1.B. SUMMARY OF PRODUCT CHARACTERISTICS

1.B.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lamox 800 mg/g powder for use in drinking water for chickens and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Amoxicillin trihydrate 800 mg/g

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for use in drinking water. White to off-white powder.

4. CLINICAL PARTICULARS

4.1. Target species

Chickens (broilers)

Pigs

4.2. Indications for use, specifying the target species

Treatment of infections in chickens and pigs caused by bacteria susceptible to amoxicillin, including for pigs *Actinobacillus pleuropneumoniae* and *Streptococcus suis* and for chickens *Escherichia coli*

4.3. Contra-indications

Do not use in known cases of hypersensitivity to penicillin or other substances of the beta-lactam group.

Do not use in layer hens producing eggs for human consumption.

Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.

Do not use in case of known resistance to the active substance or other beta-lactam antibiotics.

4.4. Special warning for each target species.

The product is not effective against beta-lactamase producing bacteria.

4.5. Special precautions for use

Special precautions for use in animals

Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for amoxicillin, bacteriological sampling and susceptibility testing are recommended.
Official, national and regional antimicrobial policies should be taken into account when the product is used

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

Avoid inhalation of dust. Wear protective clothing, gloves, dust mask and safety glasses when handling and reconstituting the product.
Wash hands after use. In case of accidental exposure of the eyes, rinse with abundant water.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following inhalation, ingestion and skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins 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.
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 with breathing are more serious symptoms and require urgent medical attention.

4.6. Adverse reactions (frequency and seriousness)

Hypersensitivity reactions may occur, the severity varying from skin rash to anaplyactic shock. If suspected adverse reactions occur, treatment should be discontinued.

4.7. Use during pregnancy, lactation or lay

Do not use in layer hens producing eggs for human consumption. Use in breeder hens only according to the benefit / risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects.
The safety of the product has not been established in pregnant or lactating sows. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8. Interaction with other medicinal products and other forms of interaction

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

4.9. Amounts to be administered and administration route

In drinking water use.

Chickens

The recommended dosage is 10-20 mg/kg body weight Lamox 800 mg/g (8-16 mg/kg amoxicillin trihydrate) per day administered in the drinking water. The higher dose is advised when treating severe infections. Treatment should be given for a period of 3-5 consecutive days. The following formula may be used to calculate the amount of Lamox 800 mg/g required per day:

$$\text{gram Lamox 800 mg/g per day} = \frac{\text{number of animals x average body weight (kg)}}{\text{50 (for 20 mg/kg) or 100 (for 10 mg/kg)}}$$

If the required amount of Lamox 800 mg/g is calculated by the total daily water intake, the following is a guide:

- Birds 0-4 weeks of age: 6-12 g Lamox 800 mg/g/100 litres water uptake/day
- Birds older than 4 weeks: 10-20 g Lamox 800 mg/g/100 litres water uptake/day

Pigs

In pigs, the recommended dosage is 20 mg/kg body weight Lamox 800 mg/g (16 mg amoxicillin trihydrate) daily for 3-5 consecutive days.

Bolus medication

It is recommended to administer Lamox 800 mg/g once daily in the drinking water within a restricted time span. The water supply is closed for about 2 hours (shorter in warm weather conditions) before medication. The calculated total daily amount of powder is scattered onto the surface of 5-10 litres of clean water and stirred until evenly dispersed. This solution is then added, whilst stirring, into an amount of drinking water that will be consumed within approximately 2 hours. Maximum solubility of Lamox 800 mg/g in water of 20^{o}C is approximately 6 g/litre. When all medicated water has been consumed, turn on the normal water supply again.

Continuous medication

If continuous medication is preferred then the medicated water should be refreshed at least twice daily. If the required amount of Lamox 800 mg/g is calculated by a total daily water intake, the following can be used as a guide:

- Pigs 0-4 months of age: 20 g Lamox 800 mg/g/100 litres water/day
- Pigs older than 4 months: 30 g Lamox 800 mg/g/100 litres water/day

In all cases ensure that there is no access to unmedicated water whilst medicated water is being offered. Any unused medicated water should be discarded after 12 hours.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid under-dosing. The uptake of medicated water depends on the clinical condition

of the animals. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.

