Safeguarding public health

MHRA

Public Assessment Report

Mutual Recognition Procedure

Potassium Chloride 15% w/v Concentrate for Solution for Infusion

MRP no: UK/H/0860/001/MR
UK licence no: PL 24598/0003

Applicant: Noridem Enterprises Limited

Medicines and Healthcare products Regulatory Agency

Potassium Chloride 15% w/v Concentrate for Solution for Infusion
PL 24598/0003; UK/H/0860/001/MR

LAY SUMMARY

On 11th November 2007, Austria, Belgium, Denmark, Germany, Greece, Ireland, The Netherlands, Norway, Portugal, Spain and Sweden approved Noridem Enterprises Limited Marketing Authorisations (licences) for the medicinal product Potassium Chloride 15% w/v Concentrate for Solution for Infusion (PL 24598/0003). This application was by mutual recognition procedure with the UK as Reference Member State (RMS). A national licence had previously been granted in the UK on 26th August 2004. This is a prescription-only medicine (POM) that works by replacing a substance called potassium that the body has lost.

Potassium chloride is a type of medicine called an electrolyte. Electrolytes help keep the water levels in different parts of the body in the right balance. Your body needs the right amount of potassium. Potassium helps your muscles, heart and other organs to work properly. Potassium also helps balance the water levels that affect many electrical and chemical processes in your body. Without the right amount of potassium, your heart may start beating abnormally, which could be life-threatening. If you cannot take potassium by mouth, it may be administered by drip (infusion).

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of using Potassium Chloride 15% w/v Concentrate for Solution for Infusion outweighed the risks, hence a Marketing Authorisation has been granted.

TABLE OF CONTENTS

Module 1

Product Name	Potassium Chloride 15% w/v Concentrate for Solution for Infusion
Type of Application	Known Active Substance Initial application Bibliographic (Article 10a) Chemical substance Prescription only
Active Substance	Potassium chloride
Form	Concentrate for Solution for Infusion 15% w/v
MA Holder	Noridem Enterprises Ltd, Evagorou & Makariou, Mitsi Building 3, Suite 115, 1065 Nicosia, Cyprus
RMS	United Kingdom
CMS	Austria, Belgium, Denmark, Germany, Greece, Ireland, The Netherlands, Norway, Portugal, Spain, Sweden
Procedure Number	UK/H/0860/001/MR
Timetable	Day 90: 11/11/2007

Module 2

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

UK: Potassium Chloride 15% w/v Sterile Concentrate BP.
IE: Potassium Chloride 15% w/v concentrate for solution for infusion
BE: Potassium Chloride Noridem 15% w/v Sterile Concentrate
DK: Kaliumklorid Noridem 2mmol/ml
ES: Potassium Chloride Noridem 150mg/ml (15%), concentrate for solution for infusion
SE: Potassium Chloride Noridem 2mmol/ml, concentrate for solution for infusion
NO: Kaliumklorid Noridem

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Potassium Chloride 150mg/ml or 15% w/v (2mmol/ml)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion (sterile concentrate).

A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The prevention and treatment of potassium deficiency when oral replacement therapy is not feasible.

4.2. Posology and method of administration

Method of administration:
Slow intravenous infusion.

Dilute with a suitable infusion fluid and mix well before use to produce a potassium concentration of 20 mmol per litre and not more than 40 mmol per litre. Infuse at a rate not exceeding 20 mmol potassium per hour. In the treatment of severe hypokalaemia or diabetic ketoacidosis, the higher concentration and a higher infusion rate may be required. In this case, the infusion should be into a high blood flow vein and continuous ECG monitoring is advisable.

Adults and the elderly:
Up to 6 g (80 mmol) daily after dilution to a concentration of 20 mmol/litre and no greater than 40 mmol/litre.

Infants and children:
Up to 3 mmol per kg per day after dilution to a concentration of 20 mmol/litre.
For children weighing 25kg or over, refer to the adult dosage.

4.3 Contra-indications

Potassium chloride is contraindicated in patients with hyperkalaemia.

