PACKAGE LEALFET: INFORMATION FOR THE USER

IRUXOL® MONO 1.2 U/g OINTMENT
Clostridiopeptidase A

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, please ask your doctor or pharmacist.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What IRUXOL® Mono is and what it is used for
IRUXOL® Mono ointment contains clostridiopeptidase (a collagenase enzyme) and protease enzymes. Each gram of ointment contains not less than 1.2 units of Clostridiopeptidase A and not less than 0.24 units of associated proteases as active ingredients. These enzymes can be used to remove dead tissue (debride) from wounds such as leg ulcers, diabetic ulcers and pressure sores. By removing the dead tissue, IRUXOL® Mono ointment cleanses the wound and speeds up wound healing.

2. Before you use IRUXOL® Mono
Do not use IRUXOL® Mono ointment if you are allergic to protease enzymes or any of the other ingredients of this medicine (listed in section 6).

Take special care with IRUXOL® Mono ointment if:
• you are diabetic and have been told that the wound contains dry gangrenous material.

If you are using other medicines please see following section.

Using other medicines
IRUXOL® Mono ointment should **not** be used if you are applying other products to the wound that may interfere with the medicine such as:
• antiseptics

• antibiotics (tyrothricin, gramicidin and tetracyclines)
• heavy metals
• detergents
• soaps
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using IRUXOL® Mono with food and drink
There are no known effects of food or drink with IRUXOL® Mono.

Pregnancy and breast-feeding
Do not use IRUXOL® Mono ointment if you know, or think you may be, **less than** three months pregnant, unless the doctor has told you to.
The ointment is safe to use if you are more than three months pregnant and while breast-feeding.
Ask your doctor or pharmacist for advice before taking or using any medicines.

Driving and using machinery
IRUXOL® Mono is unlikely to affect driving or the use of machines.

3. How to use IRUXOL®Mono

Always use IRUXOL® Mono exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Only apply this medicine to the skin. You should **avoid** contact with the eyes and the mouth.

To ensure the medicine works successfully IRUXOL® Mono must be applied to a moist wound.
• If the wound is dry or becomes dry, it should be moistened with a salt solution (or similar) before applying the ointment.
• Dry or hard crusts should be softened using a moist dressing.

Apply approximately a 2mm layer of IRUXOL® Mono ointment either to a dressing or directly to the wound. Ensure the ointment is in close contact with the wound surface. This should normally be done once a day. On occasions a twice daily application will be recommended.

Treatment should be discontinued when the whole surface of the wound is cleaned.

If there is no improvement to your wound after 14 days of treatment, contact your doctor, nurse or pharmacist.

If you use more IRUXOL® Mono than you should or if you swallow IRUXOL® Mono
• Should the medicine be accidently swallowed you should contact your doctor or local hospital emergency department **immediately**.
• There is no danger if too much IRUXOL® Mono is applied to your wound but there is no increased effect if you apply more than the recommended amount.

4. Possible side effects

The components of IRUXOL® Mono are paraffin waxes and the active enzyme, none of which are absorbed by the body. Local allergy can occur, such as local pain or rash (contact dermatitis). If this becomes problematic, or you feel unwell while using IRUXOL® Mono ointment, discontinue use and consult your doctor or nurse. Like all medicines, IRUXOL® Mono can cause side effects, although not everyone gets them. You may experience the following side effects when using this medicine:
• pain at the site of the wound.
• local skin reactions such as rash, reddening, itching and burning.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store IRUXOL® Mono

• Keep out of the reach and sight of children.
• IRUXOL® Mono should be stored below 25°C.
• **Do not** use your medicine after the expiry date which embossed on the end of the carton and on the tube. The expiry date refers to the last day of that month.
• Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What IRUXOL® Mono contains
The active substances are clostridiopeptidase 1.2U and not less than 0.24U associated proteases. The other ingredients are liquid paraffin and white soft paraffin.

What IRUXOL® Mono looks like and the contents of the pack
IRUXOL® Mono is a brown ointment with a faint odour. It is available in 10g and 20g aluminium tubes. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Smith & Nephew GmbH
Friesenweg 30
22763 Hamburg
Germany

Manufacturer
Nordmark Pharma GmbH
25436 Uetersen
Germany

This leaflet was last revised June 2022.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Iruxol Mono 1.2 U/g ointment
clostridiopeptidase A

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram of ointment contains not less than 1.2 unts of clostridiopeptidase A and not less than 0.24 units of associated proteases. Also contains liquid paraffin and white soft paraffin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Ointment
1 x 20g tube

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration.
Directions: See insert leaflet.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 25°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PA Holder:
Smith and Nephew GmbH,
Friesenweg 30,
22763 Hamburg, Germany

12. MARKETING AUTHORISATION NUMBER(S)

PA22696/001/001

13. BATCH NUMBER

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use only if carton seal is unbroken

16. INFORMATION IN BRAILLE

Iruxol Mono 1.2 U/g ointment

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC {number} [product code]
SN {number} [serial number]
NN {number} [national reimbursement number or other national number identifying the medicinal product]>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

TUBE

1. NAME OF THE MEDICINAL PRODUCT

Iruxol Mono 1.2 U/g ointment
clostridiopeptidase A
For enzymatic wound debridement

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram of ointment contains not less than 1.2 unts of clostridiopeptidase A and not less than 0.24 units of associated proteases. Also contains liquid paraffin and white soft paraffin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Ointment
1 x 20g tube

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For topical administration.
Directions: See insert leaflet.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 25°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

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2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC {number} [product code]
SN {number} [serial number]
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