4.10. Overdose (symptoms, emergency procedures, antidotes)

None known.

4.11. Withdrawal periods

Meat and offal of chickens: 2 days
Meat and offal of pigs: 2 days
Eggs: Not permitted for use in layer hens producing eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: beta-lactam antibiotics, penicillins. ATC vet code: QJ01CA04

5.1. Pharmacodynamic properties

The active ingredient, amoxicillin, is a bactericidal, mainly time-dependant antibiotic of the beta-lactam class. It acts by inhibition of bacterial cell wall synthesis. Amoxicillin is not resistant to the action of beta-lactamases, which can hydrolyse the molecules causing the beta-lactam ring structure to open, rendering it antibiotically inactive.
Amoxicillin is generally active against most Gram-positive and some Gram-negative bacteria including *Actinobacillus pleuropneumoniae* and *Streptococcus suis* in pigs and *Escherichia coli* in chickens. Resistance amongst *E. coli* strains is not uncommon.
In general, practical development of resistance in vitro against amoxicillin like all penicillins occurs slowly and stepwise, with an existing cross-resistance with other penicillins which is of practical significance by staphylococci.
Both long term treatment and sub-therapeutic dosages can select for antimicrobial resistance.

5.2. Pharmacokinetic properties

Following oral medication amoxicillin is rapidly absorbed with bioavailability of 63% in chickens and 39% in pigs. Maximum plasma concentrations (between 1-2 µg/ml) are reached within 1-2 hours. Serum protein binding is low. Amoxicillin is widely distributed throughout the body. Amoxicillin is mainly eliminated via the kidneys in the active form. A smaller part of the administered dose of amoxicillin is excreted in the bile and also in the milk. Plasma half-life times of amoxicillin in chickens and pigs are approximately 1 hour and 2.5 to 4 hours, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium glycine carbonate
Macrogol 4000

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.
Shelf-life after dilution or reconstitution according to directions: 12 hours.

6.4. Special precautions for storage

Do not store above 25^{o}C. Store in the original container tightly closed in order to protect from moisture.

6.5 Nature and composition of immediate packaging

100 g polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg polypropylene container with polypropylene lid and inner bag of LDPE.
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

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

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

8. MARKETING AUTHORISATION NUMBER

Hungary: 701/1997. FVM

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 October 1999/16 December 2005

10. DATE OF REVISION OF THE TEXT

24 February 2010

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

1.B.2 LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 g polypropylene container with polypropylene lid and inner bag of LDPE
1 kg polypropylene container with polypropylene lid and inner bag of LDPE
5 kg polypropylene container with polypropylene lid and inner bag of LDPE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lamox 800 mg/g powder for use in drinking water for chickens and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Amoxicillin trihydrate 800 mg/g

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g
1 kg
5 kg

5. TARGET SPECIES

Chickens (broilers), pigs

6. INDICATION(S)

Treatment of infections in chickens and pigs caused by bacteria susceptible to amoxicillin, including for pigs *Actinobacillus pleuropneumoniae* and *Streptococcus suis* and for chickens *Escherichia coli*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered orally, in drinking water use.
Average dose: 10-20 mg/kg body weight Lamox 800 mg/g (8-16 mg/kg amoxicillin trihydrate) per day in chickens and 20 mg/kg body weight Lamox 800 mg/g (16 mg amoxicillin trihydrate) daily in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal of chickens: 2 days
Meat and offal of pigs: 2 days
Eggs: Not permitted for use in layer hens producing eggs for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Avoid inhalation of dust. Wear protective clothing, gloves, dust mask and safety glasses when handling and reconstituting the product.
Wash hands after use. In case of accidental exposure of the eyes, rinse with abundant water.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following inhalation, ingestion and skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins 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.
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 with breathing are more serious symptoms and require urgent medical attention.

