

**SODIUM CHLORIDE 0.9% W/V INJECTION BP.**

**PL 02848/0227**

**UKPAR**

**TABLE OF CONTENTS**

Lay Summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 12
Summary of Product Characteristics	
Product Information Leaflet	
Labelling	

## **SODIUM CHLORIDE 0.9% W/V INJECTION BP.**

**PL 02848/0227**

### **LAY SUMMARY**

The MHRA has granted Antigen International Limited a Marketing Authorisation (licence) for the medicinal product Sodium Chloride 0.9%w/v Injection BP (PL 02848/0227).

This is a prescription-only medicine (POM) mainly used to dissolve (and dilute) drugs acting as a carrier solution for injectable drugs. It is used as a saline washout solution during surgical procedures. It is also used as a medium of cleaning and preparing equipments for dialysis of blood and as a solution to initiate and terminate blood transfusions.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of using Sodium Chloride 0.9% w/v Injection BP outweigh the risks, hence a Marketing Authorisation has been granted.

**SODIUM CHLORIDE 0.9% W/V INJECTION BP.**

**PL 02848/0227**

**SCIENTIFIC DISCUSSION**

**TABLE OF CONTENTS**

Introduction	Page 4
Pharmaceutical assessment	Page 5
Preclinical assessment	Page 7
Clinical assessment (including statistical assessment)	Page 8
Overall conclusions and risk benefit assessment	Page 11

## **INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the UK granted marketing authorisation for the medicinal product Sodium Chloride 0.9% w/v Injection BP to Antigen International Limited on 31<sup>st</sup> of August 2007. The product is a prescription-only medicine.

This application was submitted as an abridged application according to Article 10(1) of Directive 2001/83/EC, claiming essential similarity to the original product 0.9% w/v Sodium Chloride Intravenous Infusion BP, PL 04296/0021 licensed to B Braun Medical Limited in 1989 and so the 10-year period of data exclusivity has expired.

The Product contains the active ingredient sodium chloride and is indicated for:

- a) The reconstitution, dilution and making of certain drugs.
- b) As a saline irrigant.
- c) As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

## **PHARMACEUTICAL ASSESSMENT**

### **DRUG SUBSTANCE**

No materials of animal or human origin are used in the production of the active substance.

An appropriate specification based on the European Pharmacopoeia has been provided.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Active sodium chloride is stored in appropriate packaging. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided and comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer during validation studies.

No stability data are provided and deemed necessary for this widely used active ingredient, however a retest period of one year is proposed and accepted.

### **DRUG PRODUCT**

#### **Other ingredients**

Other ingredient is water for injections which complies with its respective European Pharmacopoeial monograph. Satisfactory specifications and Certificates of Analysis have been provided for this excipient. No materials of animal or human origin are contained in or used in the manufacture of this product. No genetically modified organisms are included in this product.

#### **Manufacture**

A description and flow-chart of the manufacturing method have been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on all batches. The results are satisfactory.

#### **Finished product specification**

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. 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 packaged in 5ml and 10ml ampoules of Polyethylene. This polyethylene does not contain any additives and is in compliance with the Ph Eur monograph. Specifications and Certificates of Analysis for packaging used have been provided. This is satisfactory. All primary product packaging complies with EU

legislation regarding contact with solutions for parenteral and ophthalmic use Directive 2002/72/EC (as amended).

**Stability**

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 24 months when stored below 25°C has been set, which is satisfactory.

**Conclusion**

It is recommended that Marketing Authorisation is granted for this application.

The requirements for essential similarity of the proposed and reference products have been met with respect to qualitative and quantitative content of the active substance and the pharmaceutical form. No bioequivalence study is reported or deemed necessary.

## **PRECLINICAL ASSESSMENT**

This application for a generic product claims essential similarity to 0.9% Sodium Chloride Intravenous Infusion BP, PL 04296/0021 licensed to B Braun Medical Limited in 1989, which has been licensed within the EEA for over 10 years.

No new preclinical data have been supplied with this application and none is required for an application of this type.