4.4 Special warnings and precautions for use

Potassium chloride concentrate must be diluted with sodium chloride solution for injection (0.9% w/v) or other suitable diluent, thoroughly mixed and given by slow intravenous infusion under ECG control, ensuring adequate urine flow and with careful monitoring of electrolytes.

Concentrated potassium solutions are for intravenous admixtures only. Do not use undiluted. Direct injection may be instantaneously fatal.

Initial potassium replacement therapy should not involve glucose infusions, because glucose may cause a further decrease in the plasma-potassium concentration.

Repeated measurements of plasma-potassium concentration are necessary to determine whether further infusions are required and to avoid the development of hyperkalaemia.

Patients with mild to moderate renal impairment and adrenal insufficiency should be closely monitored. Considerable care should also be taken with patients having cardiac disease, acute dehydration, heat cramps, extensive tissue destruction eg severe burns.

Care should be taken with elderly patients since renal function may be impaired.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with ACE inhibitors may result in hyperkalaemia.

There is an increased risk of hyperkalaemia with use of angiotensin-II receptor antagonists, cyclosporin, potassium-sparing diuretics, tacrolimus and potassium-containing salt substitutes.

In patients receiving digoxin, hypokalaemia may result in digoxin toxicity. Caution is therefore advised if discontinuing a potassium preparation in patients maintained on digoxin.

Blood transfusions can contain significant serum potassium levels. If exchange resins or sodium cycles are administered with potassium supplements, serum potassium levels are reduced by sodium replacement of the potassium.

Potassium can enhance the antiarrhythmic effect of quinidine.

Concurrent use of adrenocorticoids, glucocorticoids and mineralocorticoids may all decrease the effects of potassium supplements.

4.6 Pregnancy and lactation

There are no adequate data on the use of potassium chloride in pregnant women. Caution should therefore be exercised when prescribing to pregnant women.

Potassium salts are likely to be excreted in milk. Caution should therefore be exercised when prescribing to women who are breast-feeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Hyperkalaemia: Adverse reactions involve the possibility of potassium intoxication. Signs and symptoms include parasthesias of extremities, flaccid paralysis, muscle or respiratory paralysis, areflexia, weakness, listlessness, mental confusion, weakness and heaviness of legs, hypotension, cardiac arrhythmia, heart block, ECG abnormalities.

Cardiovascular: Rapid infusion or injection can be toxic to the heart. Cardiac arrhythmias can occur and even cardiac arrest.

Reactions due to technique of administration: Febrile response, infection at injection site, venous thrombosis, phlebitis extending from the injection site and extravasation.

4.9 Overdose

If excretory mechanisms are impaired or if potassium is administered too rapidly, potentially fatal hyperkalaemia can result.

Signs: Signs of hyperkalaemia include cardiac arrhythmias, chest pain, muscle weakness and paralysis.

Treatment: In the event of hyperkalaemia, all potassium-containing medications and foods should be discontinued immediately. If the condition is serious, the first priority is to ensure stability of the cardiac rhythm. Continuous ECG monitoring is essential. Administration of calcium gluconate (but not to patients on digitalis) may be needed to reduce cardiotoxic effects. Intravenous glucose and insulin may be necessary to facilitate the transfer of potassium into cells. Severe and unresponsive hyperkalaemia can be effectively treated with haemodialysis, peritoneal dialysis or use of ion exchange resins.

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Eletrolyte solution
ATC Code B05X A01.

Potassium is the predominant cation within cells. It is involved in numerous cellular metabolic processes and is necessary for the conduction of nerve impulses in such tissues as the heart, brain and skeletal muscle.

In hypokalaemia, prolongation of the QT interval and depression of the ST segment may be seen whereas hyperkalaemia results in increased height of T-waves, lengthened PR interval, and even asystole or ventricular fibrillation.

5.2 Pharmacokinetic properties

Potassium is quickly transferred to the intracellular fluid by an active transport system which maintains high levels within cells. Extracellular fluid contains 4-5 mmol per litre while intracellular fluid contains 150 mmol per litre.

