



Saving lives and money

Why translation matters in healthcare

Translation in
healthcare & the pharmaceutical sector

Leticia Arcos Álvarez
7 November 2019



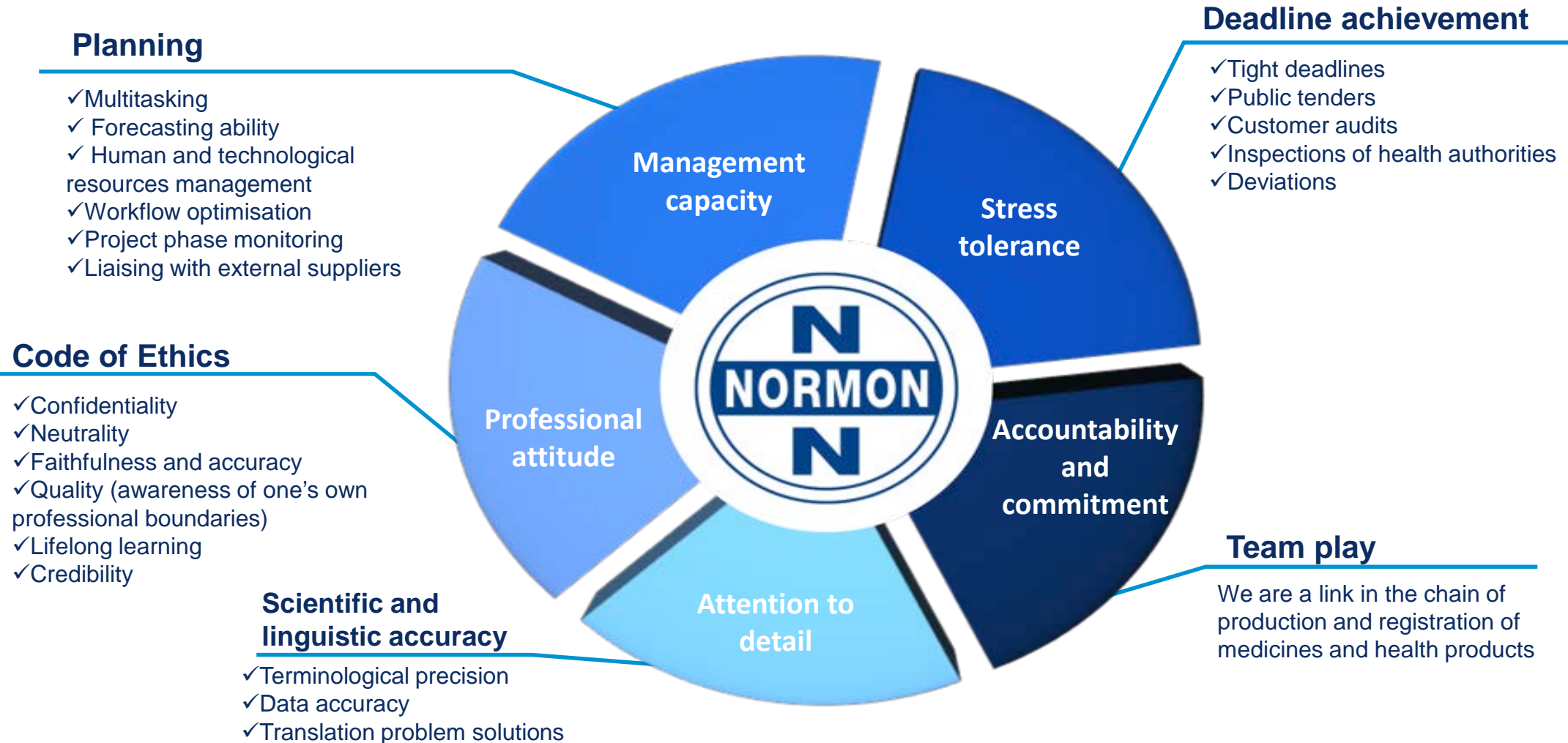




INTERNATIONAL



- ✓ BUSINESS AGREEMENTS WITH COMPANIES IN MORE THAN 90 COUNTRIES IN 5 CONTINENTS
- ✓ INTERNATIONALISATION OF NORMON BOTH AS A HOLDER AND AS A MANUFACTURER FOR THIRD PARTIES AND LICENCES FOR OTHER COMPANIES