## CLINICAL ASSESSMENT

### 1. INTRODUCTION

This is a national abridged standard application for a marketing authorisation for Sodium Chloride 0.9% w/v Injection BP, PL 02848/0227. This application has been submitted under article 10.1 first paragraph of EC Directive 2001/83, as an essentially similar product to 0.9% Sodium Chloride Intravenous Infusion BP (PL 04296/0021), licensed to B Braun Medical Ltd in 1989.

### 2. BACKGROUND

Sodium Chloride 0.9% w/v Injection BP is well established as a solution for infusion in many different clinical conditions where fluid and electrolyte losses can become a severe hazard for the patient and it has also been used for sterile irrigations, mouthwashes and as a diluent for the intravenous injections of compatible drug additives. The good safety profile accounts for its widespread use as a diluent.

### 3. INDICATIONS

1. In the reconstitution, dilution and making up of certain drugs.
2. As a saline irrigant.
3. As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

### 4. DOSE & DOSE SCHEDULE

Route of administration: For parenteral administration, or as appropriate to the reconstituted drug.

Dosage:

The volume given and administration rate depends on the additive.

### 5. TOXICOLOGY

No new toxicology data or no preclinical expert report have been submitted and none are required.

### 6. CLINICAL PHARMACOLOGY



**6.1 PHARMACOKINETICS**

Sodium chloride is well absorbed from the gastro-intestinal tract. Sodium is predominantly excreted via the kidneys and renal reabsorption of sodium is extensive. Small amounts of sodium are excreted in faeces and in sweat.

**6.2 PHARMACODYNAMICS**

Sodium Chloride 0.9% w/v Injection BP is a sterile solution of physiological saline containing approximately 150 mmol of sodium and chloride per litre.

**7. EFFICACY**

No new efficacy data have been submitted or are required.

**8. SAFETY**

No new safety data have been submitted or are required.

**9. EXPERT REPORT**

No new clinical data and no clinical expert report have been submitted. The applicant was requested to submit a clinical report even if no new data is required. An updated clinical report was submitted and is appropriate.

**10. SUMMARY OF PRODUCT CHARACTERISTICS**

The SPC is fully in line with that for the reference product.

**11. PATIENT INFORMATION LEAFLET**

The PIL is satisfactory.

**12. LABELLING**

The labelling is satisfactory.

**13. MARKETING AUTHORISATION FORM**

This is satisfactory.

**14. DISCUSSION**

This is a national abridged application for a marketing authorisation for Sodium Chloride 0.9% w/v Injection BP. The good safety profile of sodium chloride 0.9% accounts for its widespread use as a diluent. No new preclinical, efficacy and safety data are submitted or required for this application.

## 15. CONCLUSIONS

The efficacy and safety of Sodium Chloride 0.9% w/v Injection BP are satisfactory for the grant of a product licence.

## **OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**

### **QUALITY**

The important quality characteristics of Sodium Chloride 0.9% w/v Injection BP 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.

### **PRECLINICAL**

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

### **EFFICACY**

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

The SPC, PIL and labelling are satisfactory and consistent with that for reference product.

### **RISK BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with Sodium Chloride is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is considered to be positive.

**SODIUM CHLORIDE 0.9% W/V INJECTION BP.****PL 02848/0227****STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the marketing authorisation application on 6 <sup>th</sup> January 2004
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 12 <sup>th</sup> February 2004
3	Following assessment of the application the MHRA requested further information relating to the clinical dossier on 14 <sup>th</sup> June 2004 and quality dossiers on 8 <sup>th</sup> July 2004, 9 <sup>th</sup> November 2006
4	The applicant responded to the MHRA's requests, providing further information on clinical dossier on the 22 <sup>nd</sup> August 2006 and quality dossier on 10 <sup>th</sup> November 2006
5	The application was determined on 31 <sup>st</sup> August 2007

**SUMMARY OF PRODUCT CHARACTERISTICS****1 NAME OF THE MEDICINAL PRODUCT**

Sodium Chloride 0.9% w/v Injection BP.

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml of solution contains 9 mg of Sodium Chloride.

For excipients, see 6.1

**3 PHARMACEUTICAL FORM**

Solution for Injection.

Clear, colourless, sterile solution.

