PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Foston 20% w/v, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Toldimphos sodium: 20%w/v anhydrous
Sodium sulphite: 0.2 % w/v
phenylethyl alcohol: 0.6% w/v

3. PHARMACEUTICAL FORM
solution for injection

4. PACKAGE SIZE
50 ml injection solution

5. TARGET SPECIES
An organically combined phosphorus preparation for use in cattle and dogs

6. INDICATION(S)
An organically combined phosphorus preparation for use in cattle and dogs

7. METHOD AND ROUTE(S) OF ADMINISTRATION
IV, IM or SC

8. WITHDRAWAL PERIOD
Meat: zero days; milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY
For uses, dosage, administration, contra-indications, disposal advice and warnings: see package leaflet.

10. EXPIRY DATE
BN / EXP end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Following withdrawal of the first dose, use the product within 14 days. Keep container in outer carton. Wash hands after use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For uses, dosage, administration, contra-indications, disposal advice and warnings: see package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

FOR ANIMALTREATMENT ONLY.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributor for N. Ireland:
Intervet Ireland Ltd.
Dublin 24

MA Holder
Intervet UK Ltd.
Walton Manor, Walton
Milton Keynes MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4426

17. MANUFACTURER'S BATCH NUMBER

BN / EXP end of:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**
   Foston 20% w/v, solution for injection

2. **STATEMENT OF ACTIVE AND OTHER SUBSTANCES**
   20% w/v solution of Toldimphos Sodium

3. **PHARMACEUTICAL FORM**
   solution for injection

4. **PACKAGE SIZE**
   50 ml

5. **TARGET SPECIES**

6. **INDICATION(S)**

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**
   IV,IM or SC

8. **WITHDRAWAL PERIOD**
   Withdrawal periods: Meat: zero days; milk: zero hours.

9. **SPECIAL WARNING(S), IF NECESSARY**
   For uses, dosage, administration, contra- indications, disposal advice and warnings: see package leaflet.

10. **EXPIRY DATE**
    EXP
    Once broached, use by:

11. **SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C. Keep container in outer carton.
Following withdrawal of the first dose, use the product within 14 days.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For uses, dosage, administration, contra- indications, disposal advice and warnings: see package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Licensed distributor for Northern Ireland: Intervet Ireland Ltd.
MA Holder
Intervet UK Ltd., Walton Manor, Walton, Milton Keynes, MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4426

17. MANUFACTURER'S BATCH NUMBER

BN

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Intervet UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Manufacturer responsible for batch release
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Foston 20% w/v, solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active substance	%w/v
Toldimphos sodium	20.0

Other substances

Sodium sulphite anhydrous	0.2
Phenylethyl alcohol	0.6

Clear, sterile aqueous solution for injection.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose:

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Observe aseptic precautions during administration throughout the course of therapy. Wash hands after use.

10. WITHDRAWAL PERIOD(S)

Meat – zero days
Milk – zero hours

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Following the withdrawal of the first dose, use the product within 14 days. Keep the container in the outer carton. Discard unused material. Keep out of the sight and reach of children. When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided on the carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Use during pregnancy

The use of this product in pregnant animals has not been fully evaluated.

Lactation:

Can be used in lactating animals.

Overdose:

No special precautions required.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2016.

15. OTHER INFORMATION

For animal treatment only.

Pack sizes

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.

Legal category

POM-V To be supplied only on veterinary prescription.

Marketing authorisation number

Vm 01708/4426

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Approved: 01/08/2017