Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Decentralised Procedure

Cefazolin 1g Powder for solution for injection/infusion

Cefazolin 2g Powder for solution for injection/infusion

(cefazolin sodium)

Procedure No: UK/H/6690/001-002/DC

UK Licence No: PL 24598/0053-0054

Noridem Enterprises Limited.

LAY SUMMARY

Cefazolin 1g Powder for solution for injection/infusion
Cefazolin 2g Powder for solution for injection/infusion

(cefazolin sodium)

This is a summary of the Public Assessment Report (PAR) for Cefazolin 1g Powder for solution for injection/infusion (PL 24589/0053; UK/H/6690/001/DC) and Cefazolin 2g Powder for solution for injection/infusion (PL 24589/0054; UK/H/6690/002/DC).

It explains how the applications for Cefazolin 1g and 2g Powder for solution for injection/infusion were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Cefazolin 1g and 2g Powder for solution for injection/infusion.

The products may be collectively referred to as 'Cefazolin Powder for solution for injection/infusion' throughout the remainder of this public assessment report (PAR).

For practical information about using Cefazolin Powder for solution for injection/infusion, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cefazolin Powder for solution for injection/infusion and what is it used for?
Cefazolin 1g Powder for solution for injection/infusion is a 'generic medicine'. This means that Cefazolin 1g Powder for solution for injection/infusion is similar to a 'reference medicine' already authorised in the European Union (EU) called Vifazolin 1g Powder for solution for injection (Vianex SA, approved in Greece under 42001/07/6-6-08).

Cefazolin 2g Powder for solution for injection/infusion is a 'hybrid generic medicine'. This means that it is similar to a reference medicine containing the same active substance but is available at a different strength (Vifazolin 1g Powder for solution for injection instead of 2g powder for solution/infusion).

The company has provided additional own data to demonstrate the safety and efficacy of Cefazolin 2g Powder for solution for injection/infusion regarding this difference from the reference medicine.

Cefazolin Powder for solution for injection/infusion is used to treat bacterial infections caused by cefazolin-susceptible bacteria, e.g.:
• Infections of skin and soft tissue
• Infections of bones and joints

Cefazolin can also be used before, during and after surgery to prevent possible infections.

How do Cefazolin Powder for solution for injection/infusion work?
This medicine contains the active substance, cefazolin (as cefazolin sodium**),** which is an antibiotic, belonging to a group of medicines called cephalosporins. Cefazolin works by killing bacteria that cause infections.

How is Cefazolin Powder for solution for injection/infusion used?
The pharmaceutical form of this medicine is a powder for solution for injection or infusion. It will be given as an injection or infusion (into a vein) after being dissolved, or into a muscle (intramuscularly) as a deep intramuscular injection. The doctor will inform you about the necessary duration and frequency of administration of Cefazolin Powder for solution for injection/infusion.

The recommended doses are:
Adult patients with normal kidney function
• Infections caused by bacteria susceptible to this medicine:
1 – 2 g daily, divided into 2 – 3 doses.
• Infections caused by bacteria less susceptible to this medicine:
3 – 4 g daily, divided into 3 – 4 doses.
An increase of the daily dose up to 6 g in three or four equal doses is

possible.

Use in children and adolescents
Prematures and infants below the age of one month:
The safety in infants below the age of one month has not been determined.

Children over the age of one month:
• Infections caused by bacteria susceptible to this medicine:
25 – 50 mg / kg body weight / day divided in 2 – 4 single doses, every 6, 8 or 12 hours.
• Infections caused by bacteria less susceptible to this medicine:
Up to 100 mg /kg body weight/day divided in 3 – 4 single doses, every 6 – 8 hours.

This product is not recommended for children under 1 month of life.

Elderly patients
No dosage adjustment is required for elderly patients with normal renal function.

Special dosage recommendations
Prevention of infections during surgical procedures 1 g cefazolin 30 - 60 minutes before surgery.
In case of long surgical procedures (2 hours or more), additional 0.5 g - 1 g cefazolin during the operation.
Patients with impaired kidney function
In patients with impairment of the kidney function, the elimination of cefazolin is slower. For this reason, the doctor will adjust the dosage according to the severity of the kidney impairment by reducing the maintenance dose or prolongation of the dosage intervals.