**4 CLINICAL PARTICULARS****4.1 THERAPEUTIC INDICATIONS**

1. In the reconstitution, dilution and making up of certain drugs.

2. As a saline irrigant.

3. As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

**4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

Route of administration: For parenteral administration, or as appropriate to the reconstituted drug.

Dosage:

The volume given and administration rate depends on the additive.

**4.3 CONTRAINDICATIONS**

None known when used as a diluent or priming solution.

**4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

If administered subcutaneously, be aware that any additions could render it hypertonic and thus cause pain at the injection site.

**4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

None known when used as a diluent or priming solution.

**4.6 PREGNANCY AND LACTATION**

The solution is physiological saline and may be used during pregnancy and lactation.

**4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

None known.

**4.8 UNDESIRABLE EFFECTS**

None known when used as a diluent or priming solution so any undesirable effects may be related to the additive.

**4.9 OVERDOSE**

Overdose is very unlikely as vials contain a maximum of 10ml.

Because the infusion is iso-osmotic with plasma administration of an excessive volume of Sodium Chloride Intravenous Infusion 0.9% w/v produces an isotonic expansion of the extracellular fluid compartment which may result in oedema. The concentration of sodium in plasma is usually normal. Hypernatraemia may occur when patients who are dependent on parenteral fluids are given isotonic saline without free water to replace daily water loss through the skin. Irritability, lethargy and weakness are early neurologic signs of acute hypernatraemia. Osmotically-induced water shifts decrease the intracellular fluid volume and result in dehydration of internal organs; cerebral dehydration may provoke convulsive activity and may lead to coma and death. With judicious use of intravenous saline therapy, these effects can be avoided.

Diuretics may be used to treat oedema resulting from isotonic expansion, and appropriate replacement therapy should be employed to avoid fluid and electrolyte imbalance. Treatment of hypervolaemic hypernatraemia requires removal of sodium in excess of water and can be achieved by replacing diuretic-induced sodium and water losses with only water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

**5 PHARMACOLOGICAL PROPERTIES****5.1 PHARMACODYNAMIC PROPERTIES**

Sodium Chloride Intravenous Infusion 0.9% w/v is a sterile solution of physiological saline containing approximately 150 mmol of sodium and chloride per litre.

**5.2 PHARMACOKINETIC PROPERTIES**

Sodium chloride is well absorbed from the gastro-intestinal tract. Sodium is predominantly excreted via the kidneys and renal reabsorption of sodium is extensive. Small amounts of sodium are excreted in the faeces and in sweat.

**5.3 PRECLINICAL SAFETY DATA**

No relevant information other than that which is shown in other sections of the Summary of Product Characteristics.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 LIST OF EXCIPIENTS**

Water for injections.

**6.2 INCOMPATIBILITIES**

The addition of sodium chloride to mannitol 20% or 25% may cause precipitation of the mannitol. Do not add any other agent to this solution unless compatibility is known.

**6.3 SHELF LIFE**

2 years.

Use immediately after first opening of the ampoule. Discard unused contents.

**6.4 SPECIAL PRECAUTIONS FOR STORAGE**

Do not store above 25°C.

Do not refrigerate.

**6.5 NATURE AND CONTENTS OF CONTAINER**

5 ml or 10 ml hermetically sealed translucent plastic ampoules, polyethylene Ph. Eur. packed in cardboard cartons to contain 10 or 100 ampoules.

**6.6 SPECIAL PRECAUTIONS FOR DISPOSAL**

If only part of the ampoule is used, discard the remaining solution.

**7 MARKETING AUTHORISATION HOLDER**

Antigen International Ltd.

Roscrea

County Tipperary

Ireland.

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 02848/0227

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

31/08/2007

**10 DATE OF REVISION OF THE TEXT**

31/08/2007



Item Code to go here

## SUMMARY OF PRODUCT CHARACTERISTICS

**Sodium Chloride 0.9% w/v Injection BP****1. NAME OF THE MEDICINAL PRODUCT**

Sodium Chloride 0.9% w/v Injection BP

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1 ml of solution contains 9 mg of Sodium Chloride.  
For excipients, see 6.1

**3. PHARMACEUTICAL FORM**

Solution for Injection. Clear, colourless, sterile solution.

