SUMMARY of PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
AMOXYN 100% Soluble Powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Amoxicillin trihydrate 1000.0 mg/g

3. PHARMACEUTICAL FORM
Powder for oral solution or administration in the feed.

4. CLINICAL PARTICULARS
4.1. Target species
Chicken, turkey and swine.

4.2. Indications for use
For the treatment and control of bacterial infections caused by organisms sensitive to amoxicillin, such as *E. coli, Salmonella spp., Pasteurella spp., Actinobacillus spp., Haemophilus spp., Clostridium spp., Streptococcus suis* and other streptococci, and penicillin sensitive staphylococci.

4.3. Contraindications
Not for use in laying poultry when eggs are intended for human consumption. In common with other aminopenicillin products, the product 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 for use in animals
None.
Special safety 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)
As for all penicillins, on rare occasions allergie reactions may occur. If suspected adverse reactions occur, treatment should be discontinued.

4.7. Use during pregnancy, lactation and lay
Do not use in birds in lay when eggs are intended for human consumption.
The safety of the veterinary product has not been established in pregnant and lactating sows. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

4.8. Interaction with other medicaments and other forms of interaction
The bactericidal effect of amoxicillin is neutralized by simultaneous use of bacteriostatic antibiotics.

4.9. Amounts to be administered and administration routels
To be administered orally, in medicated drinking water or in the feed.
Dosage: 10-20 mg amoxicillin trihydrate per kg of body weight.
Administration:
In chickens and turkeys, the product should be administered via the drinking water as follows:
Continuous medication
Concentrations of 7.5 to 15.0 g of the product per 100 litres (75-150 p.p.m. amoxicillin trihydrate per litre) are administered as the only source of drinking water over the entire day.
Pulse dose medication

The daily dose of 10-20 mg/kg amoxicillin trihydrate is administered in limited quantity of water to be consumed by the birds within 4-6 hours. After the medicated water has been consumed, unmedicated water must be provided for the remainder of the day.
In pigs, the product may be administered via the drinking water or in the feed.
Water medication
To ensure an intake of 10-20 mg amoxicillin trihydrate, the product is administered at concentrations of 10 to 20 g of of the product per 100 litres (100-200 p.p.m. amoxicillin trihydrate per litre) as the only source of drinking water over the entire day.
Feed medication
The product is incorporated in the daily ration at a concentration of 0.2 to 0.4 kg per tonne of complete feed.
Treatment should be performed for 3-5 days in chickens and turkeys and for 5-7 days in pigs.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary
In the target animal tolerance studies, the product failed to induce any toxic effect even when administered at the threefold therapeutic dose 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 unitiated if necessary.

4.11. Withdrawal periods
Meat and offal of chickens, turkeys and pigs: 3 days.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: beta-lactam antibiotics. ATCvetcode: QJ01CA04.

5.1. Pharmacodynamic properties
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. Actual MIC_{90} of the drug against *Streptococcus spp*., *Erysipelothrix rhusiopathiae*, *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Haemophilus spp*. is usually $\leq$0.25 μg/ml, whereas against *Salmonella spp*. and *E. coli* it varies between 1-4 μg/ml.

5.2. Pharmacokinetic particulars
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. Oral bioavailability of amoxicillin is known to be 63% in chickens and 39% in pigs. Amoxicillin is widely distributed in body fluids and tissues also providing relatively high concentrations in the respiratory tract. Thus, amoxicillin is considered to be one of the drugs of choice for respiratory tract infections and pneumonia in both humans and animals. The elimination occurs mainly in the unchanged form via the kidneys.

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
None.

6.2. Incompatibilities
None.

6.3. Shelf-life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate container: 3 months.
Shelf-life after reconstitution in drinking water: 12 hours.

6.4. Special precautions for storage
Do not store above 25^{o}C. Keep the primary container tightly closed.

6.5. Nature and contents of container
Plastic containers of 100 g and 1 kg.
Multiwalled paper sack of 10 kg.

6.6. Special precautions for the disposal of unused product or waste materials, if any

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 AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 g in polypropylene container with polyethylene inner bag.
1 g in polypropylene container with polyethylene inner bag.
10 kg in multiwalled, polyethylene layered paper bag.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxyn 100% Soluble Powder
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Amoxicillin trihydrate 1000 mg/g

3. PHARMACEUTICAL FORM

Powder for oral solution or administration in the feed.

4. PACKAGE SIZE

100 g
1 kg
10 kg

5. TARGET SPECIES

Swine, chicken, turkey.