Duration of treatment
The treatment duration depends on the severity of the infection as well as on the patient's recovery from their illness.

Section 3 of the package leaflet can be consulted for detailed information on dosing recommendations, the route of administration and the duration of treatment.

This medicine can only be obtained with a prescription.

What benefits of Cefazolin Powder for solution for injection/infusion have been shown in studies?

No additional clinical studies were needed as Cefazolin Powder for solution for injection/infusion is a generic/hybrid medicine considered to be therapeutically equivalent to the reference medicinal product; Vifazolin 1g Powder for solution for injection (Vianex SA, Greece), that is an aqueous solution that is given by injection or infusion and contains the same active as the reference medicine; Vifazolin 1g Powder for solution for injection. Therefore, the benefits and risks are taken as being the same as those of the reference medicine

What are the possible side effects of Cefazolin Powder for solution for injection/infusion?

Because Cefazolin Powder for solution for injection/infusion is either generic or hybrid generic medicines that are considered therapeutically equivalent to the reference medicinal product; Vifazolin 1g Powder for solution for injection (Vianex SA, Greece), the possible side effects are taken as being the same as those of the reference medicine.

For the full list of all side effects reported with Cefazolin Powder for solution for injection/infusion, section 4 of the package leaflet can be consulted.

For the full list of restrictions, see the package leaflet.

Why is Cefazolin Powder for solution for injection/infusion approved?

It was concluded that, in accordance with EU requirements, Cefazolin Powder for solution for injection/infusion has been shown to have comparable quality and to be therapeutically equivalent to

Vifazolin 1g Powder for solution for injection (Vianex SA, Greece)Therefore, the MHRA decided, as for Vifazolin 1g Powder for solution for injection (Vianex SA, Greece) that the benefits of Cefazolin Powder for solution for injection/infusion is greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Cefazolin Powder for solution for injection/infusion?

A Risk Management Plan has been developed to ensure that Cefazolin Powder for solution for injection/infusion is used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPC) and the package leaflet for Cefazolin Powder for solution for injection/infusion, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Cefazolin Powder for solution for injection/infusion

The UK, Belgium, Cyprus, The Czech Republic, France, Germany, Poland and Slovakia agreed to grant Marketing Authorisations for Cefazolin Powder for solution for injection/infusion on 11 November 2018. Marketing Authorisations were granted in the UK to Noridem Enterprises Limited on 10 December 2018.

The full PAR for Cefazolin Powder for solution for injection/infusion follows this summary.

For more information about treatment with Cefazolin Powder for solution for injection/infusion, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in January 2019.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Member States considered that the applications for Cefazolin 1g Powder for solution for injection/infusion (PL 24589/0053; UK/H/6690/001/DC) and Cefazolin 2g Powder for solution for injection/infusion (PL 24589/0054; UK/H/6690/002/DC) could be approved. Cefazolin Powder for solution for injection/infusion is a prescription Only Medicine (POM) indicated for the treatment
the treatment of the following infections caused by cefazolin-susceptible micro-organisms:

- skin and soft tissue infections
- bone and joint infections.

Perioperative prophylaxis. For surgical operations with increased risk of infections with anaerobic pathogens, e.g. colorectal surgery, a combination with an appropriate drug with activity against anaerobes is recommended.

The use of cefazolin should be limited to cases where parenteral treatment is needed.
Susceptibility of causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

These applications were submitted using the Decentralised Procedure (DCP), with the UK as a Reference Member State (RMS) and Belgium, Cyprus, The Czech Republic, France, Germany, Poland and Slovakia as Concerned Member States (CMS). The application for Cefazolin 1g Powder for solution for injection/infusion was submitted under Article 10(1) of Directive 2001/83/EC, as amended, as a generic application. The application for Cefazolin 2g Powder for solution for injection/infusion was submitted under Article 10(3) of Directive 2001/83/EC, as amended, as a hybrid application. The reference medicinal product for these applications is Vifazolin 1g Powder for solution for injection approved in Greece to the Marketing Authorisation Holder (MAH) Vianex SA (42001/07/6-6-08) since 04 February 1998, originally approved in 1978.