**4. CLINICAL PARTICULARS****4.1 Therapeutic indications**

- In the reconstitution, dilution and making up of certain drugs.
- As a saline irrigant.
- As a priming fluid for haemodialysis procedures and to initiate and terminate blood transfusions.

**4.2 Posology and method of administration**

Route of administration: For parenteral administration, or as appropriate to the reconstituted drug.

Dosage:

The volume given and administration rate depends on the additive.

**4.3 Contraindications**

None known when used as a diluent or priming solution.

**4.4 Special warnings and precautions for use**

If administered subcutaneously, be aware that any additions could render it hypertonic and thus cause pain at the injection site.

**4.5 Interaction with other medicinal products and other forms of interaction**

None known when used as a diluent or priming solution.

**4.6 Pregnancy and lactation**

The solution is physiological saline and may be used during pregnancy and lactation.

**4.7 Effects on ability to drive and use machines**

None known.

**4.8 Undesirable effects**

None known when used as a diluent or priming solution so any undesirable effects may be related to the additive.

**4.9 Overdose**

Overdose is very unlikely as vials contain a maximum of 10ml. Because the infusion is iso-osmotic with plasma, administration of an excessive volume of Sodium Chloride Intravenous Infusion 0.9% w/v produces an isotonic expansion of the extracellular fluid compartment which may result in oedema. The concentration of sodium in plasma is usually normal. Hypernatraemia may occur when patients who are dependent on parenteral fluids are given isotonic saline without free water to replace daily water loss through the skin. Irritability, lethargy and weakness are early neurologic signs of acute hypernatraemia. Osmotically-induced water shifts decrease the intracellular fluid volume and result in dehydration of internal organs; cerebral dehydration may provoke convulsive activity and may lead to coma and death. With judicious use of intravenous saline therapy, these effects can be avoided.

Diuretics may be used to treat oedema resulting from isotonic expansion, and appropriate replacement therapy should be employed to avoid fluid and electrolyte imbalance. Treatment of hypervolaemic hypernatraemia requires removal of sodium in excess of water and can be achieved by replacing diuretic-induced sodium and water losses with only water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

**5. PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties**

Sodium Chloride Intravenous Infusion 0.9% w/v is a sterile solution of physiological saline containing approximately 150mmol of sodium and chloride per litre.

## PATIENT INFORMATION LEAFLET

**Sodium Chloride 0.9%w/v Injection BP**

Please read this leaflet carefully. It provides a summary of information about the product you may be about to use or be given by your doctor. Keep this leaflet you may need to read it again.

**WHAT IS SODIUM CHLORIDE 0.9%w/v INJECTION BP?**

Sodium Chloride 0.9%w/v Injection BP is a sterile solution and is presented in polyethylene ampoules (Mini-Plasco®), in packs of 10 or 100 ampoules.

- A 5ml ampoule contains: 5ml of water and 0.045g of sodium chloride.
- A 10ml ampoule contains: 10ml of water and 0.09g of sodium chloride.

**WHAT IS SODIUM CHLORIDE 0.9%w/v INJECTION BP USED FOR?**

Sodium Chloride 0.9%w/v Injection BP is mainly used to dissolve (and dilute) drugs acting as a carrier solution for injectable drugs. It is used as a saline washout solution during surgical procedures. It is also used as a medium of cleaning and preparing equipments for dialysis of blood and as a solution to initiate and terminate blood transfusions.

**BEFORE YOU USE SODIUM CHLORIDE 0.9%w/v INJECTION BP**

Check the solution in the ampoule is clear and colourless. Do not use the solution if it is not clear or colourless. Check the ampoule is intact. Do not use the solution if the ampoule is not intact.

This solution may be used during pregnancy and breast-feeding as it is almost similar to normal body fluids.


**HOW TO USE SODIUM CHLORIDE 0.9%w/v INJECTION BP**

Sodium Chloride 0.9%w/v Injection BP is used to first dissolve a drug, it is then injected into the body via a vein or as per the recommended route of administration of the dissolved drug.