Potassium is mainly excreted by the kidneys, although about 10% is excreted by the colonic mucosa.

5.3 Preclinical safety data

There is no additional information relevant to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Water for Injections

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.

6.3. Shelf life

Unopened: 2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5. Nature and contents of container

Polypropylene ampoules, of 5, 10 or 20 ml, packed into cartons of 20 ampoules.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and handling

Do not use unless the solution is clear and practically free from particles.
Discard after single use.
Discard any unused portion.

Potassium chloride concentrate must be diluted before use by not less than 50 times its volume with sodium chloride 0.9% w/v intravenous infusion (0.9% w/v), dextrose 5% w/v intravenous solution to a maximum concentration of 40 mmol potassium per litre.

The solution must be mixed well before use.

7. MARKETING AUTHORISATION HOLDER

Noridem Enterprises Ltd., (trading as Fannin)
Evagorou & Makariou,
Mitsi Building 3, Suit.115,
1065 Nicosia, Cyprus.

8 MARKETING AUTHORISATION NUMBER

24598/0003

9 DATE OF THE FIRST AUTHORISATION OR RENEWAL

7 September 2005

10 DATE OF REVISION OF THE TEXT

17/07/2008

Module 3

Patient Information Leaflet

Potassium Chloride 15% w/v Concentrate for Solution for Infusion

Potassium Chloride

Please read all of this leaflet carefully. It includes important information on how you should take this medicine correctly and safely.

- Keep this leaflet. You may need to read it again.
- If you are the parent of a child who is to be given this medicine, read the leaflet replacing 'you' with 'your child' throughout.
- This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in the leaflet, please tell your doctor, nurse or pharmacist.
- If you have any further questions, please ask your doctor, nurse or pharmacist.

The name of your medicine is Potassium Chloride 15% w/v Concentrate for Solution for Infusion.

In the rest of this leaflet Potassium Chloride 15% w/v Concentrate for Solution for Infusion is called Potassium Chloride.

In this leaflet:

1. What Potassium Chloride is and what it is used for

Potassium Chloride is a type of medicine called an electrolyte. Electrolytes help keep the water levels in different parts of your body in the right balance.

Potassium Chloride works by replacing a substance called potassium that your body has lost.

Your body needs the right amount of potassium. Potassium helps your muscles, heart and other organs to work properly. Potassium also helps balance the water levels that affect many electrical and chemical processes in your body. Without the right amount of potassium your heart may start to beat abnormally, which could be life-threatening.

If you cannot take potassium by mouth, your doctor or nurse will give you this medicine as a drip (infusion).

2. Before you take Potassium Chloride

The doctor or nurse giving you this medicine will ask some questions about you. They need the following information before you have this medicine for the first time.

Do not take Potassium Chloride

- If you have hyperkalaemia (high levels of potassium in your blood).

Do not take Potassium Chloride if the above statement is true.

Take special care with Potassium Chloride

Tell your doctor or nurse before your treatment starts if:

- You have problems with your kidneys or adrenal glands
- You have problems with your heart
- You have been told you are very dehydrated (you do not have enough water in your body)
- You have heat cramps
- You have a lot of your skin damaged (such as extreme burns)
- You are elderly (over 65 years old)
- You have problems passing urine
- You are having a drip (infusion) containing the sugar called glucose.

Taking other medicines

Please tell your doctor about any medicines you may be taking or have recently been taking. Remember also any medicines you may be taking that do not need a prescription.

If you are taking any of the following medicines it is very important to tell your doctor:

- ACE inhibitors such as lisinopril, captopril, enalapril (may make the amount of potassium in your blood too high)
- Angiotensin-II receptor antagonists such as losartan, valsartan, candesartan (may make the amount of potassium in your blood too high)
- Blood transfusion (may make the amount of potassium in your blood too high)
- Ciclosporin (may make the amount of potassium in your blood too high)
- Corticosteroids such as cortisone, hydrocortisone, prednisone, prednisolone, betamethasone (may make your potassium chloride not work properly)
- Digoxin (may give you more side effects)
- Potassium-sparing diuretics such as spironolactone (may make the amount of potassium in your blood too high)
- Quinidine (may make your heart start to beat abnormally)
- Tacrolimus (may make the amount of potassium in your blood too high).