6. INDICATIONS

For the treatment and control of respiratory and gastrointestinal infections in swine and poultry caused by amoxicillin sensitive organisms, such as *E. coli*, *Salmonella spp*., *Pasteurella spp*., *Actinobacillus spp*., *Haemophilus spp*., *Clostridium spp*., *Streptococcus suis* and other streptococci and penicillin sensitive staphylococci.

7. METHOD AND ROUTES OF ADMINISTRATION

For oral administration in the drinking water or incorporated in the daily ration.
Average dose: 10-20 mg amoxicillin trihydrate per kg of body weight daily.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal of chickens, turkeys and pigs: 3 days

9. SPECIAL WARNINGS

People with known hypersensitivity to penicillins should avoid contact with the veterinary medicinal product - see the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
After first opening of container: 3 months.
After reconstitution in drinking water: 12 hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the primary container tightly closed.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED, IF ANY

Any unused veterinary medicinal product or waste materials derived from this veterinary medicinal product should be disposed of in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURE'S BATCH NUMBER

Batch: {number}

PRODUCT INFORMATION

PACKAGE LEAFLET
Amoxyn 100% soluble powder

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

Marketing authorization holder: Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary
Manufacturer responsible for batch release: Lavet Pharmaceuticals Ltd., 2143 Kistarcsa, Batthyány u. 4/B, Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxyn 100% soluble powder
Amoxicillin trihydrate

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

Active substance: Amoxicillin trihydrate 1000.0 mg/g

4. INDICATIONS

For the treatment and control of respiratory and gastrointestinal infections in swine and poultry caused by amoxicillin sensitive organisms, such as *E. coli*, *Salmonella spp*., *Pasteurella spp*., *Actinobacillus spp*., *Haemophilus spp*., *Clostridium spp*., *Streptococcus suis* and other streptococci and penicillin sensitive staphylococci.

5. CONTRAINDICATIONS

Not for use in laying poultry when eggs are intended for human consumption.
Do not use in animals with known hypersensitivity to amoxicillin or to other beta-lactams. Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamsters or gerbils. Do not use in ruminants and horses.

6. ADVERSE REACTIONS

As for all penicillins, on rare occasions allergic reactions may occur. If suspected adverse reaction occur, treatment should be discontinued.

7. TARGET SPECIES

Chicken, turkey, swine.

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

To be administered orally, in the drinking water or in the feed.
Dosage: 10-20 mg amoxicillin trihydrate per kg of body weight daily, administered for 3-5 days in chickens and turkeys, and 5-7 days in pigs.

9. ADVICE on CORRECT ADMINISTRATION

Administration: To ensure the intake of the required dose, product may be administered on a continuous basis or pulse dosed in the drinking water or incorporated in the feed.
Chicken, turkeys: 75-150 mg product per litre of drinking water continuously or
10-20 mg product per kg of body weight per day administered in limited quantities of water consumed by the birds within 4-6 hours. After the medicated water has been consumed, unmedicated water is provided for the remainder of the day.
Pigs: 100-200 mg product per litre of drinking water on a continuous basis or 2x5- 10 mg product per kg of body weight administered at approximately 12 hourly intervals in limited quantities of water to be consumed within 2 hours. After all the medicated water has been consumed, supply unmedicated water. In the case of in-feed medication, product is incorporated in the daily ration at a concentration of 200-400 mg per kg of completed feed.
Medicated water should be refreshed at 12-hour intervals.
To ensure thorough dispersion, the product should first be mixed with a suitable quantity of feed before incorporation into the final mix.

10. WITHDRAWAL PERIOD

Meat and offal of chickens, turkeys and pigs: 3 days

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep primary container tightly closed.
Shelf-life of the product as packaged for sale: 2 years.
Shelf-life after first opening the immediate container: 3 months.
Shelf-life after reconstitution in drinking water: 12 hours.

12. SPECIAL WARNINGS

Special precautions for use in animals:

During the target animal tolerance study, no adverse effect was observed even at the threefold therapeutic dose administered for 2 times the recommended duration.
If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

Special precautions to be taken by the 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.

Pregnancy, lactation:

The safety of the veterinary product has not been established in pregnant and lactating sows. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

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

Any unused veterinary medicinal product or waste materials derived from this veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
100 g in polypropylene container with polyethylene inner bag.
1 g in polypropylene container with polyethylene inner bag.
10 kg in multiwalled, polyethylene layered paper bag.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.