Working languages

- ✓ English
- ✓ Spanish
- ✓ French
- ✓ Arabic
- ✓ German
- ✓ Portuguese
- ✓ Italian
- ✓ Russian
- ✓ Hungarian
- ✓ Thai
- ✓ Czech
- ✓ Danish
- ✓ Chinese

Departments supported

- ✓ Regulatory Affairs
- ✓ FDA
- ✓ Quality Assurance
- ✓ Quality Control
- ✓ Medical Devices
- ✓ Drug Safety
- ✓ Marketing
- ✓ Microbiology
- ✓ Analytical Technical Services
- ✓ Manufacturing Plant Technical Services
- ✓ Product Technical Operations
- ✓ Dental Division
- ✓ International Sales
- ✓ Legal Affairs

Text genres

- ✓ Package Leaflets
- ✓ Summary of Product Characteristics
- ✓ Labelling
- ✓ Analytical methods
- ✓ Clinical trials
- ✓ Bioequivalence studies
- ✓ Patient Leaflet Readability Tests
- ✓ Stability Reports
- ✓ Validation Studies
- ✓ Calibration Tests
- ✓ Equipment Qualifications and Cleaning Procedures
- ✓ Manufacturing Process Deviations
- ✓ Marketing Authorisations
- ✓ Manufacturing Guides
- ✓ Brochures and Advertising campaigns
- ✓ Legal agreements and certificates

Translation request

- ✓ **Any Department requests a translation assignment.**
- ✓ The Translation Supervisor **assesses the language combination, text genre, project volume, project tasks, deadline desired and availability** of in-house human resources.
- ✓ The requesting Departments are **asked** for any **reference documentation**.

Project implementation

- ✓ **If** the project can be implemented **in-house**, the Translation Supervisor **assigns translation and reviewing tasks** to be carried out **in-house with SDL Trados Studio 2019 and SDL MultiTerm**. **If** documents are scanned (i.e. **non-editable**), **Administrative Officers** take part to transcribe and **get documentation ready**.
- ✓ **If** the project needs to be **outsourced**, the Translation Supervisor **requests a quotation to a LSP**.
- ✓ All **files** are **sent and received on a SDL Trados Studio project/return package workflow** regardless of whether they are assigned to in-house members or to outsourced LSPs.
- ✓ **Conceptual doubts** are gathered and **rendered to** each **Department concerned**.

Project delivery

- ✓ The Translation Supervisor receives the **return package** within enough time for a **QA before delivery**.
- ✓ **Target texts** are **exported** and a **2nd QA** is **performed** on the target documentation as is.
- ✓ **Target documents** are **delivered** to each Department concerned within time.
- ✓ **Feedback** on terminology, phraseology, customer individual preferences, etc. is **collected and processed** through glossaries, Translation Memory changes, DBs, etc. for further projects.

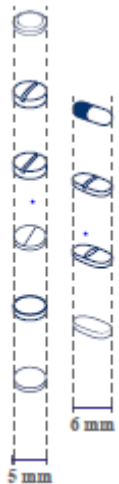
Patient Information Leaflets

- ✓ Accuracy and suitability are validated thanks to **readability tests** conducted on a mixed population sample concerning age, gender and academic background ([Directive 2004/27/EC](#) and [Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use](#)).
E.g. Readability test of Anidulafungin Normon 100 mg powder for concentrate for solution for infusion.
- ✓ Compliance with **QRD templates** provided in all EEA languages on the [EMA Website](#) for the labelling and package leaflet of medicinal products according to Directive 2001/83/EC.
- ✓ **Terminology** consistency and **standardisation** to render accuracy and neutrality throughout texts. Use of [MedDRA dictionary](#) (Medical Dictionary for Regulatory Activities, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)) and of the [Standard Terms Database](#), (drawn up in response to a request from the European Commission and built in compliance with ISO 11239:2012, ISO/TS 20440:2016 and ISO 11239).
- ✓ **Bilingual Patient Information Leaflets**, e.g. EN-TH; EN-AR and FR-AR.

Drug product packages

Braille information on product name, dosage and pharmaceutical form ([Art. 56a Directive 2004/27/EC](#)).

Intersemiotic translation: pictures reflecting pharmaceutical form, warning on excipients and packaging information. ([Art. 62 Directive 2001/83/EC](#))

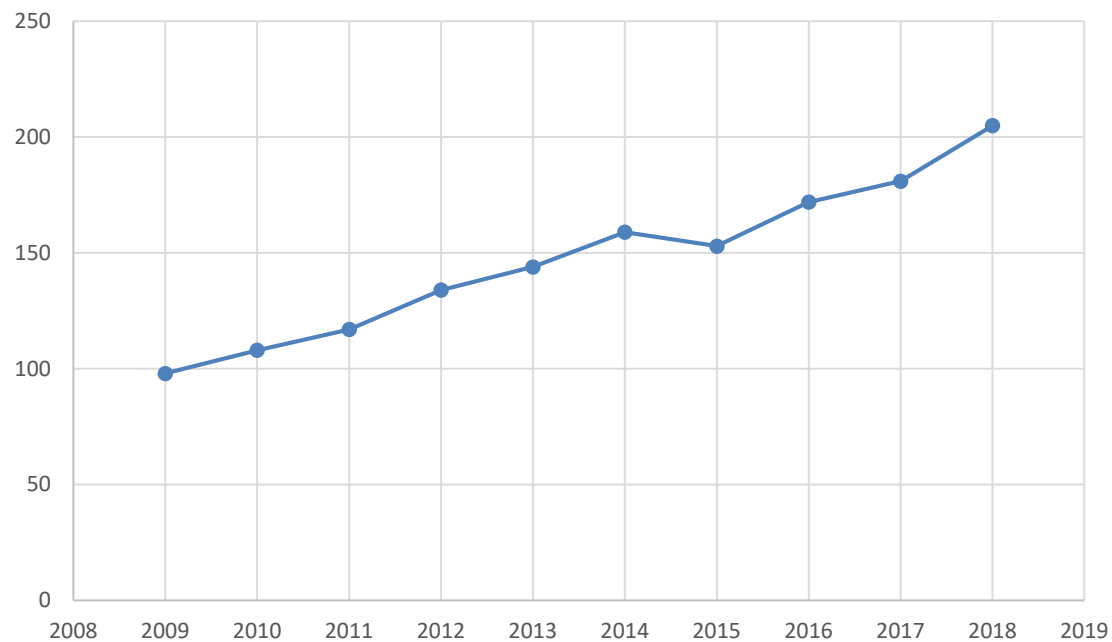


Bilingual drug product packages, e.g. FR-AR, EN-ZH and EN-AR.

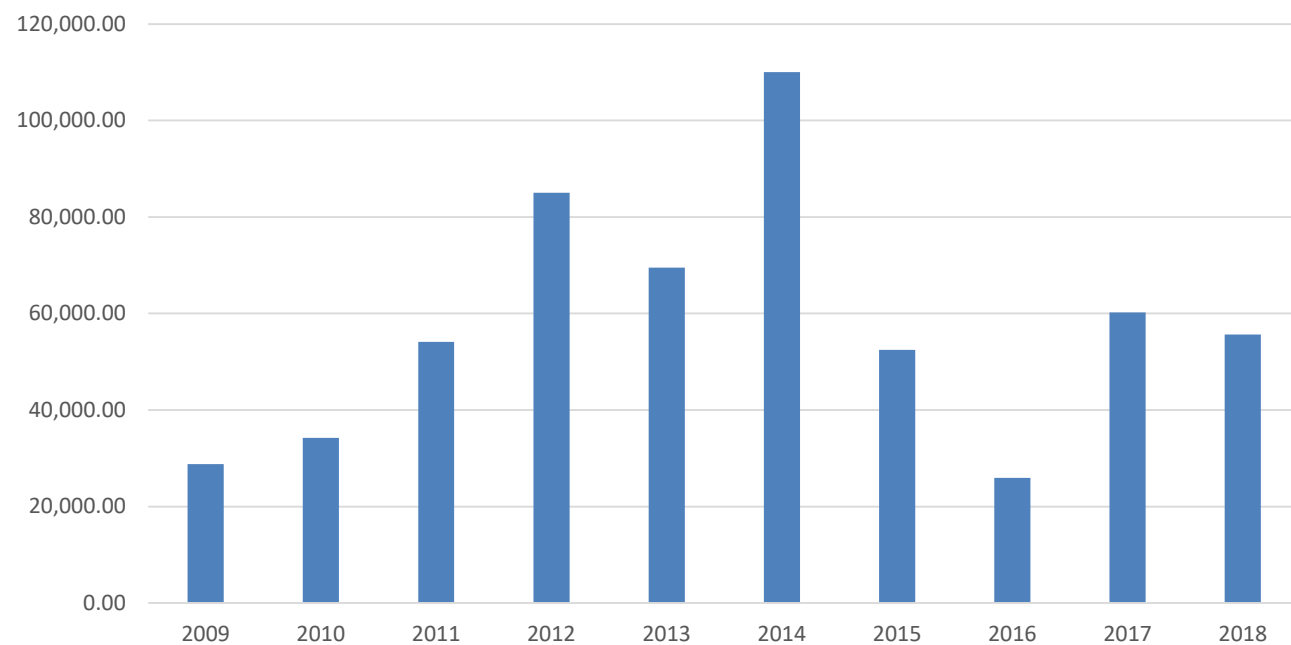
Colour consistency depending on the Therapeutic Area of the medicinal product for easy recognition.



Million Units manufactured



Total EUR of Outsourced Translation



- ✓ Vocation development
- ✓ Extremely enriching profession
- ✓ Much of our professional success depends on the enthusiasm with which one works



**Translation is like...
a generic drug product!**

- Both are based on a reference product
- Both are client-oriented in the target culture
- Both meet the same quality standards as their respective reference products
- The ultimate goal of both is globalisation either of knowledge & information or of healthcare access and medical therapy



Thank you very much for your attention!

Leticia Arcos Álvarez

Translation Supervisor

Regulatory Affairs Department

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www.normon.es

Bonus content: Readability Test of Anidulafungin NORMON 40mg powder for solution for injection/infusion

2.- Inclusion criteria:

- Participants of both genres (men or women).
- Be over 18 years of age.
- Appropriate cultural level and understanding of the clinical study.
- Agree to participate voluntarily in the study and who give their written informed consent.
- Be able to read and speak Spanish as if it were their mother tongue.
- Not have training in medicine or health sciences (doctors, nurses, pharmacists, health personnel in general...).
- Not have participated in this type of tests in the last 6 months.

Conduct of the test

Phases	Estimate time
1. First revision of the package leaflet	0.5 weeks
2. Preparation of the questionnaire and answer sheet and sending to the sponsor for approval	0.5 week
4. Recruitment of subjects	throughout the study
5. Pilot interviews with 4 subjects. Report and proposal for changes depending on findings	0.5 weeks
6. First group of interviews with 10 subjects. Analysis and evaluation.	1 week
7. Second group of interviews with 10 subjects. Analysis and evaluation.	1 week
8. Final report	1 week
TOTAL 4-5 weeks	

5.1. READING TEST: QUESTIONNAIRE AND EVALUATION

Anidulafungin Normon 100 mg powder for concentrate for solution for infusion (generic).

The evaluation of the replies to each of the reading-test questions, which appear below, is carried out by assessment of the following points:

- 1.- Capacity to locate the response in the leaflet.
- 2.- Capacity to understand the answer which appears in the package leaflet and put it in their own words.

The replies to the reading test for **Anidulafungin Normon 100 mg powder for concentrate for solution for infusion (generic)**, will be considered correct when they coincide or are like those given below:

1.- Is Anidulafungin Normon indicated to treat a type of fungal infection of the blood or other internal organs called invasive candidiasis?

Part 1

R: Yes, it is indicated for the treatment of this type of infection.

2.- Can Anidulafungin Normon be taken by persons who are allergic to Anidulafungin or any of the other ingredients of this medicine?

Part 2

R: No, they cannot take it.

OVERALL CONCLUSIONS

After conducting the readability test of the package leaflet for the medication "**Anidulafungin Normon 100 mg powder for concentrate for solution for infusion (generic)**", the following conclusions were drawn:

1. Regarding part A of the test (location), all the questions meet the acceptance criteria, since they were correctly interpreted by at least 95% of the volunteers.
2. Regarding part B of the test (capacity to understand), all the questions meet the acceptance criteria, since they were also correctly interpreted by at least 95% of the volunteers.
3. In conclusion, the tested package leaflet meets the readability requirements of the European Union contained in the document "Guideline on the readability of the label and package leaflet of medicinal products for human use". **Revision 1. 12 January 2009**

Bonus content: EN-TH Patient Information Leaflet of Esomeprazole NORMON 40mg powder for solution for injection/infusion

เอกสารกำกับยาภาษาอังกฤษ

1. NAME OF THE MEDICINAL PRODUCT

Esomeprazole NORMON 40 mg Powder for solution for injection/infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains esomeprazole 40 mg (as sodium salt).

Excipients with known effect:

Each vial contains 3.28 mg sodium approximately.

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. essentially "sodium-free"

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for injection/infusion

White to off-white porous powder

Tabulated list of adverse reactions

The following adverse drug reactions have been identified or suspected in the clinical trials programme for esomeprazole administered orally or intravenously and post-marketing when administered orally. The reactions are classified according to frequency: very common >1/10; common >1/100 to <1/10; uncommon >1/1,000 to <1/100; rare >1/10,000 to <1/1,000; very rare <1/10,000; not known (cannot be estimated from the available data).

System Organ Class	Frequency	Undesirable Effect
Blood and lymphatic system disorders	Rare	Leukopenia, thrombocytopenia
	Very rare	Agranulocytosis, pancytopenia
Immune system disorders	Rare	Hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock
	Uncommon	Peripheral oedema

อีโซเมปราโซล

ความแรง 40 มิลลิกรัม

ชนิด ยาผงสำหรับเตรียมสารละลายเพื่อฉีดหรือหยดเข้าหลอดเลือด

Esomeprazole NORMON

(อีโซเมปราโซล นอมอน)

1. ยานี้คืออะไร

1.1 ยานี้มีชื่อสามัญว่าอะไร

- ยานี้มีชื่อสามัญว่าอีโซเมปราโซลโซเดียม (esomeprazole sodium) เป็นยาลดกรดในกระเพาะอาหาร กลุ่ม proton pump inhibitor

1.2 ยานี้ใช้เพื่ออะไร

ยานี้ใช้เพื่อยับยั้งการหลั่งกรดในกระเพาะอาหารเมื่อผู้ป่วยไม่สามารถกินยาได้ เช่น

- รักษาอาการกรดไหลย้อน
- รักษาแผลในกระเพาะอาหารจากการใช้ยากลุ่ม NSAID
- ป้องกันการเกิดแผลในกระเพาะอาหารและลำไส้เล็กส่วนต้นจากการใช้ยากลุ่ม NSAID ในผู้ป่วยกลุ่มเสี่ยง
- ใช้ป้องกันเลือดออกซ้ำของแผลในกระเพาะอาหารและลำไส้เล็กส่วนต้นหลังการส่องกล้อง

Bonus content: EN-AR Patient Information Leaflet of Cefotaxime NORMON 250mg powder and solvent for injectable solution IV

LEAFLET

Read this leaflet carefully before using the medicine.

Keep this leaflet. You may need to read it again.

If you have any question, consult your doctor or pharmacist.

This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.

This leaflet contains:

1. WHAT CEFOTAXIME NORMON POWDER AND SOLVENT FOR INJECTABLE SOLUTION IS AND WHAT IT IS USED FOR
2. BEFORE USING CEFOTAXIME NORMON POWDER AND SOLVENT FOR INJECTABLE SOLUTION
3. HOW TO USE CEFOTAXIME NORMON POWDER AND SOLVENT FOR INJECTABLE SOLUTION
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE CEFOTAXIME NORMON POWDER AND SOLVENT FOR INJECTABLE SOLUTION
6. HANDLING DIRECTIONS FOR THE SANITARY PROFESSIONAL

CEFOTAXIME NORMON 250 mg

POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV

CEFOTAXIME NORMON 500 mg

POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV/IM

CEFOTAXIME NORMON 1 g

POWDER AND SOLVENT FOR INJECTABLE SOLUTION IM

CEFOTAXIME NORMON 1 g

POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV

CEFOTAXIME NORMON 2 g

POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV

The drug substance in the vial is cefotaxime.

CEFOTAXIME NORMON 250 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV: Each vial contains 250 mg of cefotaxime (I.N.N) (sodium). Each ampoule contains 2 ml of water for injection.

CEFOTAXIME NORMON 500 mg POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV/IM: Each vial contains 500 mg of cefotaxime (I.N.N) (sodium). Each ampoule contains 10 ml of water for injection.

CEFOTAXIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION IM: Each vial contains 1 g of cefotaxime (I.N.N) (sodium). The drug substance in the ampoule is lidocaine. Each ampoule contains 40 mg of lidocaine (I.N.N.) hydrochloride and water for injection in q.s. for 4 ml.

CEFOTAXIME NORMON 1 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV: Each vial contains 1 g of cefotaxime (I.N.N) (sodium). Each ampoule contains 10 ml of water for injection.

CEFOTAXIME NORMON 2 g POWDER AND SOLVENT FOR INJECTABLE SOLUTION IV: Each vial contains 2 g of cefotaxime (I.N.N) (sodium). Each ampoule contains 10 ml of water for injection.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 - 28760 MADRID, SPAIN

النشرة الداخلية

الرجاء قراءة النشرة الداخلية بعناية قبل استخدام الدواء.

- احتفظ بالنشرة الداخلية , قد تحتاج الى قرائتها مرة أخرى.

- اذا كان لديك اي استفسار , استشر الطبيب او الصيدلاني .

- تم وصف هذا الدواء خصيصا لك يجب ان لا تعطيه لشخص اخر . هذا قد يسبب الضرر لهم , حتى لو كان يعاني من نفس الاعراض .

تحتوي هذه النشرة على :

- ما هو سيفوتاكسيم نورمون باودر ومذيب لمحلول الحقن و ما استخداماته
- قبل استخدام سيفوتاكسيم نورمون باودر ومذيب لمحلول الحقن
- كيفية استخدام سيفوتاكسيم نورمون باودر ومذيب لمحلول الحقن
- الاعراض الجانبية المحتملة
- طرق تخزين سيفوتاكسيم نورمون باودر ومذيب لمحلول الحقن
- معلومات الاستخدام للفريق الطبي

سيفوتاكسيم نورمون 250 ملغم باودر ومذيب لمحلول الحقن الوريدي

سيفوتاكسيم نورمون 500 ملغم باودر ومذيب لمحلول الحقن الوريدي\العضلي

سيفوتاكسيم نورمون 1 غم باودر ومذيب لمحلول الحقن العضلي

سيفوتاكسيم نورمون 1 غم باودر ومذيب لمحلول الحقن الوريدي

سيفوتاكسيم نورمون 2 غم باودر ومذيب لمحلول الحقن الوريدي

المادة الدوائية في الفبال هي سيفوتاكسيم.

سيفوتاكسيم نورمون 250 ملغم باودر ومذيب لمحلول الحقن الوريدي: كل فيال تحتوي على 250 ملغم من سيفوتاكسيم (اي.ن.ن) (صوديوم). كل امبولة تحتوي على 2 مل ماء معقم للحقن .

سيفوتاكسيم نورمون 500 ملغم باودر ومذيب لمحلول الحقن الوريدي\العضلي: كل فيال تحتوي على 500 ملغم من سيفوتاكسيم (اي.ن.ن) (صوديوم). كل امبولة تحتوي على 10 مل ماء معقم للحقن .

سيفوتاكسيم نورمون 1 غم باودر ومذيب لمحلول الحقن العضلي : كل فيال تحتوي على 1 غم من سيفوتاكسيم (اي.ن.ن) (صوديوم). المادة الدوائية في الامبولة هي ليدوكاين . كل امبولة تحتوي على 40 ملغم من الليدوكاين (اي.ن.ن) هايدروكلوريد وماء معقم للحقن بكمية كافية ل 4 مل.

سيفوتاكسيم نورمون 1 غم باودر ومذيب لمحلول الحقن الوريدي: كل فيال تحتوي على 1 غم من سيفوتاكسيم (اي.ن.ن) (صوديوم). كل امبولة تحتوي على 10 مل ماء معقم للحقن .

سيفوتاكسيم نورمون 2 غم باودر ومذيب لمحلول الحقن الوريدي: كل فيال تحتوي على 2 غم من سيفوتاكسيم (اي.ن.ن) (صوديوم). كل امبولة تحتوي على 10 مل ماء معقم للحقن .