Taking salt-substitutes

If you are using potassium-containing salt substitutes in your diet, you must tell your doctor. You may be getting too much potassium if you take this medicine at the same time.

Pregnancy and breast-feeding

- If you are pregnant, or think you may be pregnant you must tell your doctor.
- If you are breast-feeding you must tell your doctor.

Your doctor will advise you if you should have this medicine.

Please read the other side of this leaflet.

3. How to take Potassium Chloride

A doctor or a nurse will usually give you this medicine.

Your doctor or nurse will give you the correct dose as a drip into your vein (your doctor or nurse may call this an IV or intravenous infusion).

Your doctor will decide the amount (dose) of your medicine that you should receive and how long you will need to take it for.

Your doctor will also decide the strength of the medicine to give to you. The medicine is very strong, and must always be made weaker by adding more liquid (diluting) before you receive it.

Your doctor will monitor your heart while you receive your medicine.

Your doctor will also take some blood tests, and check the amount of urine you make. This is to check the amount of potassium in your blood while you are having your medicine.

If you have a very low amount of potassium in your blood, or you have diabetic ketoacidosis (a complication of diabetes), you may receive the medicine more quickly than usual.

Adults and the elderly

The usual dose is up to 80 mmol (millimoles) per day. The medicine will be made at a strength of 20 - 40 mmol/litre.

Infants and children

The usual dose is up to 3 mmol (millimoles) per kg of bodyweight per day. The medicine will be made at a strength of 20 mmol/litre. For children weighing 25Kg or over, refer to the adult dosage.

If you take more Potassium Chloride than you should

A doctor or a nurse will usually give you this medicine. If you think you may have received too much medicine, please tell your doctor or nurse at once.

Too much potassium in your blood will cause serious side effects that may be life-threatening. Please read carefully the important advice at the beginning of the next section, Section 4, about how you can spot the signs of too much potassium in your blood.

If you forget to take Potassium Chloride

A doctor or a nurse will usually give you this medicine. If you think you have missed a dose, please tell your doctor or nurse.

If you have any further questions on the use of your medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Potassium Chloride can cause side effects, but not everyone gets them. The expected benefit of your medicine will usually be greater than the risk of you suffering any harmful side effects.

Important: Side effects or symptoms to look out for, and what to do if you are affected.
The first signs of having too much potassium in your blood are abnormal heartbeats, chest pain, possible heart attack, muscle weakness, paralysis or difficulty breathing. If you get any of these symptoms you must seek urgent medical advice.

The following other side effects may occur in some people:

Immune system problems:

- Fever.

Heart and circulation problems:

- Low blood pressure (you may feel light-headed).

Infusion site problems:

- Pain, redness, soreness and swelling at the site of the drip.

Nervous system problems:

- Prickling or tingling of the hands or feet
- Paralysis where the muscles are floppy
- Loss of reflexes
- Weakness, lack of energy
- Mental confusion
- Weakness and heaviness of legs.

If any of these side effects gets serious, or if you notice any troublesome symptoms which you think may be side effects, please tell your doctor, nurse or pharmacist.

5. How to store Potassium Chloride

Keep your medicine out of the reach and sight of children.

Do not use your medicine after the expiry date (EXP) given on the carton and the label on the plastic container (ampoule). The expiry date is the last day of the month written on the packaging.

Store below 25°C.

Only use your medicine if it is a clear and colourless liquid. Open it and use it straight away.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Potassium Chloride contains

The active medicine is Potassium Chloride. The other ingredient is Water for Injections.

The medicine contains 15 % w/v (150 mg per ml) of Potassium Chloride. Each ml (millilitre) of this medicine contains 2 mmol of potassium.

What Potassium Chloride looks like

Potassium Chloride is a concentrate for solution for infusion. This means it is a concentrated (strong) solution in a plastic container. It is a clear, colourless liquid. The solution must have more liquid added (diluted) to make a weaker solution that can then be given to you as a drip (an infusion).

