SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Foston 20% w/v, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	%w/v
Toldimphos sodium	20.0
Other substances	
Sodium sulphite anhydrous	0.2
Phenylethyl alcohol	0.6

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Clear, sterile aqueous solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and dogs

4.2 Indications for use, specifying the target species

An organically combined phosphorus preparation for the support of metabolic activity in cattle and dogs including:

- skeletal defects - rickets and osteomalacia or promotion of rapid union in fractures, particularly when associated with vitamin D therapy.

- tetany and paresis - caused by disorders of calcium, magnesium and phosphorus metabolism (post-parturient paresis, lactation tetany, grass tetany, etc.)

In these cases, the product has a synergistic effect when given in conjunction with specific magnesium or calcium therapy.

General metabolic disorders – the product is a useful form of therapy in the treatment of debility, whether during convalescence or the result of nutritional disorders. It may be useful after difficult parturition in debility of the newborn and deficiency syndromes in cattle and dogs of all ages.

4.3 Contra-indications

None

4.4 Special warning for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Observe aseptic precautions during administration throughout the course of therapy.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Can be used in lactating animals. The use of this product in pregnant animals has not been fully evaluated.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Dose:

Cattle	10-25ml
Dogs (depending on size and weight)	1-3ml

Administer by intravenous, intramuscular or subcutaneous injection. Dosage to be repeated to clinical effect.

In severe cases where rapid absorption is required the dosage may be given as half by intravenous injection and half by intramuscular or subcutaneous injection. Multiple injection sites may be used.

For chronic conditions 5-10 subcutaneous or intramuscular injections should be given at 48 hours intervals with the following dose rates:

Cattle 2.5 - 5ml
Dogs 1 - 2ml

The stopper should not be punctured more than 25 times.

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

No special precautions required.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Meat – zero days
Milk – zero hours

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Phosphorus is one of the fundamentally important elements of the body which is involved in many vital processes. Foston contains the aromatic phosphorus compound Toldimphos which falls between phosphorus and phosphoric acid in the stages of oxidation in the body.

Toldimphos does not replace deficient phosphorus but stimulates metabolism and:
- increases calcium concentration in blood without simultaneous administration of calcium preparations.
- normalises GOT values.
- has a beneficial effect on serum cholesterol.

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5.2 Pharmacokinetic particulars

Elimination experiments in dogs have shown that almost 90% of the substance was recovered in urine 4 hours after intravenous injection and 8 hours after intramuscular injection. After 24 hours, 97 to 93% excretion occurred. Toldimphos was excreted unchanged in dogs.

Toldimfos is rapidly absorbed and distributed in the body. In cattle, maximal plasma concentrations are observed within 10 to 20 minutes after intramuscular administration. Elimination occurs mainly via the urinary pathway. Repeated dosing does not lead to bioaccumulation of the product.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium sulphite anhydrous
Phenylethyl alcohol
Sodium Carbonate Anhydrous
Propylene glycol
Water for injections

Sodium hydroxide solution is used for pH adjustment.

6.2 Major incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after opening the original packaging: 14 days.

6.4 Special precautions for storage

Do not store above 25°C.
Discard unused material.

6.5 Nature and composition of immediate packaging

A clear multidose type I (Ph Eur) glass 50ml bottle, closed with a bromobutyl rubber bung secured with a flip off cap and polypropylene disk.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd.
Walton
Milton Keynes, Bucks.
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4426

9. DATE OF FIRST AUTHORISATION OR DATE OF RENEWAL OF THE AUTHORISATION

Date: 01 September 2006

10. DATE OF REVISION OF TEXT

Date: July 2012