

PARTICULARS TO APPEAR ON THE OUTER BOX and IMMEDIATE LABEL
100 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Injectable 10% w/v solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Spectinomycin (as spectinomycin dihydrochloride pentahydrate) 10.00 % w/v.
Also contains benzyl alcohol 0.9% w/v and sodium metabisulphite 0.055% w/v as preservatives.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Calves

6. INDICATION(S)

For the treatment of respiratory disease due to infection with bacteria sensitive to spectinomycin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By intramuscular injection.

20-30 mg/kg bodyweight per day (equivalent to 10-15 ml per 50 kg bodyweight), once daily for a maximum of 5 days.

8. WITHDRAWAL PERIOD

Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 32 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for user safety warnings and special precautions for use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Following the withdrawal of the first dose, use the product within 28 days. Do not use after stated expiry date. Keep the container in the outer carton.

Date of broaching:...

Date to discard:...

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

Dispose of any unused product and empty containers in accordance with guidance from our local waste regulation authority.

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

POM-V

To be supplied only on veterinary prescription

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd.
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4012

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET

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

Marketing Authorisation Holder:

Ceva Animal Health Ltd.
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release: Ceva Santé Animale, 10 avenue de la Ballastière, 33 500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Spectam Injectable 10% w/v solution for injection

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

A sterile, pale yellow, aqueous solution of spectinomycin (as spectinomycin dihydrochloride pentahydrate) 10% w/v. Also contains benzyl alcohol 0.9% w/v as antimicrobial preservative and sodium metabisulphite 0.055% w/v as antioxidant.

4. INDICATION(S)

For the treatment of respiratory disease due to infection with bacteria sensitive to spectinomycin.

5. CONTRAINDICATIONS

None.

6. TARGET SPECIES

Calves

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

Administer by intramuscular injection: 10-15 ml per 50 Kg bodyweight), once daily for a maximum of 5 days. This is equivalent to 20-30 mg spectinomycin per kg bodyweight once daily for a maximum of 5 days.

8. WITHDRAWAL PERIOD(S)

Calves must not be slaughtered for human consumption during treatment. Calves may be slaughtered for human consumption only after 32 days from the last treatment.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Following the withdrawal of the first dose, use the product within 28 days. Do not use after stated expiry date. Keep the container in the outer carton.

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.

10. SPECIAL WARNING(S)

It is prudent to reserve the use of spectinomycin for clinical conditions which have responded poorly to other classes of antimicrobials.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

USE DURING PREGNANCY AND LACTATION: Not suitable as the product is intended only for use in calves.

USER WARNINGS:

Persons known to be hypersensitive (allergic) to spectinomycin should not handle this product.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

Avoid contact with skin and eyes. Wash any splashes off immediately with plenty of water. Wash hands thoroughly after use. Keep out of sight and reach of children. For animal treatment only.

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

Dispose of any unused product and empty containers in accordance with guidance from our local waste regulation authority.

12. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

13. OTHER INFORMATION

Vm 15052/4012

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To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

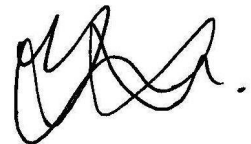
Multidose 100 ml glass vial.

FURTHER INFORMATION

Sensitivity Testing.

It is recommended that 100 mcg spectinomycin discs are used on Streptomycin Antibiotic Medium N°2 (Oxoid CM335) adjusted to pH8.

Negative results with the standard diagnostic sensitivity agar does not always indicate that the organism is not sensitive to spectinomycin.



Approved: 06 October 2022