Contents of the pack

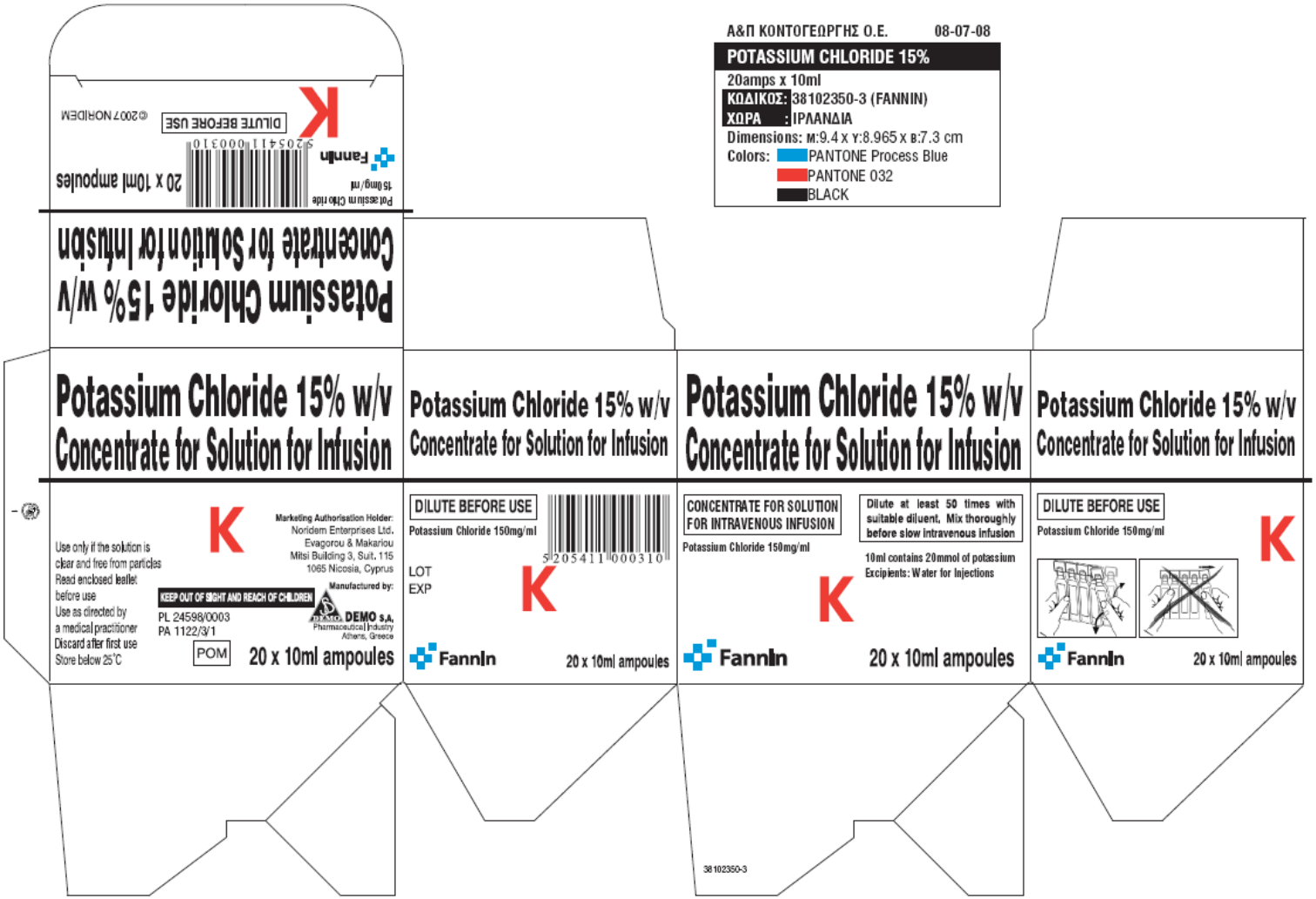
Each plastic ampoule will contain 5 ml (millilitres), 10 ml or 20 ml of your medicine. 20 ampoules come in a box. Not all pack sizes may be available.