Always use Sodium Chloride 0.9%w/v Injection BP exactly as your doctor has told you.

- If you miss a dose: follow the advice given to you by your doctor.
- If you take too much Sodium Chloride 0.9%w/v Injection BP contact your pharmacist or doctor.

Item Code to go here

GOLDSHIELD 	
Product:	Sodium Chloride 0.9% Plastic
Country:	UK
Component:	SPC/ Leaflet
Version:	3(Aguttant Req. by Patricia)
Originated:	14/2/2007
Size:	148 x 420mm
SKU No:	ISC015105LF/0406/A ISC015010LF/0406/A
Item Code:	N/A
Pharma Code:	
Crease Code:	
Origination by:	Kaustubh
Revision by:	Poonam
Revision date:	07/6/2007
Cols:	PMS 280 and Black
Account handler:	Sameer Mehta
A/Work sign Off:	
Final signatures:	
Date:	
Black	PMS 280

Pharma Code

**5.2 Pharmacokinetic properties**

Sodium chloride is well absorbed from the gastro-intestinal tract. Sodium is predominantly excreted via the kidneys and renal reabsorption of sodium is extensive. Small amounts of sodium are excreted in the faeces and in sweat.

**5.3 Preclinical safety data**

No relevant information other than that which is shown in other sections of the Summary of Product Characteristics.

Pharma Code: 280

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of Excipients**

Water for injections.

**6.2 Incompatibilities**

The addition of sodium chloride to mannitol 20% or 25% may cause precipitation of the mannitol. Do not add any other agent to this solution unless compatibility is known.

**6.3 Shelf life**

2 years.

Use immediately after first opening of the ampoule. Discard unused contents.

**6.4 Special Precautions for Storage**

Do not store above 25°C.

Do not refrigerate.

**6.5 Nature and contents of container**

5ml or 10ml hermetically sealed translucent plastic ampoules, polyethylene Ph. Eur. packed in cardboard cartons to contain 10 or 100 ampoules.

**6.6 Instructions for Use and handling**

For parenteral administration, or as appropriate to the reconstituted drug.

Solutions containing visible solid particles should not be used.

If only part of the ampoule is used, discard the remaining solution.

Keep out of the reach and sight of children.

**7. MARKETING AUTHORISATION HOLDER**

Antigen International Ltd,  
Roscrea  
County Tipperary  
Ireland.

**8. MARKETING AUTHORISATION NUMBER**

PL 02848/0227

**9. DATE OF APPROVAL/REVISION OF SPC**

March 2007.

GOLDSHIELD		Antigen Pharmaceuticals	
Product:	Sodium Chloride 0.9% Plastic		
Country:	UK		
Component:	SPC/ Leaflet		
Version:	3 (Aquetant Req. by Patricia)		
Originated:	14/2/2007		
Size:	148 x 420mm		
SKU No:	ISC015105LF/0406/A ISC015010LF/0406/A		
Item Code:	N/A		
Pharma Code:			
Crease Code:			
Origination by:	Kautubh		
Revision by:	Poonam		
Revision date:	07/6/2007		
Cols:	PMS 280 and Black		
Account handler:	Sameer Mehta		
A/Work sign Off:			
Final signatures:			
Date:	PMS		
Black	280		



Date of issue: March 2007  
Antigen International Limited,  
Roscrea, Co. Tipperary, Ireland.

**SIDE EFFECTS**

Along with desirable effects, a medicine may cause unwanted effects. It is very rare to experience side effects from Sodium Chloride 0.9%w/v Injection BP. If Sodium Chloride 0.9%w/v Injection BP is injected under the skin it can sometimes cause pain at the site of injection. If you experience severe pain after injection of Sodium Chloride 0.9%w/v Injection BP under the skin contact your doctor. If you experience any side effects inform your doctor or pharmacist.

The main cause of side effects would be the medication prescribed by your doctor for use with Sodium Chloride 0.9%w/v Injection BP. Please read the information leaflet for the medicine prescribed to you by your doctor to check for possible side effects.

