Veyxyl[®] Tabs





800 mg, tablets for oral use for dogs 800 mg, tablets for intrauterine use for cattle, pigs, horses and sheep

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Veyx-Pharma GmbH Söhreweg 6 34639 Schwarzenborn Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT Veyxyl® Tabs

800 mg, tablets for cattle, pigs, horses, sheep and dogs Amoxicillin as Amoxicillin trihydrate

STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tablet contains: Active substance:

800.0 mg Amoxicillin (equivalent to 918.4 mg Amoxicillin trihydrate)

INDICATIONS

For treatment of the following diseases caused by Gram-positive and/or Gram-negative Amoxicillin-sensitive germs:

Dogs; oral use:

Infections of the lung and respiratory system, infections of the digestive tract, urogenital infections, localised infections, bacterial secondary infections following viral infections.

<u>Cattle, pigs, horses and sheep; intrauterine use:</u> Infections of the endometrium, placental retention.

The sensitivity of the pathogens should be detected prior to the application of $Veyxyl^{\circ}$ Tabs.

This is especially relevant for infections of the digestive tract due to very high rates of resistance to amoxicillin for *E. coli and Salmonellae*.

CONTRAINDICATIONS

- Treatment of animals hypersensitive to penicillins and cephalosporins
- Severe kidney function disorders with anuria and oliguria
- Presence of β-lactamase-forming pathogens
- Oral application in ruminants and horses
- Oral application in rabbits, guinea-pigs, hamsters and other small rodents
- Do not use Veyxyl[®] Tabs in animals weighing less than 40 kg.

ADVERSE REACTIONS

Allergic reactions (allergic skin reactions, anaphylaxis)

In case of the occurrence of an allergic reaction the ${\sf Veyxyl}^{\otimes}$ Tabs treatment is to be stopped immediately.

Countermeasures:

In case of anaphylaxis: Adrenaline (epinephrine) and glucocorticoids i.v. In case of allergic skin reactions: Antihistamines and/or glucocorticoids.

Following oral application, disorders of the gastrointestinal tract can occasionally occur (vomiting, diarrhea, anorexia).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon. TARGET SPECIES Cattle, pigs, horses, sheep, dogs

DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For oral use:

Dogs above 40 kg body weight (b.w.): 10 mg Amoxicillin per kg b.w. orally twice daily over 3 - 5 consecutive days (10 mg Amoxicillin per kg b.w. are equivalent to ½ tablet Veyxyl® Tabs per 40 kg b.w.). The tablet can also be given in the feed.

In case there is no significant improvement in the disease 3 days after the treatment commenced, then the diagnosis should be reviewed and, where appropriate, a change in therapy undertaken. Assessing the pathogen's sensitivity is recommended.

The treatment should be maintained for 2 days after the clinical symptoms subside.

For intrauterine use:

Dosage per treatment:

 Horses:
 800 mg Amoxicillin, equivalent to 1 tablet Veyxyl® Tabs

 Cattle:
 400 - 800 mg Amoxicillin, equivalent to ½ - 1 tablet Veyxyl® Tabs

 Sheep, pigs:
 400 mg Amoxicillin, equivalent to ½ tablet Veyxyl® Tabs

Two treatments at an interval of two days. Assessing the pathogen's sensitivity is recommended.

ADVICE ON CORRECT ADMINISTRATION

Not applicable.

WITHDRAWAL PERIODS

Cattle, sheep and horses:	Meat and offal: Milk:	4 days 24 hours
Pigs:	Meat and offal:	4 days

SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25 °C. Store in a dry place. 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.

SPECIAL WARNINGS

Special warnings for each target species: Not applicable.

<u>Special precautions for use:</u> Special precautions for use in animals: Not applicable. Special precautions to be taken by the person administering the veterinary medicinal product to animals: Persons sensitive to penicillins should avoid direct contact with the veterinary

Persons sensitive to penicillins should avoid direct contact with the veterinary medicinal product to skin or mucous membranes.

<u>Use during pregnancy, lactation or lay:</u> Not applicable.

Interaction with other medicinal products and other forms of interaction: In terms of the antibacterial effect, there exists a potential antagonism for penicillins and chemotherapeutics with a rapidly commencing bacteriostatic effect.

Overdose (symptoms, emergency procedures, antidotes), if necessary: In case of overdosing symptoms of an excitation of the central nervous system and spasms/convulsions can occur. Veyxyl® Tabs treatment must be stopped immediately and an appropriate symptomatic treatment carried out (adminstration of benzodiazepines or barbiturates as antidotes).

Incompatibilities: Not applicable.

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.

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

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

OTHER INFORMATION

10 tablets in a slider box 100 tablets in a refill package

Not all pack sizes may be marketed.