Veyxyl® LA 20 %

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Suspension for injection for pigs, cattle, sheep, dogs and cats

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT
Veyx-Pharma GmbH
Soehreweg 6
34639 Schwarzenborn
Germany

NAME OF THE VETERINARY MEDICINAL PRODUCT
Veyxyl® LA 20 % 200 mg/ml
Suspension for injection for pigs, cattle, sheep, dogs and cats
Amoxicillin trihydrate

STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS
1 ml injection suspension contains:

Active substance:	
Amoxicillin trihydrate	229.60 mg (equivalent to 200.00 mg amoxicillin)
Excipients:	
Butylhydroxyanisole (Ph. Eur)	0.08 mg
Butylhydroxytoluene (Ph. Eur)	0.08 mg

INDICATIONS
In pigs, cattle, calves, sheep, dogs and cats to treat the following diseases caused by gram-positive and/or gram-negative amoxicillin sensitive micro-organisms:

Infections of the lungs and respiratory system, infections of the digestive tract, infections in the urogenital regions, general infections and septicaemic diseases, bacterial secondary infections following viral infections, erysipelas.

The sensitivity of the pathogens should be determined through an antibiogram prior to using Veyxyl® LA 20 %. Due to the very high degree of resistance against amoxicillin by E. coli and Salmonella, this applies especially to the treatment of infections of the digestive tract.

CONTRAINDICATIONS
- Intravenous application
- Treatment of animals hypersensitive to penicillins and cephalosporins
- Severe kidney function disorders with anuria and oliguria
- Presence of β-lactamase-forming pathogens
- Treatment of rabbits, guinea-pigs, hamsters and other small rodents

ADVERSE REACTIONS
Allergic reactions (allergic skin reactions, anaphylaxis)
In case of an allergic reaction Veyxyl® LA 20 % treatment must be stopped immediately.

Countermeasures:
In case of anaphylactic shock: epinephrine (adrenalin) and glucocorticoids i.v.
In case of allergic skin reactions: antihistamines and/or glucocorticoids

In rare cases local irritations may occur after the injection of Veyxyl® LA 20 %. The frequency of the occurrence of these undesirable effects can be reduced by decreasing the volume applied per injection site (see: Advice on correct administration). If you notice any serious effects or other effects not mentioned here, please inform your veterinary surgeon or pharmacist.

TARGET SPECIES
Pigs, cattle, sheep, dogs and cats

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
For intramuscular injection in pigs, cattle, calves, sheep, dogs and cats:
10 mg Amoxicillin per kg body weight (BW) once daily over a minimum of three consecutive days (10 mg Amoxicillin per kg BW are equivalent to 0.5 ml Veyxyl® LA 20 % per 10 kg BW).

If no marked improvement of clinical symptoms is to be observed after 3 days of treatment, the clinical diagnosis needs to be reviewed and if necessary, a change of the therapy is required. It is recommended to secure the sensitivity of the pathogens by means of an antibiogram. After decreasing clinical symptoms the treatment should be continued for two further days.

Intramuscular injection in pigs should preferably be done into the lateral musculature of the neck and in cattle into the elbow (anconaeus) musculature.

Shake intensively before use!

ADVICE ON CORRECT ADMINISTRATION
Users with a known sensitivity to penicillin and/or cephalosporin should avoid direct contact of the medicine with the skin or mucous membranes. In cattle Veyxyl® LA 20 % should be applied at differing injection sites. The maximum injection volume for Veyxyl® LA 20 % at each injection site is 20 ml in cattle.

WITHDRAWAL PERIODS

Cattle, calves, pigs and sheep:	Meat and offal	28 days
Cattle and sheep:	Milk	3 days

SPECIAL STORAGE PRECAUTIONS
Keep out of the reach and sight of children.
Do not store above 25 °C.
Keep the bottle in the outer carton and protect from light.
Shelf-life after first opening the container: 28 days.
After the expiry of this period any product remaining in the vial is to be disposed of.
Do not use after the expiry date which is stated on the label and carton.

SPECIAL WARNING(S)
Special warnings for each target species:
None.

Special precautions for use:
Special precautions for use in animals:
Veyxyl® LA 20 % should be injected at differing injection sites in cattle. The maximum injection volume of Veyxyl® LA 20 % at each injection site is 20 ml in cattle.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Users with a known sensitivity to penicillin and/or cephalosporin should avoid direct contact of the medicine with the skin or mucous membranes.

Use during pregnancy, lactation or lay:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
Mixing with other medicines must be avoided due to possible incompatibilities. With regard to the antibacterial effect, there is a potential antagonism of penicillins and chemotherapeutics with a fast occurring bacteriostatic effect.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
In case of overdosing, central-nervous excitations and spasms may occur. The treatment with Veyxyl® LA 20 % should be stopped immediately and a symptomatic therapy has to be initiated (application of benzodiazepines or barbiturates as antidotes).

Incompatibilities:
Galenic incompatibilities may occur in the presence of sulfonamides, heavy metals
and oxidative agents.

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. Ask your veterinary surgeon how to dispose of medicines no longer required.

To be supplied only on veterinary prescription.

OTHER INFORMATION
Package size:
100 ml bottle