PROPOSAL FOR LABELLING AND PACKAGE LEAFLET

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

Marketing authorisation holder and manufacturer responsible for batch release:
ANDRÉS PINTALUBA, S.A.
C/Prudenci Bertrana nº 5
Polígono Industrial Agro-Reus
43206-Reus
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

(Italy, United Kingdom)
APSASOL AMOXICILLIN TRIHYDRATE 500 mg/g
Powder for use in drinking water for pigs, chickens, ducks and turkeys
Amoxicillin trihydrate

(Bulgaria, Croatia, Cyprus, Hungary, Greece, Portugal, Poland, Romania)
APSASOL AMOXICILLIN 500 mg/g
Powder for use in drinking water for pigs, chickens, ducks and turkeys
Amoxicillin trihydrate

(Spain)
APSASOL AMOXICILINA 500 mg/g
Powder for use in drinking water for pigs, chickens, ducks and turkeys
Amoxicillin trihydrate
APSASOL AMOXICILINA 500 mg/g

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g of almost white fine powder contains:

Active substance:
Amoxicillin trihydrate …… 500 mg
(Equivalent to 435.6 mg amoxicillin)

Excipient, q.s.

4. INDICATIONS

Chicken broiler, duck broiler and turkey for meat production: Treatment of pasteurellosis and colibacillosis caused by strains of *Pasteurella* spp. and *Escherichia coli* sensitive to amoxicillin.
Pig: Treatment of infections caused by strains of *Streptococcus suis* sensitive to amoxicillin.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to penicillins or to any of the excipients.
Do not use in rabbits, guinea pigs and hamsters, neither in equidae, because amoxicillin, like all penicillins, has an important effect on caecal bacteria.
Do not use orally in animals with functional rumen.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur, the severity varying from skin rash to anaphylactic shock.
Gastrointestinal symptoms (vomiting, diarrhoea).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Pig, chicken broiler, duck broiler and turkey for meat production.

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

In drinking water use.
Dosage and treatment regimen

-Pigs: 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 4 days.

-Chicken broilers: 15 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 30 mg product/kg bodyweight/day) for 5 days.

-Duck broilers: 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 40 mg product/kg bodyweight/day) for 3 days.

-Turkeys for meat production: 15 to 20 mg of amoxicillin trihydrate/kg of bodyweight every 24 hours (corresponding to 30-40 mg product/kg bodyweight/day) for 5 days.

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 taking into account the daily water consumption.

Based on the dose to be used, and the number and weight of the animals to be treated, the exact daily amount of product can be calculated using the following formula:

$$\text{g of product/ litre of drinking water/day} = \frac{\text{Mean bodyweight (kg) of animals x dose (mg amoxicilin trihydrate/kg bw/day)}}{\text{Mean daily water consumption (litres) x 500}}$$

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

No other source of drinking water should be available during the medication period. Medicated drinking water should be refreshed every 24 hours.

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance,

The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Meat and offal:

Pigs: 6 days
Chicken broilers: 1 day
Duck broilers: 9 days
Turkeys for meat production: 5 days
Egg: Not authorised for use in birds producing eggs for human consumption. Do not use within 4 weeks before the onset of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.
Store in the original container.

Shelf-life after first opening thecontainer : 1 month
Shelf-life after reconstitution according to directions: 24 hours

Do not use this veterinary medicinal product after the expiry date stated on this label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species

The uptake of medicated water by animals can be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead.
The use of the product should be combined with good management practices, i.e. good hygiene, proper ventilation, no overstocking

Special precautions for use in animals

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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for crossresistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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 reactions 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.
Take the necessary action to prevent the powder from spreading while the product is being added to drinking water.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.
Avoid contact with the skin and eyes. Wear gloves, overalls and goggles during preparation and administration of medicated water or liquid feed. In case of contact, rinse with plenty of clean water.
Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.
Do not smoke, eat or drink while handling the product.
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.Use during pregnancy, lactation or lay

Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects.

The safety of the veterinary medicinal product has not been established during pregnancy or lactation in sows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Do not use in birds in lay and within 4 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.
Do not use together with antibiotics which inhibit bacterial protein synthesis as they can antagonise the bactericidal effect of penicillins.
Do not administer together with bacteriostatic antibiotics.

Overdose (symptoms, emergency procedures, antidotes)

Not described. Amoxicillin has a wide margin of safety.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATA ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be supplied only on veterinary prescription
Administration by a veterinary surgeon or under their direct responsibility
EXPIRY DATE:
<EXP {month/year}>

Once opened, use by …

PACK SIZE
<400 g> <1 kg>

Not all pack sizes may be marketed.

MARKETING AUTHORISATION NUMBER

BATCH NUMBER
Batch {number}