



**Veterinary Medicine User Leaflet** EN  
Veterinarian Prescription only medicine  
For animal use only

**1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE:**

Norodine 24 Veterinary, solution for injection,  
I.M, I.V, S.C

**2. ACTIVE INGREDIENTS:**

Each ml contains:  
Trimethoprim 40 mg/ml (4.00%w/v)  
Sulfadiazine 200 mg/ml (20.00%w/v)  
The medicine also contains the excipients:  
Chlorocresol 0.1% w/v  
Sodium Formaldehyde Sulfoxylate Dihydrate 0.1% w/v  
N-methyl Pyrrolidone 51.50% w/v  
For the full list of excipients, see section 12 "further information".

**3. Indications for use:**

Indicated in the treatment of sensitive organisms in horses, cattle, pigs, dogs and cats.

Therapeutic Group: Antibiotics

**4. Contraindications:**

Should not be given by routes other than those recommended. Not to be administered intraperitoneally, intra-arterially or intrathoracically. Do not administer to animals with known sulphonamide sensitivity, severe liver parenchymal damage or blood dyscrasias.

**5. Adverse reactions:**

Anaphylactic shock, potentially fatal, has been observed on rare occasions following administration of potentiated sulphonamide preparations, particularly by the intravenous route. Veterinary surgeons should be mindful of this possibility during the injection process. Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which refers to the online form for reporting adverse events, or by entering the link: <https://sideeffects.health.gov.il>

**6. Target Species:**

Horses, cattle, pigs, dogs and cats

**7. Amounts to be administered and administration route:**

**Cattle and Pigs:**

The recommended dose rate is 1 ml per 16 kg bodyweight (15 mg of active ingredients per kilogram bodyweight) by intramuscular or slow intravenous injection. May be administered by intravenous injection when rapid blood levels of Trimethoprim and Sulfadiazine are required.

**Horses:**

The recommended dose rate is 1 ml per 16 kg bodyweight (15 mg of active ingredients per kilogram bodyweight), by slow intravenous injection.

**Dogs and Cats:**

The recommended dose rate is 1 ml per 8 kg bodyweight (30 mg of active ingredients per kilogram bodyweight), by subcutaneous injection only.

The recommended site in dogs is the loose skin at the top of the neck.

A single injection may be sufficient in uncomplicated conditions, but in severe infections it may be repeated daily until 2 days after symptoms resolve, up to a maximum of 5 days.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

**8. Withdrawal period:**

Cattle: Meat: 12 days. Milk: 60 Hours

Pigs: Meat: 20 days.

Not for use in horses intended for human consumption.

**9. Special warnings and precautions for use:**

- Special precautions for use in animals: For intravenous administration the product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance

the injection should be interrupted and shock treatment initiated.  
Adequate drinking water should be available during the therapeutic effect of the product.

- Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken to avoid accidental injection and contact with the skin.  
Wash hands after use.  
Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.

2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

3. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

**• Use during pregnancy, lactation or lay:**

The safety of the veterinary medicinal product has not been established in Horses, Cattle, Pigs, Dogs, Cats during pregnancy, lactation, lay or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

**• Interaction with other medicinal products and other forms of interaction:**

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

**• Overdose:**

No treatment specified

**10. Storage instructions:**

Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.

• Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.

• Storage conditions: Store below 25°C.

Protect from light.

• Crystallization of the product at low temperatures can be reversed by gentle warming.

• Do not freeze.

• Shelf-life after first opening the immediate packaging: 28 days. Remedies should be destroyed after 28 days.

**11. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

**12. FURTHER INFORMATION:**

In addition to the active ingredient the product also contains:

N-Methyl Pyrrolidone (51.50%w/v), Chlorocresol (0.1%w/v), Sodium Formaldehyde Sulfoxylate Dihydrate (0.1%w/v), Disodium Edetate Dihydrate, Sodium Hydroxide, Water for injection

**Pharmaceutical form:**

A sterile clear yellow aqueous solution.

Packed in 50 ml and 100 ml glass bottles.

Not all pack sizes may be marketed.

**Registration holder:** Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

**Manufacturer:** Norbrook Laboratories Ltd., Station Works, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

Revised in March 2024 according to MoH's guidelines.

Product registration number: 082-29-92285-00

يجب التأكيد من إعطاء كمية كافية من ماء الشرب للحيوانات خلال العلاج.

تحذيرات خاصة تتعلق بسلامة الشخص المعالج بالمستحضر.

يجب الخروج من المكان الذي يلمسه المستحضر عن طريق الخطأ، وأن

من ملامة المستحضر للدلال.

يجب غسل اليدين بعد الاستعمال.

السلفوناميدات قد تؤدي إلى حساسية لهذه المواد وقد تكون خطيرة.

فرط الصالحة للسلفوناميدات قد يؤدي إلى حساسية مصادية مع

مضادات حيوانية أخرى. أعراض حساسية لهذه المواد قد تكون خطيرة.

1. يمنع العلاج بالدواء إذا عرف وجود حساسية للسلفوناميدات.

2. إذا تطورت أعراض بعد التعرض للمستحضر، مثل تقطّع

جلدي، يجب الوجه إلى الطبيب المعالج بالسرع وفق ممك

وعرض هذه التغيرات على الطبيب.