**STORING SODIUM CHLORIDE 0.9%w/v INJECTION BP**

Keep Sodium Chloride 0.9%w/v Injection BP and all medicines out of the reach and sight of children. Do not store above 25°C. Do not refrigerate. Do not use Sodium Chloride 0.9%w/v Injection BP after the expiry date shown on the label and carton.

- Use immediately after opening the ampoule.
- Discard any unused contents.

**FURTHER INFORMATION**

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. This leaflet should be read in conjunction with the SPC (Summary of Product Characteristics) leaflet included in this pack.

The Marketing Authorisation holder is Antigen International Limited, Roscrea, Co. Tipperary, Ireland.

PL No : PL 02848/0227

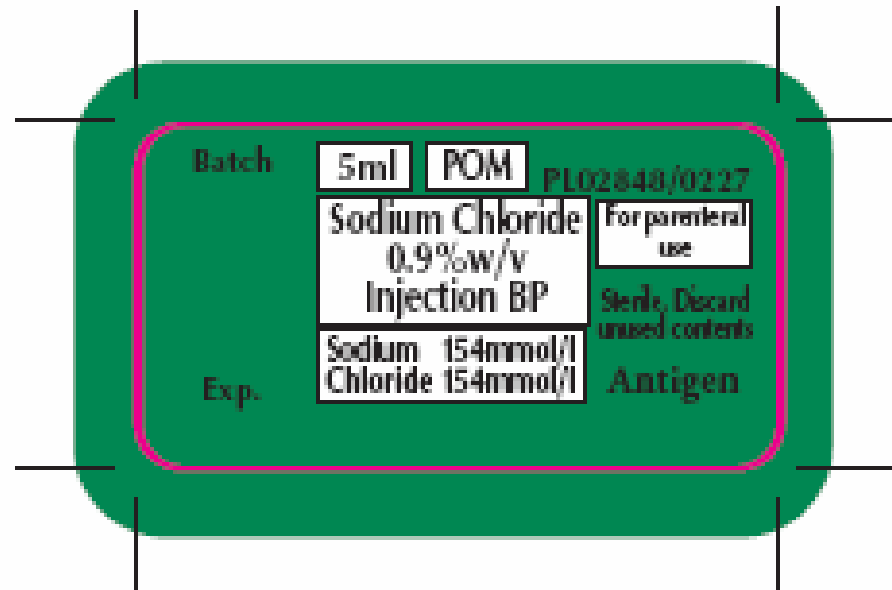
The company responsible for manufacture is Aquetant, Parc Scientifique Tony Garnier-Rhône, 1 rue Alexander Fleming, BP1744, 69353 Lyon Cedex 07, France.