The active substance in Cefazolin 2g Powder for solution for injection/infusion, cefazolin (as cefazolin sodium) is a bactericidal cephalosporin antibiotic of the first generation for parenteral administration. Cephalosporins inhibit cell wall synthesis (in the growth stage) through blocking the penicillin-binding proteins (PBPs) like transpeptidases. The outcome is a bactericidal action.

Resistance to cefazolin can rest upon one of the following mechanisms:
- Inactivation by beta-lactamases: cefazolin has a high stability against penicillinases of gram-positive bacteria, but only a low stability against plasmid-coded beta-lactamases, e.g. extended-spectrum beta-lactamases or chromosomal-coded beta-lactamases of AmpC-type.
- Reduced affinity of the PBPs to cefazolin: the acquired resistance of pneumococci and other streptococci is caused by modifications of the PBPs due to mutations. The resistance of methicillin (oxacillin)-resistant Staphylococci is due to the formation of an additional PBP with a lower affinity to cefazolin.
- Insufficient penetration of cefazolin through the outer cell wall of gram-negative bacteria can lead to an insufficient inhibition of the PBPs.
- Cefazolin can be transported outside the cell through efflux pumps.

There is a partial or total cross-resistance of cefazolin with other cephalosporins and penicillins.

Cefazolin is administered parenterally.

No new non-clinical studies were conducted, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been licensed for over 10 years.

No new clinical data have been submitted and none are required for applications of this type. Since this application concerns a generic version of cefazolin, with essential similarity to the reference product, and is intended for parenteral use, a bioequivalence study is not required and a biowaiver is considered

appropriate in line with the note for guidance on the investigation of bioequivalence: CPMP/EWP/QWP/1401/98 Rev. 1/Corr**.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturing authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The UK, Belgium, Cyprus, The Czech Republic, France, Germany, Poland and Slovakia agreed to grant Marketing Authorisations for Cefazolin Powder for solution for injection/infusion on 11 November 2018. Marketing Authorisations were granted in the UK to Noridem Enterprises Limited on 10 December 2018.

II QUALITY ASPECTS

II.1 Introduction

Each vial contains 1g or 2g of the active substance, cefazolin (as cefazolin sodium), no other pharmaceutical excipients are present.

Cefazolin 1g Powder for solution for injection/infusion is available in 15 mL, Type III colorless glass vials closed with bromobutyl Type I rubber closures and sealed with aluminium caps with a flip-top plastic cover. This strength of the medicinal product is supplied in pack sizes of 1, 10 or 50 vials.

Cefazolin 2g Powder for solution for injection/infusion is available in 20 mL, Type III colorless glass vials closed with bromobutyl Type I rubber closures and sealed with aluminium caps with a flip-top plastic cover. This strength of the medicinal product is supplied in pack sizes of 1, 10 or 50 vials.

Not all pack sizes may be marketed.

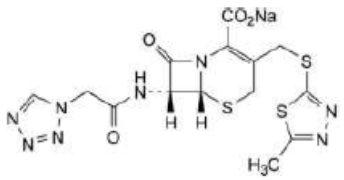
Satisfactory specifications and Certificates of Analysis for the primary packaging materials have been provided. All primary packaging complies with current European regulations concerning materials in contact with foodstuff.

II.2 DRUG SUBSTANCE

INN: Cefazolin sodium

Chemical name: Sodium (6R ,7R)-3-[[(5-methyl-1,3,4-thiadiazol-2-yl)sulfanyl]methyl]-8-oxo-7-[(1Htetrazol-1-ylacetyl)amino]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Structure:



Molecular formula: $C_{14}H_{33}N_8NaO_4S_3$

Molecular weight:: 476.5

Appearance: White or almost white powder, very hygroscopic

Solubility: Freely soluble in water, very slightly soluble in ethanol (96 per cent).

