

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Marketing authorisation holder:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:

Dales Pharmaceuticals Ltd
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Willcain solution for injection.

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

1 ml contains:

Active substances:

Procaine hydrochloride 5.0 % w/v

Epinephrine bitartate 0.0036 % w/v (equivalent to epinephrine 0.002 % w/v)

Excipients:

Chlorocresol 0.1 % w/v

Sodium metabisulphite 0.1 % w/v

4. PHARMACEUTICAL FORM

Solution for injection.

5. PACKAGE SIZE

100 ml

6. INDICATION

For minor surgical procedures including dehorning and disbudding in cattle.

7. CONTRAINDICATIONS

Do not administer by intravenous, intra-articular or epidural injection.

8. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

9. TARGET SPECIES

For cattle, horses, dogs and cats.

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

By subcutaneous injection.

Horses and cattle: 2 to 5 ml

Dogs and cats: 0.25 to 1 ml

Do not exceed the recommended dosage.

11. WITHDRAWAL PERIOD

Cattle meat: Zero days; Cattle milk: Zero hours; Horse meat: Zero days.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Protect from light.

13. SPECIAL WARNINGS

Special warning for each target species:

Use with care in horses as the coat colour at the injection site may turn permanently white.

Special precautions for use in animals:

Care should be taken not to inject the drug into a vein.

Use with care in distal limb block due to the risk of ischaemia.

User warnings:

Take care to avoid accidental self-injection. In the event of accidental self-injection, seek medical attention and show the label to the physician. Immediately wash off any splashes to the eyes or skin with copious amounts of water. Seek medical attention if irritation occurs.

Wash hands after use.

Interaction with other medicinal products and other forms of interaction:

Procaine may inhibit the action of sulphonamides and their concurrent administration should be avoided.

14. EXPIRY DATE

EXP: month/year

Discard any unused material.

When the container is breached for the first time, using the 28 day in-use shelf life, the date on which any product remaining in the container should be discarded should be calculated. This discard date should be written in the space provided on the label.

Once breached use by: / /

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Dispose of empty containers in the farm refuse. Used containers should not be recycled.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only. To be supplied only on a veterinary prescription.

POM- VPS

Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person

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

Keep out of the sight and reach of children.

19. MARKETING AUTHORISATION NUMBER

Vm 36408/4014

20. MANUFACTURER'S BATCH NUMBER

Lot: {number}

21. OTHER INFORMATION

Local representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury,
Shropshire, SY4 4AS, United Kingdom.

Approved: 18/08/21

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending to the right.