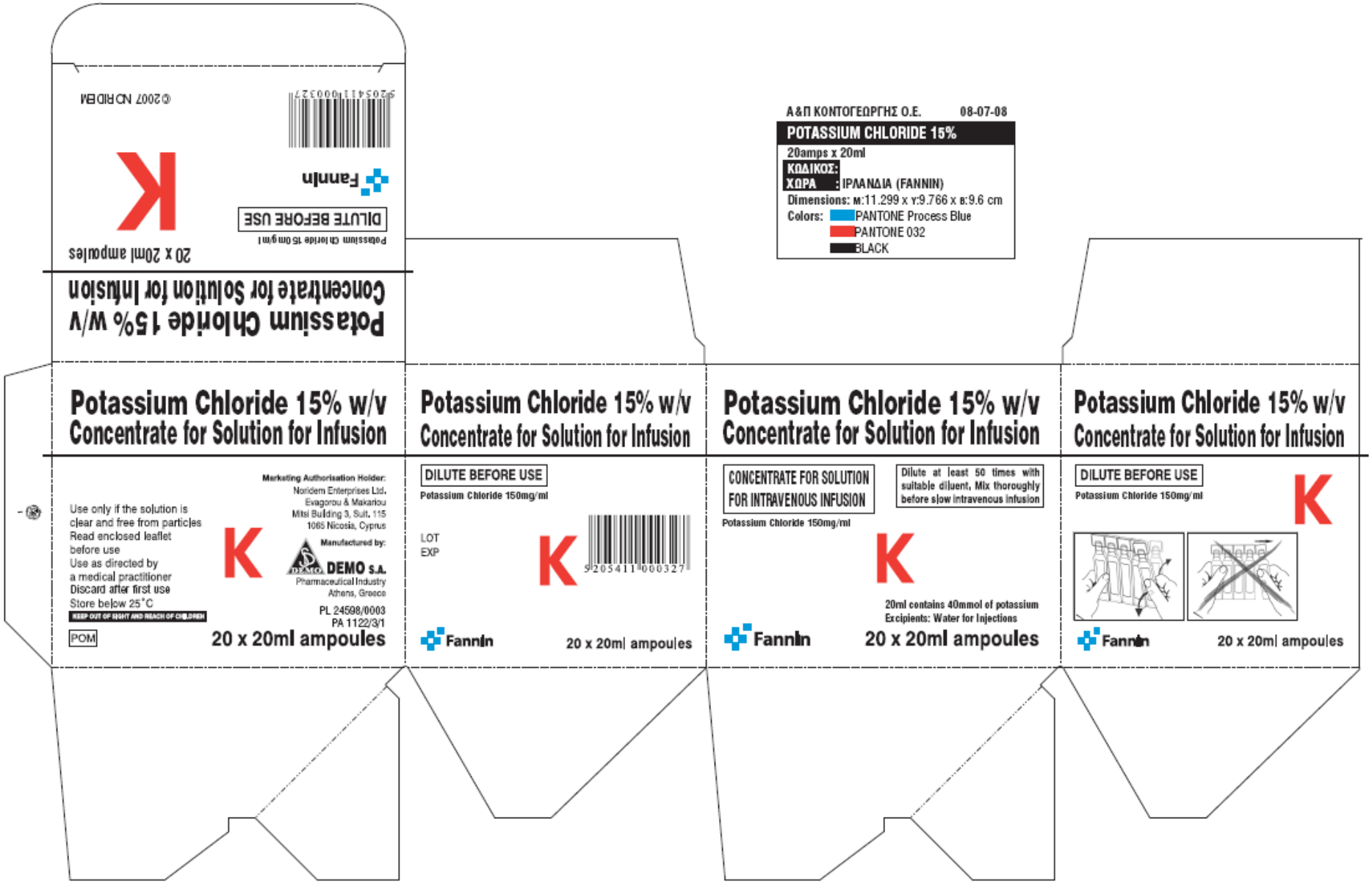
Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Suit.115, 1065 Nicosia, Cyprus.
Manufacturer: Demo S.A., 21st Km National Road Athens-Lamia, 14568 Athens, Greece.

