For Veterinary Use Only.

Histeral®

Solution for Injection

Veterinary Antihistaminic Anti-allergic

COMPOSITION:

Histeral Solution for Injection is a clear, colorless, odorless, liquid solution containing in each ml 20 mg of tripelenamine HCl.

PHARMACOLOGICAL PROPERTIES:

Tripelennamine is an antihistaminic and anti-allergic agent, which is an H-1 receptor blocker in terms of mechanism of action. H1 receptor blockers which are defined as pharmacological antagonists for histamines are bound to histamine receptors by competing with histamine in tissues. Capillary antagonize vein permeability increase. They prevent allergic reactions of histamine including itch and burn by blocking H-1 receptors on sensitive nerve endings. On the other hand either H-1 or H-2 antihistaminics cannot prevent histamine release. They have also parasympatholytic effects. It declines all excretion except gastric fluid. When given parenterally its effects are more distinct than its oral effects. It is transformated in liver and its metabolites are excreted through urination.

AREA OF USE / INDICATIONS:

H-1 antihistaminic is used in order to prevent histaminic effects causing mainly allergic and anaphylactic reactions in body. Skin problems: Pruritis (itchiness), urticaria, different types of dermatitis, watery eczema, acute eczematous otitis, beetle bite or stings.

General conditions: In laminitis depending on nutrition and birth, paroxymal myoglobinuria or azoturia, intestinal oedema, photosensitization, lame horses, stomatitis, motion sickness and drug sensitivities

Respiratory problems: Acute lung oedema, secondary pneumonia, asthma in horse pulmonary emphysema

Genital and mammary problems: It is used in acute septic and gangrenous mastitis, septic metritis and retentio secondinarium successfully.

USAGE AND DOSAGE:

It is administered only intramuscularly in horse, cat, and dogs:

Horse : 1 ml / 40 kg/live weight (0.5 mg / kg / live weight) IM

Dog-Cat : 0.5 ml /10 kg/live weight (0.5 mg / kg /live weight) IM

It is administered 3 times daily at 8 hours intervals. During administration the drug needs to be warmed up to around body temperature in palm.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR INTENDED SPECIES:

One of the main side effects of H-1 antihistamines are their sedation and anticholinergic effects. When the drug is used at therapeutic doses central nerve system depression or incoordination may occur. Only intramusculary administration should be preferred in horses because central nerve system stimulation may be considered as hyperexcitability, nervosity, and muscle tremors.

Use during pregnancy: Avoid using in early stages of pregnancy.

UNDESIRED/SIDE EFFECTS

Sedation, inertia, inactiveness, distractibility in human, increased sleeping tendency, dizziness, and ataxia may occur considering its effects suppressing central nerve system.

DRUG INTERACTIONS:

Their use together with drugs affecting central nerve system, including neuroleptics, tranquilizers, narcotics, and anaesthetics increases effects of those drugs because of synergistic interaction. Besides they decline those effects of steroids, androgens, pregesterons, and hydrocortizon.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

Administration at higher doses may cause hyperexcitability, ataxia, widening of pupilla, and even toxic effects with convulsions. When observing poisoning signs terminate drug administration and initiate symptomatic therapy.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): It is not to be used in edible animals.

CONTRAINDICATIONS:

It is contraindicated when used together with tranquilizer, narcotic, and anesthetics. It may cause hyperexcitability, ataxia, widening of pupillas, and even toxic effects with convulsions.

GENERAL WARNINGS:

Consult your veterinary surgeon in case an unexpected effect is observed. Keep out of reach of children.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

In case administrator injects himself/herself accidentally consult a physician, and bring the package insert.

STORAGE CONDITIONS AND SHELF LIFE:

Protect from light. Store at room temperature (15-25℃).
Shelf life is 4 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Presented to the market as 20, 50 and 100 ml amber vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 24.03.2006

MINISTRY OF AGRICULTURE AND RURAL AFFAIR MARKETING AUTHORIZATION DATE AND NO:

19.04.2002-11/1038

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk.

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NAME AND ADDRESS OF MANUFACTURER COMPANY:

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Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat