SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
DOXYPRIM 40% soluble powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active substance: Doxycycline hyclate 400.0 mg
Excipients: glucose monohydrate
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Powder for oral solution and administration in feed.

4. CLINICAL PARTICULARS
4.1. Target species
Chickens, turkeys and pigs.

4.2. Indications for use, specifying the target species
Treatment of respiratory, intestinal and systemic infections caused by doxycycline-sensitive organisms.
In chickens and turkeys indications include:

* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
* airsacculitis (*Mycoplasma meleagridis*)
* infectious synovitis (*Mycoplasma synoviae*)
* fowl cholera (*Pasteurella multocida*)
* turkey bordetellosis (*Bordetella avium*)
* infectious coryza (*Haemophilus paragallinarum*)
* colibacillosis (*E. coli*)
* necrotic enteritis (*Clostridium perfringens*)
* chlamydiosis (*Chlamydia psittaci*).

In pigs the product is indicated for treatment of respiratory infections caused *by Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and *Bordetella bronchiseptica.*

4.3. Contraindications
Not for use in laying poultry when eggs are intended for human consumption.

4.4. Special warnings for each target species
None.

4.5. Special precautions for use
Special precautions for use in animals
None.
Special precautions to be taken by the person administering the product to animals
Wear gloves when handling the product. Avoid direct contact with the skin, eyes and mucous membranes. Wash hands after use. Wash any splashes from skin or eyes immediately with water.

4.6. Adverse reactions (frequency and seriousness)
DOXYVIT is of low toxicity and side effects are very rarely encountered. If suspected adverse reactions do occur, treatment should be discontinued. During the toxicological examinations and the clinical trials no undesirable effects were detected in either species.

4.7. Use during pregnancy, lactation or lay
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 in accordance with risk/benefit assessment by the responsible veterinarian.

Not for use in laying poultry, when eggs are intended for human use.

4.8. Interaction with other medicaments and other forms of interaction

No undesirable interaction of doxycycline with other medicaments is known. By contrast to older tetracyclines, doxycycline is less susceptible to interactions with calcium. Correspondingly, its absorption is not significantly affected by the concurrent ingestion of feed.

4.9. Amounts to be administered and administration route

To be administered orally, in oral solution or in medicated feed.

Dosage:

In chickens and turkeys 10-20 mg doxycycline hyclate per kg of body weight daily, administered in the drinking water for 5 days.

In pigs 15 mg doxycycline hyclate per kg of body weight daily, administered in the drinking water or in the feed for 5 days.

Administration:

In chickens and turkeys, the product may be administered pulse dosed when the daily requirement is given is limited quantity of water to be consumed by the birds within 4-8 hours or supplied continuously in the drinking water at concentrations between 67 and 133 mg/litre.

In pigs, to ensure the intake of 15 mg doxycycline hyclate per kg daily, the product should be administered continuously in the drinking water at a concentration of 100 to 150 mg per litre of drinking water or in the feed at a concentration of 200 to 250 mg/kg.

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

During the target animal tolerance studies, no adverse effect was observed in either species. If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

4.11. Withdrawal periods

Meat and offal of chickens and turkeys: 4 days.

Meat and offal of pigs: 3 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: tetracyclines. ATCvetcode: QJ01AA02

5.1. Pharmacodynamic properties

Doxycycline is a semisynthetic tetracycline antibiotic. It acts by inhibiting protein synthesis at the ribosomal level, predominantly by binding to the 30S ribosomal subunits of bacteria. Doxycycline is a broad-spectrum antibiotic. It exhibits a wide range of activity against both aerobic and anaerobic gram-positive and gram-negative bacteria, rickettsia, chlamydia, mycoplasma, spirochetes, and protozoa. With few exceptions, its in vitro activity is superior to all of the conventional tetracyclines. In pigs and poultry, the *in vitro* activity of doxycycline against the most important respiratory pathogens usually varies between 0.125 and 0.5 μg/ml (against *B. bronchiseptica* up to 1 μg/ml).

5.2. Pharmacokinetic particulars

After oral administration to pigs and poultry, doxycycline is substantially absorbed from the gastrointestinal tract. The binding rate to plasma proteins is >90%. It is widely distributed in the organisms; at the steady state, the volume of distribution (V_{SS}) is >1.0 L/kg. Doxycycline is not metabolised to any significant extent and it is excreted primarily in faeces, mostly in a microbiologically inactive form.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Citric acid monohydrate, glucose anhydrate.

6.2. Incompatibilities
Doxycycline may form insoluble complexes with divalent ions, especially iron or calcium, zinc and magnesium.

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: 24 hours

6.4. Special precautions for storage
Do not store above 25°C.
Store in the original container tightly closed in order to protect from moisture.

6.5. Nature and composition of immediate packaging
100 g in polypropylene container with polyethylene inner bag
1 kg in polypropylene container with polyethylene inner bag
10 kg in polypropylene container with polyethylene inner bag
Not all pack sizes may be marketed.