This leaflet was approved in May 2008.

Module 4
Labelling




Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
20 x 20ml ampoules
DILUTE BEFORE USE
Potassium Chloride 150mg/ml
Fannin
Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
Use only if the solution is clear and free from particles
Read enclosed leaflet before use
Use as directed by a medical practitioner
Discard after first use
Store below 25°C
KEEP OUT OF SIGHT AND REACH OF CHILDREN
POM
Marketing Authorisation Holder:
Noridem Enterprises Ltd.
Evagorou & Makariou
Mitsi Building 3, Suit. 115
1065 Nicosia, Cyprus
Manufactured by:
DEMO S.A.
Pharmaceutical Industry
Athens, Greece
PL 24598/0003
PA 1122/3/1
20 x 20ml ampoules
Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
DILUTE BEFORE USE
Potassium Chloride 150mg/ml
LOT
EXP
5 205411 000327
Fannin
20 x 20ml ampoules
Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
CONCENTRATE FOR SOLUTION FOR INTRAVENOUS INFUSION
Dilute at least 50 times with suitable diluent, Mix thoroughly before slow intravenous infusion
Potassium Chloride 150mg/ml
20ml contains 40mmol of potassium
Excipients: Water for Injections
Fannin
20 x 20ml ampoules
Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
DILUTE BEFORE USE
Potassium Chloride 150mg/ml
Fannin
20 x 20ml ampoules
Potassium Chloride 15% w/v
Concentrate for Solution for Infusion
20 x 20ml ampoules
DILUTE BEFORE USE
Potassium Chloride 150mg/ml
Fannin
5 205411 000327
© 2007 NORIDEM
Α&Π ΚΟΝΤΟΓΕΩΡΓΗΣ Ο.Ε. 08-07-08
POTASSIUM CHLORIDE 15%
20amps x 20ml
ΚΩΔΙΚΟΣ:
ΧΩΡΑ : ΙΡΛΑΝΔΙΑ (FANNIN)
Dimensions: Μ:11.299 x Υ:9.766 x Β:9.6 cm
Colors: PANTONE Process Blue
PANTONE 032
BLACK

Α&Π ΚΟΝΤΟΓΕΩΡΓΗΣ Ο.Ε. 17-07-08

POTASSIUM CHLORIDE 15%

20amps x 5ml

ΚΩΔΙΚΟΣ:

ΧΩΡΑ : ΙΡΛΑΝΔΙΑ (FANNIN)

Dimensions: Μ:9.5 x Υ:6.865 x Β:7.6 cm

Colors: PANTONE Process Blue
PANTONE 032
BLACK


POTASSIUM CHLORIDE
15% W/V CONCENTRATE FOR SOLUTION FOR INFUSION
750 mg in 5 ml
Dilute before use
Fannin
K
5 ml contains
10 mmol of potassium
PL 24598/0003
PA 1122/3/1


POTASSIUM CHLORIDE
15% W/V CONCENTRATE FOR SOLUTION FOR INFUSION
1.5 g in 10 ml
Dilute before use
Fannin
K
10 ml contains
20 mmol of potassium
PL 24598/0003
PA 1122/3/1


POTASSIUM CHLORIDE
15% W/V CONCENTRATE FOR SOLUTION FOR INFUSION
3 g in 20 ml
Dilute before use
Fannin
K
20 ml contains
40 mmol of potassium
PL 24598/0003
PA 1122/3/1

Module 5
Scientific discussion during initial procedure

1. INTRODUCTION

Background

This application was submitted by Noridem Enterprises Limited for Potassium Chloride 15% w/v Concentrate for Solution for Infusion, via the Mutual Recognition Procedure. The UK acted as Reference Member State for the procedure, which was granted a UK licence on 26th August 2004.

Potassium Chloride 15% w/v Concentrate for Solution for Infusion is indicated for the prevention and treatment of potassium deficiency when oral replacement therapy is not feasible.