10. EXPIRY DATE

EXP {month/year}
After first opening of the immediate packaging: 3 months.
After dilution or reconstitution according to directions: 12 hours.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C. Store in the original container tightly closed in order to protect from moisture.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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 THE 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)

Hungary: 701/1997. FVM

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

1.B.3 PRODUCT INFORMATION

PACKAGE LEAFLET
Lamox 800 mg/g powder for use in drinking water for chickens and pigs

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

Marketing authorisation holder:
Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary
Manufacturer for the batch release:
Lavet Pharmaceuticals Ltd., 2143 Kistarcsa, Batthyány u. 4/b., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lamox 800 mg/g powder for use in drinking water for chickens and pigs
Amoxicillin trihydrate

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

Active substance: Amoxicillin trihydrate 800 mg/g

4. INDICATION(S)

Treatment of infections in chickens and pigs caused by bacteria susceptible to amoxicillin, including for pigs *Actinobacillus pleuropneumoniae* and *Streptococcus suis* and for chickens *Escherichia coli*

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to penicillin or other substances of the beta-lactam group.
Do not use in layer hens producing eggs for human consumption.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
Do not use in case of known resistance to the active substance or other beta-lactam antibiotics.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur, the severity varying from skin rash to anaplyactic shock. If suspected adverse reactions occur, treatment should be discontinued.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broilers)

Pigs

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

Chickens: 10-20 mg/kg body weight Lamox 800 mg/g (8-16 mg/kg amoxicillin trihydrate) per day, administered in the drinking water for 3-5 days. The higher dose is advised when treating severe infections.

Pigs: 20 mg/kg body weight Lamox 800 mg/g (16 mg amoxicillin trihydrate) per day, administered in the drinking water for 3-5 days.

9. ADVICE ON CORRECT ADMINISTRATION

Chickens

The following formula may be used to calculate the amount of Lamox 800 mg/g required per day:

$$\text{gram Lamox 800 mg/g per day} = \frac{\text{number of animals x average body weight (kg)}}{\text{50 (for 20 mg/kg) or 100 (for 10 mg/kg)}}$$

If the required amount of Lamox 800 mg/g is calculated by the total daily water intake, the following is a guide:

- Birds 0-4 weeks of age: 6-12 g Lamox 800 mg/g/100 litres water uptake/day
- Birds older than 4 weeks: 10-20 g Lamox 800 mg/g/100 litres water uptake/day

Pigs

The product may be administered as a bolus medication or on a continuous basis.

Bolus medication

It is recommended to administer Lamox 800 mg/g once daily in the drinking water within a restricted time span. The water supply is closed for about 2 hours (shorter in warm weather conditions) before medication. The calculated total daily amount of powder is scattered onto the surface of 5-10 litres of clean water and stirred until evenly dispersed. This solution is then added, whilst stirring, into an amount of drinking water that will be consumed within approximately 2 hours. Maximum solubility of Lamox 800 mg/g in water of 20^{o}C is approximately 6 g/litre. When all medicated water has been consumed, turn on the normal water supply again.

Continuous medication

If continuous medication is preferred then the medicated water should be refreshed at least twice daily. If the required amount of Lamox 800 mg/g is calculated by a total daily water intake, the following can be used as a guide:

- Pigs 0-4 months of age: 20 g Lamox 800 mg/g/100 litres water/day

- Pigs older than 4 months: 30 g Lamox 800 mg/g/100 litres water/day

10. WITHDRAWAL PERIOD

Meat and offal of chickens: 2 days
Meat and offal of pigs: 2 days
Eggs: Not permitted for use in layer hens producing eggs for human consumption

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C. Store in the original container tightly closed in order to protect from moisture.

12. SPECIAL WARNING(S)

The product is not effective against beta-lactamase producing bacteria.
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for amoxicillin, bacteriological sampling and susceptibility testing are recommended.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Do not use in layer hens producing eggs for human consumption. Use in breeder hens only according to the benefit / risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects.
The safety of the product has not been established in pregnant or lactating sows. Use only according to the benefit/risk assessment by the responsible veterinarian.
Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

User warnings

Avoid inhalation of dust. Wear protective clothing, gloves, dust mask and safety glasses when handling and reconstituting the product.
Wash hands after use. In case of accidental exposure of the eyes, rinse with abundant water.
Penicillins and cephalosporins may cause hypersensitivity (allergy) following inhalation, ingestion and skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins 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.
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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 with breathing are more serious symptoms and require urgent medical attention.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

24 February 2010

15. OTHER INFORMATION

Pack sizes:
100 g polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg polypropylene container with polypropylene lid and inner bag of LDPE.

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.