Cefazolin sodium is the subject of a European Pharmacopoeia monograph

All aspects of the manufacture and control of the active substance, Cefazolin sodium, are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 MEDICINAL PRODUCT

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious solution for injection/infusion containing 1g or 2g of cefazolin (as cefazolin sodium) per each ml of solution that is comparable to the reference medicinal product; Vifazolin 1g Powder for solution for injection (Vianex SA; Greece).

A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* dissolution and impurity profiles have been provided for the proposed and reference product.

None of the excipients contain materials of animal or human origin.

This product does not contain or consist of genetically modified organisms (GMO).

Manufacturing Process
Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate description of the manufacturing process. The manufacturing process has been validated with commercial-scale batches and has shown satisfactory results.

Control of Finished Products
The finished product specifications are acceptable. Test methods have been described that have been validated adequately. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for all working standards used.

Stability of the Products
Finished product stability studies were performed in accordance with current guidelines on batches of finished product in the packaging proposed for marketing. The data from these studies support a shelf life of 3 years, for the unopened vial with storage conditions of 'Store below 30°C. Keep the vials in the outer carton in order to protect from light.'

In-use shelf life after reconstitution/dilution:
Chemical and physical stability has been demonstrated for 12 hours at 25 °C and for up to 24 hours at 2-8 °C.
From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than the times stated above for the chemical and physical in-use stability.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

A post-approval stability commitment is made
- to continue the ongoing studies up to the proposed shelf-life (36 M),
- to place the first 3 commercial batches onto long-term and accelerated studies and
- to place one batch annually on long-term studies.

The applicant commits to repeat the compatibility study with a batch near the end of its shelf-life.

II.4 Discussion on chemical, pharmaceutical and biological aspects
It is recommended that Marketing Authorisations are granted for these applications, from a quality point of view.

III NON-CLINICAL ASPECTS

III.1 Introduction

The pharmacodynamic, pharmacokinetic and toxicological properties of cefazolin (as cefazolin sodium) are well known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The Applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

III.3 Pharmacokinetics

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

III.4 Toxicology

No new data have been submitted and none are required for applications of this type. Refer to Section III.1, Introduction, above.

Impurities

There are no named impurities in the drug product specifications for either strength. Any unspecified impurity is controlled to NMT 2% (shelf life). The applicant states that the limits of NMT 1.0% (shelf-life) for any specified impurity is in accordance with the available BP product monograph.
In addition, according to the Guideline on setting specifications for related impurities in antibiotics the identification threshold for fermentation products is 0.2%.

III.5 Ecotoxicity/Environmental Risk Assessment (ERA)

Since Cefazolin Powder for solution for injection/infusion is intended for generic substitution, this will not lead to an increase of the environmental exposure. An environmental risk assessment is therefore not deemed necessary.

III.6 Discussion of the non-clinical aspects

It is recommended that Marketing Authorisations are granted, from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Introduction.

According to the regulatory requirements of CHMP Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**) a bioequivalence study is not required for parenteral aqueous solutions and the applicant has not submitted any.

No new efficacy or safety studies have been performed and none are required for applications of this type. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of cefazolin (as cefazolin sodium).

Based on the data provided, Cefazolin Powder for solution for injection/infusion can be considered a generic of Vifazolin 1g Powder for solution for injection (Vianex SA; Greece).

IV.2 Pharmacokinetics

In line with the guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**), the test product is to be administered as a parenteral aqueous solution containing the same qualitative and quantitative composition in terms of active substance and excipients and is of the same pharmaceutical form as the currently approved product. No bioequivalence study has been submitted with this application and none is required.

IV.3 Pharmacodynamics

The clinical pharmacodynamics properties of cefazolin (as cefazolin sodium) are well-known. No new pharmacodynamic data were submitted and none are required for applications of this type.

IV.4 Clinical Efficacy

The clinical efficacy of cefazolin (as cefazolin sodium) is well-known. No new efficacy data are presented or and none are required for applications of this type.