حامل ترخيص التسويق والشركة المصنعة

LABRATORIOS NORMON, S.A.

Ronda de valdecarrizo, 6 - 28760 Tres Cantos – Madrid (Spain)

Bonus content: FR-AR Patient Information Leaflet of OMEPRAZOLE NORMON® 40mg lyophilisat pour perfusion intraveineuse

NOTICE: INFORMATION POUR L'UTILISATEUR

Dénomination du médicament

OMEPRAZOLE NORMON® 40 mg, lyophilisat pour perfusion intraveineuse

Boîte de 1 flacon. Boîte de 50 flacons.

DCI : Oméprazole

Veuillez lire attentivement l'intégralité de cette notice avant de prendre ce médicament car elle contient des informations importantes pour vous.

- Gardez cette notice, vous pourriez avoir besoin de la relire.
- Si vous avez d'autres questions, demandez plus d'information à votre médecin ou à votre pharmacien.
- Ce médicament vous a été personnellement prescrit. Ne le donnez pas à d'autres personnes. Il pourrait leur être nocif, même si les signes de leur maladie sont identiques aux vôtres.
- Si l'un des effets indésirables devient grave ou si vous remarquez un effet indésirable non mentionné dans cette notice, parlez-en à votre médecin ou à votre pharmacien.

Que contient cette notice:

Effets indésirables peu fréquents

- Gonflement des pieds et des chevilles.
- Troubles du sommeil (insomnie).
- Etourdissement, fourmillements, somnolence.
- Vertiges.
- Modifications des résultats du test sanguin contrôlant le fonctionnement de votre foie.
- Eruptions cutanées, urticaire et démangeaisons de la peau.
- Malaise général et manque d'énergie.

Effets indésirables rares

- Troubles sanguins tels qu'une diminution du nombre de globules blancs ou des plaquettes. Ces effets peuvent provoquer une faiblesse, des ecchymoses ou faciliter la survenue d'infections.

أوميبرازول نورمون 40 مغ. مجفد للتسريب في الوريد علبة من 1 قنينة و علبة من 50 قنينة

تسمية عالمية مشتركة: أوميبرازول

الأعراض الجانبية الأخرى هي:

- أعراض جانبية متكررة:

- آلام الرأس.
- تأثير على المعدة و المعى: إسهال, آلام المعدة, قبض انتفاخ.
- غثيان, قيئ.
- سلبية حميدة على مستوى المعدة.
- أعراض جانبية قليلة التردد:
- انتفاخ الأرجل و الكاحل.
- اضطراب النوم (أرق).
- دوار, تنمل, نعاس.
- دوخة.

- تغيرات في نتائج فحوصات الدم المراقبة لوظيفة الكبد.
- طفح جلدي شدي و حكة على الجلد.
- تعب عام و فقدان الطاقة.
- أعراض جانبية نادرة:

الرجاء قراءة هذه النشرة بعناية قبل اخذ هذا الدواء, لأنه يحتوي على معلومات هامة من أجلك :

- حافظ على هذه النشرة, قد تحتاج للاطلاع عليها مرة أخرى.
- إذا كان لديك أي أسئلة أخرى, أو أي شك, اطلب المزيد من المعلومات من الطبيب أو من الصيدلي.
- هذا الدواء تم وصفه إليك شخصيا. لا تناوله شخصا آخر أبدا و لو في وجود أعراض مماثلة, قد يضره ذلك.
- في حالة تفاقم بعض الأعراض الجانبية أو إذا لاحظت أثرا جانبيا غير مدرج في هذه النشرة, اطلع الطبيب أو الصيدلي عليه.

على ماذا تحتوي هذه النشرة :

1. ما هو أوميبرازول نورمون 40 مغ. مجفد للتسريب في الوريد وفي أي الحالات يجب استعماله؟

**Bonus content: FR-AR Drug product package of Exemestane NORMON
25mg comprimés pelliculés**



Bonus content: EN-ZH Drug product package of Cisatracurium NORMON 2mg/ml solution for injection and for infusion



Bonus content: EN-AR Drug product package of Exemestane NORMON 25mg film-coated tablets

