Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Phosphonortonic 20% Injectable Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Toldimfos sodium trihydrate	20.00 % w/v
Excipients	
Anhydrous Sodium Sulphite	0.20 % w/v
Phenethyl alcohol	1.00 % w/v

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle.

4.2 Indications for use, specifying the target species

Phosphonortonic supplies organic phosphorus and is indicated in the treatment of disorders of phosphorus metabolism in horses and cattle.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance.
Do not use the product in animals suffering from renal failure.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be used in lactating animals.
No data are available on the effect of the product in pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administration is by intravenous and intramuscular routes in several sites.
The doses recommended may be repeated every 2 or 3 days or daily according to the severity of the case: 5 to 10 injections in chronic affections.

Horses - Cattle
* Adult animals: 10 - 25 ml
* Foals - Calves: 5 - 10 ml

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Cattle
Meat and offal: zero days.
Milk: zero hours.

Horses
Meat and offal: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism, mineral supplements, toldimfos.

ATC vet code: QA12CX90

Phosphonortonic 20% Injectable Solution provides a high level of assimilable phosphorus by the most direct routes of administration.

In the animal, all forms of phosphorus are oxidised almost exclusively into the +5 state of oxidisation (in the form of phosphate). This oxidisation is necessary for phosphorus to exert its metabolic effects.
Phosphinates do not escape this phenomenon and the phosphorus supplied by Toldimphos sodium (level of oxidisation +1) is oxidised into phosphate.

The pharmacological properties of Toldimphos sodium are identical to those of phosphates. In its mineral form (notably calcium phosphate), phosphorus plays a part in the formation of bones and teeth.
Organic derivatives of phosphate are present in high amounts in all cells; they intervene in many metabolic pathways and play an important role in the transfer of cellular energy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Sodium Sulphite
Anhydrous Sodium Carbonate
Phenethyl Alcohol
Disodium Edetate
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

100 ml amber, type II glass vials closed with chlorobutyl rubber stoppers and aluminimum caps with or without a flip off cap containing a clear, colourless, aqueous solution for injection.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
First Floor, Segrave House
19/20 Earlsfort Terrace
Dublin 2

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/022/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2015