For Veterinary Use Only.

Hemadur®-K

Solution for Injection

Veterinary Vitamine

COMPOSITION:

Hemadur-K is a straw-coloured, transparent, and sterilized solution comprising 10 mg Vitamine K-1 (Phytonadione, Phytomenadiodine) per ml.

PHARMACOLOGICAL PROPERTIES:

Vitamin K is needed to form blood coagulation factor, factor II (prothrombin), factor VII (proconvertin), factor IX (plasma thromboplastin component), and factor X (Stuart's factor) in liver. Those factors are synthesized as zymogenes, their being converted to active biologically is dependent on vitamin K existence. When vitamin K is deficient the tendency to bleed gets increased, and it appears in ecchymosis, epistaxis, hematuria, gastrointestinal bleedings, and post-operative and intra-cranial bleedings.

Phytonadione has similar structure to natural vitamin K. Its gastrointestinal absorbtion is executed through intestinal lymphatics, and requires bile salts. Vitamin K is not efficient on anti-coagulant characteristics of heparin. Under usual conditions vitamin K is synthesized by intestinal bacterial flora, and its deficiency depending on malnutrition is observed rarely. But when preventing balast discharge vitamin K absorbtion is effected negatively.

After intramuscular administration quickly absorbed Vitamin K1 accumulates in liver first, and then its density gets decreased suddenly. Its existence on any tissue exluding liver is rare, and it is not stored in body. Vitamin K1 which has been converted to an epoxy derivation by being oxidized in liver, is converted again to Vitamin K1 by epoxyde reductase enzyme, and used again. Its unused parts are excreted through urination as glucuronide and sulphate compounds.

AREA OF USE / INDICATIONS:

Hemadur-K Solution for Injection; In Cattle, horse, pig, goat, dog and cats.

Acute bleedings (Acute Hypoprothrombinemia)

Post-partum bleedings

Capillary bleedings on breast tissue

Post-operative bleedings

Conditions preventing vitamin K synthesis (liver diseases, conditions preventing balast synhesis or flow, digestive system diseases with diarrhea, and chemo administration affecting bacterial population negatively)

Poisinings trough vitamin K antagonists (e.g. ecoumarin based rodenticides), snakebites

It is used in order to stop bleeding in internals bleedings caused by coumarin derivative substances taken by eating bad or moldy alfalfa.

USAGE AND DOSAGE

I - Non-Acute Conditions

1 Under non-acute conditions general pharmacological dose in horses and cattle is 0.5-2.5 mg/kg live weight.

Under non-acute conditions in practice 0.5-2.5 ml/10 kg live weight is given intra-muscularly or subcutaneously in horses and cattle.

2) General pharmacological doses in sheep, goat, dog, and cats under non-acute conditions are as follows:

0.25-2.5 mg/kg live weight

under non-acute conditions 0.25-2.5 ml/10 kg live weight is given intra-muscularly or subcutaneously in sheep, goat, dog, and cats in practice.

II- Acute Conditions

Considering acute bleedings

In cattle, horse, pig, sheep, and goats in practice, 0.5–2.5 ml is administered intravenously for 10 kg live weight. 0.25 -2.5 mg/kg live weight is administered considering acute bleedings in dog and cats. It should be used at 2.5 mg / kg live weight dose in second generation rodenticide poisonings. In obligatory cases when requiring intravenous administration it may be diluted by normal saline (0.9% sodium chloride), 5% dextrose. It should not be diluted by outher liquids. It should be used immediately after being diluted. Intra-venous vitamin K amount per minute should not excess 5 mg (0.5 ml).

SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES

Intra-muscular or subcutanous injection is preferable for vitamin K injection mostly. Intravenous administrations are risky. It may cause death.

When it is not possible to avoid intra-venous injection the drug should be administered very slowly.

Drug administration and auxiliary dosage are set by checking prothrombin time and by clinical observation.

6-8 hours after administration if there is no shortage on prothrombin time, the given dose sould be re-administered.

No clinical result is to be acquired in bleedings caused by heparin administrations and hepatic lacerations.

Use during pregnancy: Vitamin K1 is not proved to be secure for use in pregnant animals. It is preferable to initiate the therapy at lower doses because it may be disadvantageous in terms of pregnancy in target species when used at recommended doses.

UNDESIRED/SIDE EFFECTS

It may cause anaphylactic shock in sensitive animals. Temporary pain and puffiness may occur on administration area.

DRUG INTERACTIONS

It should not be administered by being mixed with antibiotics and corticosteroids. Phenylebutazone, salycilic acid, chloramphenicol, sulfanamides, metrinidazole, erythromycine, anabolic steroids, and thyroid preparations prevent vitamin K efficiency.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

When it is not possible to avoid intravenous administration, oversensitivity reactions, cardiac or respiratory paralysis may occur especially right after quick administration.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): Zero (0) day for flesh and milk.

CONTRAINDICATIONS

Avoid use in animals with vitamin K1 sensitivity.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed.

Keep out of reach of children. Keep away from food products.

STORAGE CONDITIONS AND SHELF LIFE

Store in its package at room temperature (15 -30^{0}C). Protect from direct sunlight. Shelf life is 2 years as of the production date.

COMMERCIAL PRESENTATION FORM

Presented to the market as 10, 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: 17.02.2009

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO: 17.02.2009/21–013

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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