1.B1. SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOXYCOL Soluble Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Amoxicillin trihydrate	640.0 mg/g
Colistin sulphate	3,200 Mio IU/g

Excipient:

Glucose monohydrate

3. PHARMACEUTICAL FORM

Powder for oral solution and medicated feeding stuff.

4. CLINICAL PARTICULARS

4.1. Target species

Swine and chicken.

4.2. Indications for use

AMOXYCOL Soluble Powder is indicated for the treatment and control of bacterial infections caused by organisms sensitive to the combination of amoxicillin and colistin, such as *E. coli, Salmonella spp., Pasteurella spp., Actinobacillus spp., Haemophilus spp., Clostridium spp., Streptococcus suis* and other streptococci and penicillin sensitive staphylococci. The product is particularly proposed for treatment of complicated or mixed enteric infections involving the above organisms.

4.3. Contraindications

Not for use in laying poultry when eggs are intended for human consumption. In common with other aminopenicillin products, AMOXYCOL should not be given to small herbivores such as guinea pigs, hamsters and rabbits nor horses.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

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

Wear rubber gloves and dust musk when mixing and handling the product. Wash any splashes from skin and eyes immediately. Avoid inhalation of dust. Persons who are allergic to penicillins should avoid direct contact with the product. If severe allergic symptoms develop following exposure such as swelling of the face, lips or eyes or difficulty breathing, urgent medical attention is required.

4.6. Adverse reactions (frequency and seriousness)

AMOXYCOL Soluble Powder is of low toxicity and side-effects are very rarely encountered. If suspected adverse reactions do occur, treatment should be discontinued. During the toxicological and clinical examinations no undesirable effects were detected.

4.7 Use during pregnancy, lactation or lay

Do not use in laying birds when eggs are intended for human consumption.

4.8. Interaction with other medicaments and other forms of interaction

No major undesirable interactions of amoxicillin trihydrate and colistin sulphate as the active substances of the drug product with other medicaments are known.

4.9. Amounts to be administered and administration route

The recommended dosage of the product is 25 mg AMOXYCOL Soluble Powder per kg of body weight per day, administered via the drinking water or in the feed.

If the required amount of AMOXYCOL is calculated by the total daily water or feed intake, the following is a guide:

- pigs: 1 g AMOXYCOL/4-6 litres of water daily
  0.5 g AMOXYCOL/kg of feed
- chickens < 4 weeks of age: 1 g AMOXYCOL/7.5-10 litres of water daily

> 4 weeks of age: 1 g AMOXYCOL/5-7.5 litres of water daily

Treatment should be performed for 3-5 days.

4.10. Overdose (symptoms, emergency procedures, antidotes)

Overdosage of AMOXYCOL Soluble Powder may very rarely occur because of good tolerance by the species to be used in. In the tolerance studies, the product failed to induce any toxic effect even when administered at a dosage of three times the recommended for two times the recommended duration.

If suspected toxic reactions do occur due to extreme overdosage, the medication should be discontinued and appropriate symptomatic treatment should be performed if necessary.

4.11. Withdrawal periods

Edible tissues of pigs and chickens: 4 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotic combinations. ATC vet code: QJ01RA96

5.1. Pharmacodynamic properties

AMOXYCOL Soluble Powder is a water soluble formulation containing amoxicillin trihydrate and colistin sulphate as active substances.

Amoxicillin belongs to the group of aminopenicillins. It is bactericidal in action and exhibits a wide range of activity against both aerobic and anaerobic Gram-positive and Gram-negative bacteria. It is, however, not active against beta-lactamase-producing organisms. Resistance of Gram-negative bacteria to amoxicillin is relatively common.

Colistin is a polypeptide antibiotic being rapidly bactericidal in action. It is a cationic, surface-active agent that distrupts the structure of the cell membrane phospholipids and increases cell permeability by a detergent-like action. It is highly active against many species of Gram-negative organisms, such as *Escherichia coli*, *Salmonella* spp. and *Pseudomonas aeruginosa*, but not against Gram-positive bacteria. Acquired resistance against colistin is rare.

The absorption of colistin form the gastro-intestinal tract is slow and limited, therefore it acts primarly against susceptible bacteria in the gastro-intestinal tract.

The combination of amoxicillin and colistin exerts at least additive or even a potentiating effect against important bacterial pathogens, including *Salmonella spp*. and *E. coli*. It seems to be advantageous in combating to strains with acquired resistance to one of the components. Moreover, the presence of colistin may reduce the chance of emergence of resistance to amoxicillin which is of great importance in a therapeutic point of view.

5.2. Pharmacokinetic properties

Pharmacokinetics of amoxicillin is characterized by a rapid and extensive absorption from the gastrointestinal tract resulting in high plasma and tissue concentrations within 1-2 hours after administration. The elimination occurs mainly in the unchanged form via the kidneys.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glucose monohydrate

6.2. Incompatibilities

None known.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 3 months.

6.4. Special precautions for storage

Store between 15 and 25°C at a dry place. Protect from light.

Keep out of the reach of children.

6.5. Nature and contents of container

AMOXYCOL Soluble Powder is available in

* 100 g and 1 kg in plastic container,

* 10 kg in multiwalled paper sack, respectively.

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 this veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

LAVET Pharmaceuticals Ltd.,

1161 Budapest

Ottó u. 14.

Hungary

8. MARKETING AUTHORIZATION NUMBER(S)

LT/2/071776/001

LT/2/071776/002

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF THE AUTHORIZATION

Date of first authorization: 15/11/2007

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.

1.B2. LABELLING AND PACKAGE INSERT

A. LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycol Soluble Powder, amoxicillin trihydrate and colistin sulphate

2. STATEMENT of ACTIVE AND OTHER SUBSTANCES

Amoxicillin trihydrate	640 mg/g
Colistin (as sulphate)	3,200,000 IU/g

3. PHARMACEUTICAL FORM

Water soluble powder

4. PACKAGE SIZE

1 kg and 10 kg, respectively.

5. TARGET SPECIES

Pigs and chickens.

6. INDICATIONS

AMOXYCOL Soluble Powder is indicated for the treatment and control of bacterial infections caused by organisms sensitive to the combination of amoxicillin and colistin, such as *E. coli, Salmonella spp., Pasteurella spp., Actinobacillus spp., Haemophilus spp., Clostridium spp., Streptococcus suis* and other streptococci and penicillin sensitive staphylococci. The product is particularly proposed for treatment of complicated or mixed enteric infections involving the above organisms.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration via the drinking water or in the feed.

8. WITHDRAWAL PERIOD

Edible tissues of pigs and chickens: 4 days

9. SPECIAL WARNINGS

Wear rubber gloves and dust musk when mixing and handling the product. Wash any splashes from skin and eyes immediately. Avoid inhalation of dust. Persons who are allergic to penicillins should avoid direct contact with the product. If severe allergic symptoms develop following exposure such as swelling of the face, lips or eyes or difficulty breathing, urgent medical attention is required.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25^{o}C at a dry place, protect from light.

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

No additional precautions required.

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

LAVET Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

16. MARKETING AUTHORIZATION NUMBER(S)

LT/2/071776/001
LT/2/071776/002

17. MANUFACTURER'S BATCH NUMBER

B. PACKAGE INSERT

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

Marketing and manufacturing authorisation holder:
LAVET Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycol Soluble Powder, amoxicillin trihydrate and colistin sulphate

3. STATEMENT of ACTIVE SUBSTANCES AND OTHER INGERDIENTS

Amoxicillin trihydrate	640 mg/g
Colistin (as sulphate)	3,200,000 IU/g

4. INDICATIONS

AMOXYCOL Soluble Powder is indicated for the treatment and control of bacterial infections caused by organisms sensitive to the combination of amoxicillin and colistin, such as *E. coli, Salmonella spp., Pasteurella spp., Actinobacillus spp., Haemophilus spp., Clostridium spp., Streptococcus suis* and other streptococci and penicillin sensitive staphylococci. The product is particularly proposed for treatment of complicated or mixed enteric infections involving the above organisms.

5. CONTRAINDICATIONS

Not for use in laying poultry when eggs are intended for human consumption. In common with other aminopenicillin products, Amoxycol should not be given to small herbivores such as guinea pigs, hamsters and rabbits nor horses.

6. ADVERSE REACTIONS

None known.

7. TARGET SPECIES

Pigs and chickens.

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

For oral administration via the drinking water or in the feed.

Recommended dosage: 25 mg Amoxycol Soluble Powder/kg b.w.

If the required amount of Amoxycol is calculated by the total daily water or feed intake, the following is a guide:

- pigs: 1 g Amoxycol/4-6 litres of water daily or

0.5 g Amoxycol/kg feed daily

- chickens < 4 weeks of age: 1 g Amoxycol/7.5-10 litres of water daily

> 4 weeks of age: 1 g Amoxycol/5-7.5 litres of water daily

Treatment should be performed for 3-5 days.

9. ADVICE on CORRECT ADMINISTRATION

The solution should be prepared freshly each day.

No other of drinking water should be available during to medication period.

10. WITHDRAWAL PERIOD

Edible tissues of pigs and chickens: 4 days

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25^{o}C at a dry place, protect from light.

12. SPECIAL WARNINGS

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

Wear rubber gloves and dust musk when mixing and handling the product. Wash any splashes from skin and eyes immediately. Avoid inhalation of dust. Persons who are allergic to penicillins should avoid direct contact with the product. If severe allergic symptoms develop following exposure such as swelling of the face, lips or eyes or difficulty breathing, urgent medical attention is required.

Lay

Do not use in laying birds when eggs are intended for human consumption.

Overdose (symptoms, emergency procedures, antidotes)

Overdosage of AMOXYCOL Soluble Powder may very rarely occur because of good tolerance by the species to be used in. In the tolerance studies, the product failed to induce any toxic effect even when administered at a dosage of three times the recommended for two times the recommended duration.

If suspected toxic reactions do occur due to extreme overdosage, the medication should be discontinued and appropriate symptomatic treatment should be performed if necessary.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS, IF ANY

No additional precautions are required.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

15. OTHER INFORMATION

For animal treatment only.