SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl Ready-To-Use 150 mg/ml suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	**mg/ml**
Amoxicillin (As Amoxicillin trihydrate)	150

For a full list of excipients please see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection
A white to off white oily suspension

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, sheep, pigs and cattle

4.2 Indications for use, specifying the target species

For the treatment of infections caused by susceptible organisms in dogs, cats, sheep, pigs and cattle. The product is not effective against beta-lactamase producing organisms.

4.3 Contraindications

Not to be used in rabbits, guinea pigs, hamsters or gerbils.
The suspension is not suitable for intravenous or intrathecal administration.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

Do not use in animals with known sensitivity to the active substance.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.
This product does not contain an antimicrobial preservative.

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

Care should be taken to avoid accidental self injection.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure taking all recommended precautions.
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 with breathing, are more serious symptoms and require urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Use of the product may result in local tissue reaction.

4.7 Use during pregnancy, lactation or lay

None

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The recommended dosage rate is 7 mg/kg bodyweight once daily for up to 5 days by subcutaneous (dogs, cats), or intramuscular (dogs, cats, sheep, pigs and cattle) injection.
If the volume to be given is greater than 15 ml (cattle) and 5 ml (sheep and pigs) the dose should be divided and the remaining should be injected in another site.
Shake the vial well to suspend the active ingredient before use.
Swab rubber septum and remove required volume aseptically.

Do not breach more than 40 times.
Massage the injection site after administration. Use a new anatomical site for repeated injections. To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid overdosing.
In common with other penicillin preparations hydrolysis takes place rapidly in the presence of water. It is important therefore that a dry syringe is used when extracting the suspension for injection to avoid contaminating the remaining contents of the vial with drops of water.

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

Amoxicillin is of a very low order of acute toxicity and is well tolerated by the parenteral route. Occasional injection site reactions may occur with the recommended dose, but no other adverse side effects are to be expected from accidental overdosing.

4.11 Withdrawal periods

Meat: Cattle: 54 days
Sheep: 47 days
Pigs: 47 days

Milk: Cattle: 60 hours from the last treatment.
Not to be used in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: QJ01CA04

Amoxicillin is a broad-spectrum semi-synthetic penicillin which is bactericidal *in vitro* against a wide range of Gram-positive and Gram-negative bacteria including the following: *Actinomyces* spp., *Bacillus* spp., *Bordetella bronchiseptica, Clostridium* spp., *Corynebacterium* spp, *Escherichia coli, Fusobacterium* spp., *Haemophilus* spp., *Leptospira* spp., *Moraxella* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., Streptococci, Staphylococci (penicillin-sensitive strains).
Clamoxyl Ready-To-Use Injection is indicated for the treatment of infections caused by Amoxicillin-sensitive organisms in dogs, cats, sheep, pigs and cattle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Aluminium Stearate
Ethyl Oleate

6.2 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

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

Carton containing 6 100ml clear colourless type III glass vials with chlorobutyl bungs with an aluminium overseal.
Carton containing 4 250ml clear colourless type II or type III glass vials with chlorobutyl bungs with an aluminium overseal.
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, if appropriate

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm: 42058/4016

9. DATE OF THE FIRST AUTHORISATION

03 December 1990

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 21 August 2020