IV.5 Clinical Safety

No new safety data were submitted and none were required for this application. The clinical safety of cefazolin (as cefazolin sodium), used in the approved indications, is known.

IV.6 Risk Management Plan (RMP)

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended.

There are no differences from the reference product in terms of proposed uses, maximum pack size / strength or pharmaceutical form / formulation that would have any implications for safety.

In line with the reference product, the applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns (labelling in the SmPC and the PIL). This is agreed. The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of an RMP coincide, they can be submitted at the same time, but via different procedures.

IV.7 Discussion of the clinical aspects

It is recommended that Marketing Authorisations are granted, from a clinical point of view.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

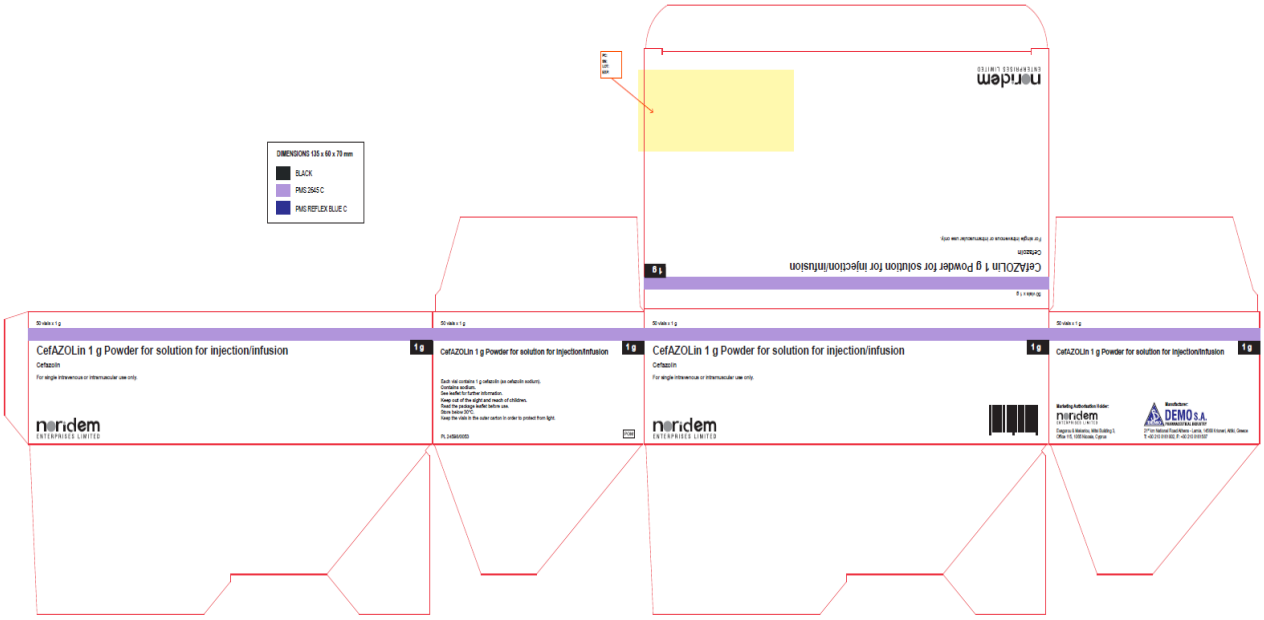
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with cefazolin (as cefazolin sodium) is considered to have demonstrated the therapeutic value of the compound. The overall benefit/risk assessment is considered to be similar to that of the reference product and positive. The grant of Marketing Authorisations is, therefore, recommended.