Based on the review of the data on quality, safety and efficacy, the RMS considered that the application for Potassium Chloride 15% w/v Concentrate for Solution for Infusion could be approved for the indications stated above.

Day 90 for the procedure was 11th November 2007, subsequent to which Marketing Authorisations were approved in Austria, Belgium, Denmark, Germany, Greece, Ireland, The Netherlands, Norway, Portugal, Spain and Sweden.

Overall Benefit/Risk Assessment

Potassium Chloride 15% w/v Concentrate for Solution for Infusion is a well-known and widely used electrolyte.

No preclinical studies were conducted, and none are required as the product is well-established for medicinal use.

No clinical studies were conducted, and none are required as the product is well-established for medicinal use.

The RMS has been assured that acceptable standards of GMP are in place at all sites responsible for the manufacture and assembly of this product prior to granting its national authorisation.

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

2. QUALITY ASPECTS

S. Active Substance

Synthesis of the drug substance from the designated starting materials has been adequately described, and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance potassium chloride, with suitable test methods and limits. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging materials and the primary packaging has been shown to comply with current guidelines concerning contact with foodstuff.

Appropriate shelf-lives have been set for active potassium chloride, based on the available stability data provided by the active substance manufacturers. No formal stability data has been provided by the applicant, which is acceptable given that the active is known to be very stable and the European Pharmacopoeia monograph contains no degradation products.

P. Medicinal Product

Other Ingredients

The only excipient used in this product is water for injections. Satisfactory certificates of analysis have been provided to show that it complies with the current European Pharmacopoeia monograph.

No excipients of human or animal origin are used in this product. No genetically modified organisms are used in this product.

Pharmaceutical Development

The objective of the development programme was to produce a solution for injection containing 15% w/v potassium chloride that complied with the current British Pharmacopoeia monograph for sterile potassium chloride concentrate and with the general European Pharmacopoeia requirements for sterile concentrates.

Manufacturing Process

An appropriate account of the manufacturing process has been provided. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specification

The finished product specification is satisfactory and in-line with the current British Pharmacopoeia monograph for sterile potassium chloride concentrate and with the general European Pharmacopoeia requirements for sterile concentrates. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container-Closure System

The product is packed into polypropylene 5ml, 10ml or 20ml ampoules packed into cartons of 20.

Satisfactory specifications and certificates of analysis have been provided for all packaging components. All primary packaging complies with the relevant regulations regarding materials for parenteral use.

Product Stability
Stability studies were performed in the packaging proposed for marketing and in accordance with current guidelines. All results from stability studies were within specified limits. These data support a shelf-life of 2 years with the storage condition 'Store below 25°C'.

Bioequivalence/Bioavailability
No bioequivalence studies have been submitted for this application and none were required.

Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), Labels
The SPC, PIL and labels are pharmaceutically acceptable.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

MAA Forms
The MAA forms are pharmaceutically satisfactory.

Expert Report
The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier.

Conclusion
The grant of a marketing authorisation is recommended.

3. PRE-CLINICAL ASPECTS
No new preclinical data have been supplied with this application and none are required for an application of this type.

4. CLINICAL ASPECTS
Clinical Pharmacology
No new data were submitted and none are required for this type of application.

Efficacy
No new data were submitted and none are required for this type of application.

Safety
No new data were submitted and none are required for this type of application.

Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL), Labels
The SPC, PIL and labels are medically acceptable. The SPC is consistent with that for other similar products.

Conclusion
The grant of a marketing authorisation is recommended.

5. OVERALL CONCLUSION

QUALITY

The important quality characteristics of Potassium Chloride 15% w/v Concentrate for Solution for Infusion are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

No new preclinical data were submitted and none were required for an application of this type.

EFFICACY

No new or unexpected significant safety concerns were found during the clinical development.

The SPC, PIL and labelling are appropriate for a product of this type.

BENEFIT-RISK ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Potassium Chloride 15% w/v Concentrate for Solution for Infusion is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is considered to be positive.