3. أظهرت الأبحاث المخبرية التي أجريت على الأرانب

والجرذان وجود آلة على طرازها فيكتوكى (سم الحجين).

N-Methyl Pyrrolidone ينبع من الماء الغير فعال على النساء الحوامل والنساء التي تظن أنها حوامل أو النساء

في جيل الصالحة للسلفوناميدات.

وتحبب آخر جرعة منه بالخطأ.

**الحمل والإرضاع:**

لم يتم فحص سلامة المستحضر لاستخدامه بالحمل، الفرج،

الذرئ، الكلب، والقطط أثناء فترة الحمل الرضاعية، أو الولادة

أجريت على الأرانب والجرذان وجود آلة على طرازها فيكتوكى (سم الحجين)، ذلك يوجد الماء الغير فعال.

N-Methyl Pyrrolidone ينبع فقط بعد قيام الطبيب

البطري المعالج بأجراء تقييم المخاطر.

**تنافعات:**

يمنع الاستعمال لدى الحيوان الذي حصل لديها عدم انتظام في نظم

القلب نتيجة أمراضه. هذه الأضطرابات في نظم القلب قد تصل

نتيجة لأوربة مهدنة وتحثير معينة.

**فرط الصالحة:**

لا يوجد علاج محدد.

**10. تطبيقات المخزنين:**

تحذير! يحبذ حفظ هذا الدواء، وكل دواء آخر، في مكان

مغلق، بعيداً عن متناول اليد ومحظوظة الأولاد وأي الأطفال.

ويمكن تخزين التسمم.

يمنع الستحمل هذا الدواء بعد تاريح انتهاء الصلاحية

تنسب إلى اليوم الأخير في نفس الشهر.

شروط التخزين: يجب خزن المستحضر بدرجة حرارة أقل من

25 درجة مئوية. يجب حفظه من الضوء.

في حالة حصول تكلّف في المستحضر بدرجة حرارة منخفضة،

يمكن تخزينه بطفّل.

يمنع التعبير.

بعد فتح المستحضر لأول مرة، يمكن استعماله حتى 28 يوماً

مرة.

**11. تعليمات بخصوص إعادة المستحضر/ بقايا المستحضر عند الانتهاء من الاستعمال:**

كل مستحضر بطريطي طبي لم يتم استعماله أو كل مادة ذات

الحصول عليها من استعمال بيطري طبي، يجب التخلص منها كفمامات، معنف رمي الدواء في نظام الصرف الصحي.

**12. معلومات إضافية:**

بالإضافة إلى المواد الغالقة، يحتوي الدواء أيضاً على:

N-Methyl Pyrrolidone (51.50%w/v), Chlorocresol (0.1%w/v), Sodium Formaldehyde Sulfoxylate Dihydrate (0.1%w/v), Disodium Eddate Dihydrate, Sodium Hydroxide, Water for injection

كيف يدور الدواء وماذا تحتوي العبوة: محلول مائي مغمّ ذات

صفات حتى اسفل.

أحجام العينات: قارورة زجاجية بحجم 50 مل و 100 مل.

صلب التسليط وغطاء:

كركمين مض، شلار تشنخ، 1 القن 97200

اسم المنتج وعنوانه:

Norbrook Laboratories Ltd.,  
Station Works, Newry, Co. Down, BT35 6JP,  
Northern Ireland, UK

تم تحرير هذه النشرة في آذار 2024 وفق تعليمات وزارة

الصحة.

رقم تسجيل الدواء في سجل الأدوية الرسمي في وزارة الصحة:

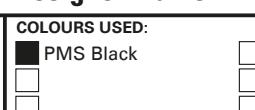
082-29-92285-00

5431

**Client Artwork Approval - Proof 4 - Norbrook Designer: Eamon McAllister (19/04/2024)**

Customer ..... Comex  
Country ..... Jerusalem  
Product ..... Norodine 24  
Volume ..... Insert  
Resource Code ..... (405)027472  
Revision Level ..... I07  
Pharma Code ..... 5431  
Size ..... A5  
Dimensions ..... 148 x 210mm  
Keyline (Die) Ref ..... Double-sided

**COLOURS USED:**



**PLEASE READ THIS IMPORTANT INFORMATION:** Please ensure this proof matches your artwork requirements. Please check all aspects of the proof i.e. text, fonts, spelling, colours, size, construction, copy position, barcodes, pharma codes, orientation of graphics etc. Mark clearly any amendments which you identify. Receiving the signed approval of this proof will authorise Norbrook Laboratories to proceed with your order. Norbrook Laboratories will not be liable for the costs of an order produced where any amendments required were not identified on the signed proof. Please return the signed approval at your earliest convenience to enable us to proceed with the order and meet your requested delivery date.

**Norbrook®**  
Artwork Department

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**CUSTOMER APPROVAL (PLEASE SIGN)**

**Signature:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

10/04/24 Proof1: As per revised literature provided by customer on 02/04/2024

15/04/24 Proof2: As per corrections from customer on email 11/04/2024

18/04/24 Proof3: Arabic: revisit the highlighted words (section 9, top right column); Hebrew: underline sub-heading in section 3

19/04/24 Proof4: Eng: section 3, underline "Therapeutic Group"; Heb: section 3, remove unnecessary space