.M.
Dogs: 1 ml / 18 kg	S.C. or I.M.
Cats: 0.25 ml (up to 4.5 kg)	S.C. or I.M.

8. WITHDRAWAL PERIOD

Withdrawal periods for cattle:
Meat: 19 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.
After withdrawal of first dose, use the product within 28 days.
Once broached, use by:

10. EXPIRY DATE

BN: / EXP end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Protect from light.
Keep the container in the outer carton.

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

Dispose of used packaging in the household refuse.

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

[Distribution category]

For animal treatment only.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4590

17. MANUFACTURER'S BATCH NUMBER

BN: / EXP end of:

PACKAGE LEAFLET FOR:

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

Marketing Authorisation Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Feldstraβe 1A
85716 Unterschleiβheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs

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

Contains sodium cephalexin equivalent to 180 mg/ml cephalexin

Active constituents:	mg/ml
Cefalexin sodium equivalent to Cefalexin	180

A white to cream coloured mobile suspension

4. INDICATION(S)

The product is indicated for antibiotic therapy in cattle, cats and dogs. Cefalexin is a broad spectrum cefalosporin antibiotic with bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria.

The following micro-organisms have been shown to be sensitive to cefalexin in vitro:

Staphylococcus spp. (including penicillin-resistant strains)

Streptococcus spp.	*Actinomyces bovis*
Corynebacterium spp.	*Haemophilus* spp.
Pasteurella spp.	*Erysipelothrix rhusiopathiae*
Escherichia coli	*Clostridium* spp.
Proteus spp.	*Salmonella* spp.
Micrococcus spp.	*Fusobacterium* spp.
Moraxella spp.	*Peptostreptococcus* spp.
Actinobacillus lignieresi	*Peptococcus* spp.

When susceptible organisms are present, the product is indicated in the treatment of infections of the respiratory tract, urogenital tract, the skin and localised infections in soft tissues in dogs and cats. In dogs it may also be effective in the treatment of infections of the gastrointestinal tract.
Trials have shown the product to be of particular value in treating metritis, foot infections, wounds and abscesses and in the treatment of septicaemic mastitis to supplement intramammary therapy in cattle.

5. CONTRAINDICATIONS

Hypersensitivity to Cefalexin is very rare, however, it should not be administered to animals which are known to be hypersensitive.

6. ADVERSE REACTIONS

Use of the product may result in localised tissue reaction.
Allergic reactions across all target species have been reported very rarely in spontaneous reports.

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).

Administration of Cefalexin at up to twice the recommended dose in cattle and at up to three times the recommended dose in dogs and cats does not produce any adverse effects. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, cats and dogs.

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

Dogs and Cats: The recommended dose is 10 mg/kg once daily for up to 5 days.
Any variation should be at the prescribing veterinary surgeons discretion, e.g. in severe or acute conditions. The following is intended as a guide:

	Weight	Dose volume
Cats: up to	4.5 kg	0.25 ml
Dogs: Small	5-9.0 kg	0.25-0.5 ml
Medium	9.0-27.0 kg	0.5-1.5 ml
Large	27.0-54.0 kg	1.5-3.0 ml

The product may be administered by either the subcutaneous or intramuscular route. After administration massage the injection site.

Cattle: The recommended dose for cattle is 7 mg/kg (1ml/25kg) once daily for up to 5 days. The product should be administered by the intramuscular route.

9. ADVICE ON CORRECT ADMINISTRATION

Before withdrawal of a dose the vial should be shaken to re-suspend the contents. This product does not contain an antimicrobial preservative. Use a dry needle and syringe. Swab the septum before removing each dose.

10. WITHDRAWAL PERIOD(S)

Cattle (meat) - 19 days
Cattle (milk) – Zero hours
Animals for human consumption must not be slaughtered during treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 30°C. Protect from light.
Shelf life following withdrawal of the first dose: 28 days
Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

Special warnings for each target species
As with other antibiotics which are excreted mainly by the kidneys, unnecessary accumulation may occur in the body when renal function is impaired. In cases of known renal insufficiency the dose should be reduced.

Special precautions for use in animals
Not suitable for intravenous or intrathecal administration.

User warnings
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.
Cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions. Wash hands after use.
3. If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Interaction with other medicinal products and other forms of interaction
Concurrent use of cephalosporins with potentially nephrotoxic substances (e.g. aminoglycosides, polymyxin antibiotics) or diuretic substances (e.g. furosemide) may increase possible nephrotoxic effects. Also see 'Special warnings for each target species'.

Incompatibilities
In the presence of water hydrolysis of cefalexin occurs. It is important, therefore, that a dry syringe is used when extracting suspension for injection to avoid contaminating the remaining contents of the vial with drops of water.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

For animal treatment only.

Pack sizes
Colourless, multidose 100 ml Type I or Type II glass vial, sealed with a bromobutyl rubber closure and an aluminium cap with tear-off lid.

Pharmacodynamic properties
Cefalexin is a semi-synthetic bactericidal antibiotic belonging to the cefalosporin group which acts by interference with bacterial cell wall formation.
Cefalexin is resistant to the action of staphylococcal penicillinase and is therefore active against the strains of *Staphylococcus aureus* that are insensitive to penicillin (or related antibiotics such as ampicillin or amoxycillin) because of production of penicillinase.
Cefalexin is also active against the majority of ampicillin-resistant *E.coli.*

Pharmacokinetic properties
Cefalexin is rapidly absorbed after injection. Peak blood concentrations are generally achieved within
one hour of administration. Cefalexin is excreted in the urine in high concentration.

POM-V To be supplied only on veterinary prescription

MA number: Vm 01708/4590

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business Park,
Citywest Road,
Dublin 24.

Approved 10 March 2022