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 kg in polypropylene container with polyethylene inner bag
10 kg in polypropylene container with polyethylene inner bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyvit 40% Soluble Powder
Doxycycline hyclate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE(S)

Active substance: Doxycycline hyclate 400.0 mg/g

3. PHARMACEUTICAL FORM

Powder for oral solution or incorporation in feed.

4. PACKAGE SIZE

100 g, 1 kg and 10 kg.

5. TARGET SPECIES

Chickens, turkeys and pigs.

6. INDICATION(S)

For the treatment of respiratory and systemic infections caused by doxycycline-sensitive organisms.
Chickens and turkeys:

* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
* airsacculitis (*Mycoplasma meleagridis*)
* infectious synovitis (*Mycoplasma synoviae*)
* fowl cholera (*Pasteurella multocida*)
* turkey bordetellosis (*Bordetella avium*)
* infectious coryza (*Haemophilus paragallinarum*)
* colibacillosis (*E. coli*)
* necrotic enteritis (*Clostridium perfringens*)
* chlamydiosis (*Chlamydia psittaci*).

In pigs the product is indicated for treatment of respiratory infections caused *by Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and *Bordetella bronchiseptica.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For in-drinking water or in-feed use.

8. WITHDRAWAL PERIOD

Meat and offal of chickens and turkeys: 4 days.
Meat and offal of pigs: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Wear gloves when handling the product. Avoid direct contact with the skin, eyes and mucous membranes. Wash hands after use. Wash any splashes from skin or eyes immediately with water.

10. EXPIRY DATE

EXP {month/year}
After first opening of container: 3 months
After reconstitution in drinking water: 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25°C at a dry place, protected from light. Close container securely after use.

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 RESTRICTION 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. MANUFACTURER'S BATCH NUMBER

1.B.3 PRODUCT INFORMATION

PACKAGE LEAFLET
Doxyvit 40% 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. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyvit 40% soluble powder
Doxycycline hyclate

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

Active substance: Doxycycline hyclate 400.0 mg/g

4. INDICATIONS

For the treatment of respiratory and systemic infections caused by doxycycline-sensitive organisms.
Chickens and turkeys:

* chronic respiratory disease (*Mycoplasma gallisepticum, E. coli*)
* airsacculitis (*Mycoplasma meleagridis*)
* infectious synovitis (*Mycoplasma synoviae*)
* fowl cholera (*Pasteurella multocida*)
* turkey bordetellosis (*Bordetella avium*)
* infectious coryza (*Haemophilus paragallinarum*)
* colibacillosis (*E. coli*)
* necrotic enteritis (*Clostridium perfringens*)
* chlamydiosis (*Chlamydia psittaci*).

In pigs the product is indicated for treatment of respiratory infections caused *by Mycoplasma hyopneumoniae, Pasteurella multocida, Actinobacillus pleuropneumoniae* and *Bordetella bronchiseptica.*

5. CONTRAINDICATIONS

Not for use in laying poultry when eggs are intended for human consumption.

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Chickens, turkeys and pigs.

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

Dosage:

- chickens, turkeys: 10-20 mg doxycycline hyclate per kg of body weight daily for 5 days.
- pigs: 15 mg doxycycline hyclate per kg of body weight daily for 5 days.

9. ADVICE on CORRECT ADMINISTRATION

Administration:

- chickens, turkeys: the daily dose may be administered pulse dosed when the daily requirement is given in limited quantity of water to be consumed by the birds within 4-8 hours or supplied continuously as 67-133 mg doxycycline hyclate per litre of drinking water.
- pigs: the daily dose may be administered in the drinking water administered continuously as 100-150

mg doxycycline hyclate per litre, or incorporated in the feed at a concentration of 00-250 mg/kg.

10. WITHDRAWAL PERIOD

Meat and offal of chickens and turkeys: 4 days.
Meat and offal of pigs: 3 days.

11. SPECIAL STORAGE CONDITIONS

Store between 15 and 25^{o}C at a dry place, protected from light. Close container securely after use. Keep out of the reach and sight of children.
Shelf life of the product as packaged for sale: 2 years.
Shelf-life after first opening the container: 3 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

12. SPECIAL WARNING(S), if NECESSARY

During the target animal tolerance studies, no adverse effect was observed in either species.
If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.
Wear gloves when handling the product. Avoid direct contact with the skin, eyes and mucous membranes. Wash hands after use. Wash any splashes from skin or eyes immediately with water.

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 product should be disposed of in accordance with local requirements.

14. DATE on which the PACKAGE INSERT WAS LAST APPROVED

15. OTHER INFORMATION

100 g in polypropylene container with polyethylene inner bag
1 kg in polypropylene container with polyethylene inner bag
10 kg in polypropylene container with polyethylene inner 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.