

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with one 100ml polyethylene terephthalate (PET) vial
Cardboard box with one 250ml polyethylene terephthalate (PET) vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACTIONIS 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. PACKAGE SIZE

100ml
250ml

4. TARGET SPECIES

Pigs and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use. Cattle: Subcutaneous use.

7. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: Meat and offal: 6 days.
Milk: zero hours.

Pigs: Meat and offal: 6 days.

8. EXPIRY DATE

Exp, {mm/yyyy}
Once broached, use within 28 days
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

14. MARKETING AUTHORISATION NUMBERS

[To be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP.]

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100ml polyethylene terephthalate (PET) vial label
250ml polyethylene terephthalate (PET) vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACTIONIS 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. TARGET SPECIES

Pigs and cattle

4. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use. Cattle: Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle: Meat and offal: 6 days.
Milk: zero hours.

Pigs: Meat and offal: 6 days.

6. EXPIRY DATE

Exp {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

9. BATCH NUMBER

Lot {number}