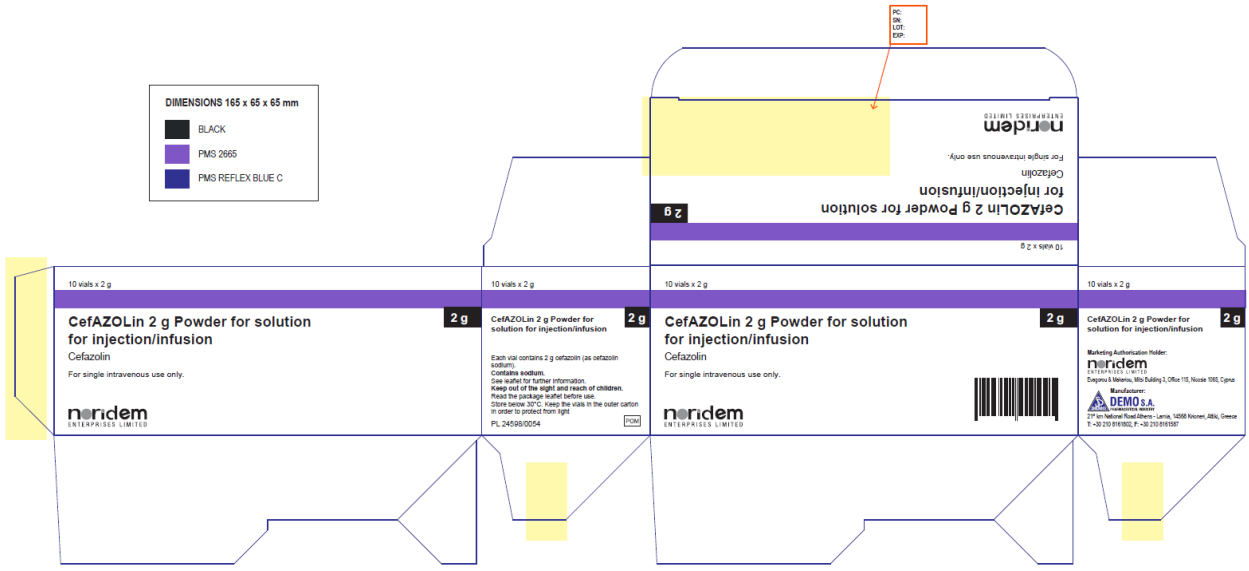
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

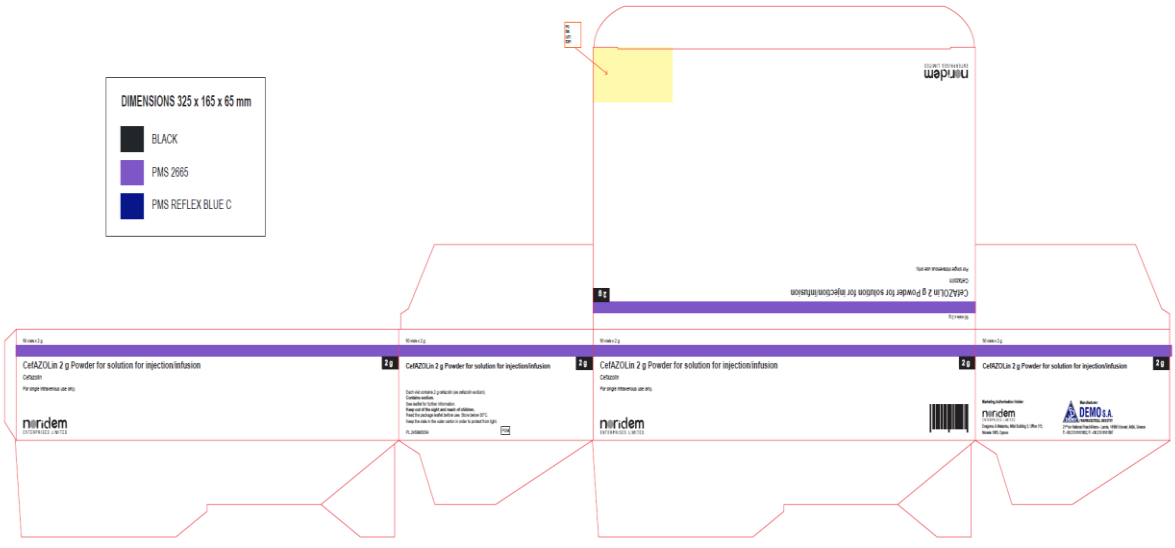
In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for Cefazolin Powder for solution for injection/infusion is presented below:


