For Veterinary Use Only.

FOSFALİN®

Solution for Injection

Veterinary Mineral

COMPOSITION:

Fosfalin Solution for Injection is a clear, colourless, viscous solution containing 200.0mg Sodium 4-dimethylamino-2-methylphenilphosphate per each ml.

PHARMACOLOGICAL PROPERTIES:

Sodium 4-dimethylamino-2-methylphenilphosphate (toldimfos sodium) is an organophosphorus compound containing approximately 14% usable phosphor. It stimulates the intermediary metabolism in the organism.

It affects the metabolism of carbohydrates and acts in the stimulation of energy reserved and in the enhancement of motoric activity. It acts as a stimulant on the regenerative activity of the body by means of activating the metabolic activities in the liver. It acts as a regulator on the lipid-cholesterin and fat metabolism while as an activator in the hematopoiesis with protein synthesis.

This substance which is similar in chemical composition with the organic phosphorus that is in the structure of phospholipids and phosphoproteins, is completely free from primary toxic effects creating the most important disadvantages of inorganic phosphorus. It is rapidly and completely absorbed through the injection area. It has a bioavailability of approximately 100%. It reaches the maximal level in blood within 20 minutes. It has a high diffusion. It penetrates into all tissues and body fluids. The serum half life in calf and dairy cattle is 1.07 and 1.15 hours, respectively. The residence time in serum is 3.6 and 3.1 hours for calf and cows, respectively. It does not undergo metabolic changes; it is basically excreted through the urine within 24 hours as the main compound. The excretion from the body through milk is highly low. Its amounts within the milk are generally below the limits of analysis. Toldimphos does not accumulate in the body.

AREA OF USE / INDICATIONS:

Fosfalin Solution for Injection is particularly administered for horses, cattle, sheep and goats, and in the following;

- Multiple metabolic disorders frequently seen in all domestic animals, acute and chronic physiological deficiencies, progressive weakness and asthenia, developed accordingly;

General weakness conditions observed in newborns; the reduction of the efficiency for feed utility; decreases of performance including the recession of growth and live weight gain; losing body resistance,

Conditions of paresis and paralysis arising from the disorders of phosphorus metabolism; clinical treatment of neurological disorders,

Hypocalcemia and meadow tetania of cattle; pregnancy toxicity of sheep; milk tetania of calf; tetania of horses,

Supporting Ca treatment for the general cases of atrophy,

Postnatal liver degenerations; puerperal liver coma; puerperal haemoglobinuria; ketosis and prevention of similar diseases of metabolism,

- As a supportive to accelerate the growth in normal animals; to enhance the performances; to increase the resistance; to increase fattening performances and the performances of work and sports animals,
- Stimulation and regulation of the metabolism of farm animals during growth period; acceleration of feed utility and live weight gain,
- As a protective and supportive treatment for growth deficiency, rachitism and similar bone diseases.

USAGE AND DOSAGE:

Fosfalin Solution for Injection is administered to cattle, sheep-goats and cats-dog subcutaneously, intravenously and intramuscularly at a dose of 10 mg/kg live weight. Following are the treatment doses administered as a single parenteral dose and in acute events as per animal species and ages:

Horse-Cattle :5 - 20ml
Sheep-Goat :1 - 3 ml
Calf-Foal :2.5 - 6 ml
Lamb-Yean :1 - 2 ml
Cat-Dog :0.5 - 3 ml

In chronic cases, 5-10 administrations may be performed by repeating the specified doses once in each 2-3 days until a significant clinical recovery is seen in the conditions of sick animals.

With respect to the serious cases in which a rapid absorption is required, one half of the dose is administered intravenously (IV) and the other half is administered intramuscularly (IM) or subcutaneously (SC). It is recommended to administer the whole of the drug not over one injection area but on different points by dividing into several parts.

SPECIFIC CLINICAL PARTICULARS AND WARNING FOR SURGEONS:

In accordance with the provision of the veterinary surgeon, it may be used in disease conditions or to enhance the capacity and performance. In cases of protective and supportive applications intended to contain a long period, it is recommended to repeat the cures once in 4-5 weeks consisting 2 or 3 administration with 2 days interval. As for intravenous administration, Fosfalin Solution for Injection should be administered as slow injection after it reaches body temperature.

Use during pregnancy: No objections to use during pregnancy provided to use at the recommended doses.

UNDESIRED/SIDE EFFECTS

No side effects have been observed at the administration doses.

DRUG INTERACTIONS:

It may have objections in case that it is mixed with other solutions for injection or infusion. Do not inject in combination with other drugs.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

Toldimfos sodium is a substance with a very low toxicity.

No overdose at the administration doses.

WARNINGS FOR DRUG RESIDUES IN FOOD:

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

CONTRAINDICATIONS:

No contraindication is known.

GENERAL WARNINGS:

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

STORAGE CONDITIONS AND SHELF LIFE:

Store at room temperature of (15-25℃) protected fr om light.

Shelf life is 5 years (60 months) as of the production date.

COMMERCIAL PRESENTATION FORM:

Presented to the market in 20, 50 and 100ml 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:

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NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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