LABELLING AND PACKAGE LEAFLET

COLISTIN APSA 1,200,000 IU/g
Premix for medicated feeding stuff for 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 and manufacturer responsible for batch release:
ANDRÉS PINTALUBA, S.A.
Pol. Industrial Agro-Reus
C/Prudence Bertrana No. 5
Reus
Tarragona
43206
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

COLISTIN APSA 1,200,000 IU/g
Premix for medicated feeding stuff for pigs
Colistin (as sulfate)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each gram of granulated brown powder contains:

Active substance:
Colistin (as sulfate) 1,200,000 IU

4. INDICATIONS

Treatment and metaphylaxis of enteric infections caused by non-invasive *E.coli* susceptible to colistin.
The presence of disease in the herd should be established before metaphylactic treatment.

5. CONTRAINDICATIONS

Do not use in horses, particularly in foals, since colistin, due to a shift in the gastrointestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.
Do not use in case of hypersensitivity to colistin or to any of the excipients.
Do not use in case resistance to polymyxins.

6. ADVERSE REACTIONS

No undesirable effects related to the use of colistin sulphate administered orally have been described at the recommended dose in the target species. In any event, as it is an

antibiotic that acts at intestinal level, digestive alterations may appear, such as intestinal dysbiosis, accumulation of gases or mild diarrhoea.

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

7. TARGET SPECIES

Pig (piglet and pig for fattening).

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

To be administered orally, in medicated feeding stuff.

The dosage is 180,000 IU of colistin/kg of bodyweight/day in feed (equivalent to 150 mg of the product/kg B.W./day) for 7 consecutive days.

Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of colistin has to be adjusted accordingly. Carefully calculate the average bodyweight to be treated and the average daily feed consumption before each treatment.

The medicated feed should be the only source of feed for the animals for the entire duration of the treatment period.

To calculate the exact dosage of the veterinary medicinal product, the following formula can be used:

$$\frac{\text{150 mg of veterinary medicinal product/kg bodyweight /day} \times \text{Average pig bodyweight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{mg of veterinary medicinal product per kg of feed}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Pelleting process of the product medicated feeds should be performed at an average temperature of 65 °C, as a maximum of 75 °C. Under normal conditions, the maximum duration time for the process should be 20 minutes.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Meat and offal: 1 day

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original container.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 1 month.
Shelf-life after incorporation into meal and pelleted feed: 3 months.

12. SPECIAL WARNINGS

Special warnings for each target species

As an adjunct to treatment, good management and hygiene practices should be introduced in order to reduce the risk of infection and to control the potential build up of resistance.

The intake of medicated feed by animals can be altered as a consequence of illness. In case of insufficient intake of feed, animals should be treated parenterally.

Special precautions for use in animals

Do not use colistin as a substitute for good management practices.
Colistin is a last resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment and metaphylaxis of diseases, and should not be used for prophylaxis.
Whenever possible, colistin should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.
In the case of newborn animals and animals with severe gastrointestinal and renal disorders, systemic exposure to colistin may be increased. Neuro- and nephrotoxic alterations may occur.

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

People with known hypersensitivity to polymyxins, such as colistin, or tree nuts should avoid any contact with the veterinary medicinal product.
Avoid direct contact with skin and eyes while mixing the veterinary medicinal product and handling the medicated feed. In case of contact, wash with plenty of water.
Care should be taken not to inhale any dust. The wearing of approved dust masks (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), impervious gloves, overalls and safety glasses are recommended during the handling and mixing of this veterinary medicinal product.

If symptoms such as rash appear after exposure, seek medical attention and present these warnings. Swelling of face, lips or eyes, and difficulty breathing are serious sings that require urgent medical attention.
Do not smoke, eat or drink while handling the product.
Wash hands and any exposed skin with soap and water immediately after use.

Use during pregnancy, lactation or lay

Studies in laboratory animals (rat and mice) have not produced any evidence of embryotoxic, foetotoxic or teratogenic effects. No specific studies have been conducted in pregnant or lactating pigs. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

After oral administration of colistin sulphate interaction with anaesthetics and myorelaxants may not be excluded in individual cases. The combination with aminoglycosides and levamisole should be avoided. The effects of colistin sulphate may be antagonized by binary cations (iron, calcium, magnesium) and by unsaturated fatty acids and polyphosphates.
There is cross-resistance between colistin and polymyxin B.

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

Toxic signs have not been seen in pigs given twice the recommended dose (300,000 IU per kg bodyweight per day) for twice the administration period (14 days). Nevertheless, episodes of soft faeces and tympany cannot be ruled out in the event of overdose in pigs treated with colistin, which remit on interruption of treatment.

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. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only

Environmental properties
The active ingredient colistin sulphate is very persistent in soils.

Dispensing conditions: **Veterinary medicinal product subject to veterinary prescription**
Administration conditions: **Administration under the control or supervision of a veterinarian surgeon**

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Pack size: 25 kg-bags

EXPIRY DATE:
<EXP {month/year}>

Once opened, use by …

PACK SIZE
25 kg

MARKETING AUTHORISATION NUMBER

Vm 32508/4000

BATCH NUMBER
Batch {number}

Approved: 06/07/2016