45 x 45 x 90 mm
BLACK
PMS 2645 C
PMS REFLEX BLUE C
1 vial x 1 g
CefAZOLin 1 g
Powder for solution for injection/infusion
1 g
Cefazolin
For single intravenous or intramuscular use only.
1 vial x 1 g
CefAZOLin 1 g
Powder for solution for injection/infusion
1 g
Marketing Authorization Holder:
noridem ENTERPRISES LIMITED
Evagorou & Makariou,
Mitsi Building 3, Office 115,
Nicosia 1065, Cyprus
Manufacturer:
DEMO S.A. PHARMACEUTICAL INDUSTRY
21st km National Road Athens - Lamia,
14568 Krioneri, Attiki, Greece
T: +30 210 8161802, F: +30 210 8161587
1 vial x 1 g
CefAZOLin 1 g
Powder for solution for injection/infusion
1 g
Cefazolin
For single intravenous or intramuscular use only.
noridem ENTERPRISES LIMITED
1 vial x 1 g
CefAZOLin 1 g
Powder for solution for injection/infusion
1 g
Each vial contains 1 g cefazolin (as cefazolin sodium).
Contains sodium. See leaflet for further information.
Keep out of the sight and reach of children.
Read the package leaflet before use.
Store below 30°C. Keep the vials in the outer carton in order to protect from light
POM
PL 24598/0053
1 vial x 1 g
CefAZOLin 1 g
Powder for solution for injection/infusion
1 g
Cefazolin
For single intravenous or intramuscular use only.
noridem ENTERPRISES LIMITED
PC:
SN:
LOT:
EXP:


DIMENSIONS 135 x 60 x 70 mm
BLACK
PMS 2945 C
PMS REFLEX BLUE C
CefAZOLin 1 g Powder for solution for injection/infusion
Cefazolin
For single intravenous or intramuscular use only.
1 g
noridem
ENTERPRISES LIMITED


DIMENSIONS 165 x 65 x 65 mm
BLACK
PMS 2665
PMS REFLEX BLUE C
10 vials x 2 g
CefAZOLin 2 g Powder for solution for injection/infusion
Cefazolin
For single intravenous use only.
2 g
noridem
ENTERPRISES LIMITED
Each vial contains 2 g cefazolin (as cefazolin sodium).
Contains sodium.
See leaflet for further information.
Keep out of the sight and reach of children.
Read the package leaflet before use.
Store below 30°C. Keep the vials in the outer carton in order to protect from light.
PL 24598/0054
POM
Marketing Authorisation Holder:
Manufacturer:
DEMO S.A.


DIMENSIONS 325 x 165 x 65 mm
BLACK
PMS 2665
PMS REFLEX BLUE C
CefAZOLin 2 g Powder for solution for injection/infusion
Cefazolin
2 g
noridem
ENTERPRISES LIMITED


45 x 45 x 90 mm
BLACK
PMS 2665 C
PMS REFLEX BLUE C
1 vial x 2 g
CefAZOLin 2 g
Powder for solution
for injection/infusion
2 g
Cefazolin
For single intravenous
use only.
1 vial x 2 g
CefAZOLin 2 g
Powder for solution
for injection/infusion
2 g
Marketing Authorization Holder:
noridem
ENTERPRISES LIMITED
Evagorou & Makariou,
Mitsi Building 3, Office 115,
Nicosia 1065, Cyprus
Manufacturer:
DEMO S.A.
PHARMACEUTICAL INDUSTRY
21st km National Road Athens - Lamia,
14568 Krioneri, Attiki, Greece
T: +30 210 8161802, F: +30 210 8161587
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CefAZOLin 2 g
Powder for solution
for injection/infusion
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noridem
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use only.
noridem
ENTERPRISES LIMITED
PC:
SN:
LOT:
EXP:

Annex 1 - Table of content of the PAR update for MRP and DCP

Steps Taken After The Initial Procedure With An Influence On The Public Assessment Report

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)