

**ANNEX III
LABELLING AND PACKAGE LEAFLET**

A. LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin Aerosol 3.58% w/w cutaneous spray, solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

140g Aerosol containing:
Oxytetracycline hydrochloride 5g (equivalent to 3.58% w/w) and a blue marker dye.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution

4. PACKAGE SIZE

140 grams

5. TARGET SPECIES

Cattle, Sheep and Pigs.

6. INDICATION(S)

ALAMYCIN AEROSOL is a cutaneous spray indicated for the treatment of foot rot in sheep and topical infections caused by oxytetracycline-sensitive organisms in cattle, sheep and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For the treatment of foot rot, clean the affected area prior to administration. The wounds should be cleaned prior to administration. Shake the can before use. Spray for a few seconds until the lesion is adequately covered. Treated sheep should be allowed to stand on dry ground for one hour before returning to pasture.

8. WITHDRAWAL PERIOD

Meat – Zero days
Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

FOR EXTERNAL USE ONLY

Shake the can before use.

Spray for a few seconds or until the lesion is adequately covered.

Keep away from the animal's eyes

Operator warnings:

Keep away from eyes.

Avoid inhalation and contact with skin.

Wash hands after use.

Highly flammable

Must be used in a well ventilated area.
Do not smoke when using this product.
Do not spray on a naked flame or any incandescent material.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Pressurised container.
Protect from sunlight and do not expose to temperatures exceeding 50°C.
Do not pierce or burn, even after use.
Do not spray on a naked flame or any incandescent material.
Highly flammable.

12. SPECIAL 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 your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4053

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 28 October 2022