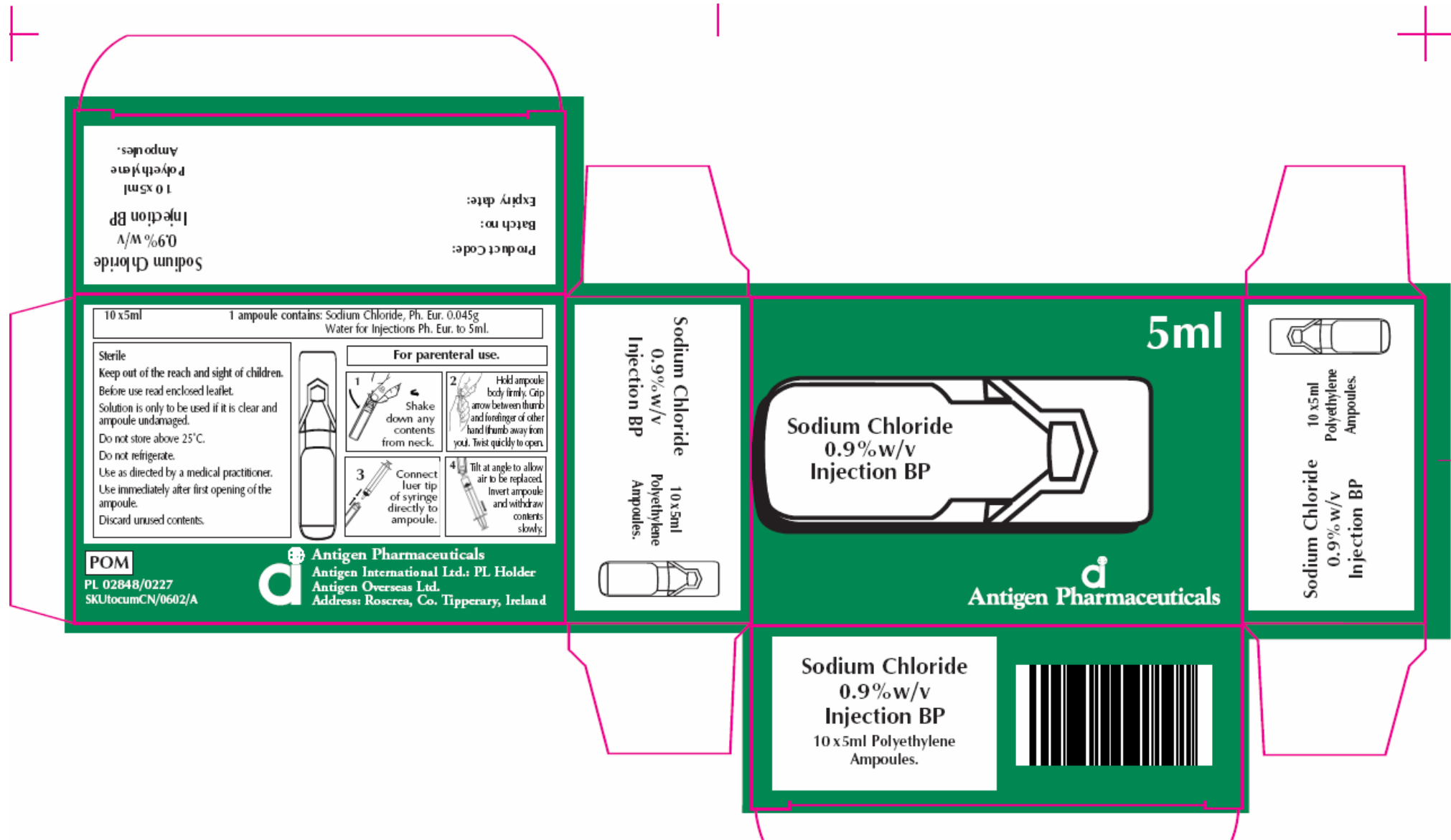
Pharma Code: 280



Antigen International Limited, Roscrea, Co. Tipperary, Ireland.


Date of issue: June, 2007.  
ISC015105LF/0406/A, ISC015010LF/0406/A






**Sodium Chloride**  
0.9%w/v  
Injection BP

100 x 5ml  
Polyethylene  
Ampoules.




**Sodium Chloride**  
0.9%w/v  
Injection BP



**Sodium Chloride**  
0.9%w/v  
Injection BP

100 x 5ml  
Polyethylene  
Ampoules.




**5ml**

**Antigen Pharmaceuticals**

**Sodium Chloride**  
0.9%w/v  
Injection BP

100 x 5ml  
Polyethylene  
Ampoules.




**For parental use.**

100x5ml  
1 ampoule containing  
Sodium Chloride Ph. Eur. 0.045g  
Water for Injection Ph. Eur. 5ml.


**STERILE**

Keep out of the reach and sight of children.  
Before use read enclosed leaflet.  
Solution is only to be used if it is clear and ampoule undamaged.  
Do not store above 25°C.  
Do not refrigerate.  
Use as directed by a medical practitioner.  
Use immediately after first opening of the ampoule.  
Discard unused contents.



**Sodium Chloride**  
0.9%w/v  
Injection BP

100 x 5ml  
Polyethylene  
Ampoules.




**Product Code:**  
Sodium Chloride  
Injection BP  
0.9%w/v  
100 x 5ml  
Polyethylene Ampoules

**1** Shake down any contents from neck.

**2** Hold ampoule body firmly cupping thumb and fingers other hand. Pull sharply to open.


**3** Connect user tip of syringe directly to ampoule.

**4** Tilt at angle to allow residual air to be withdrawn completely.

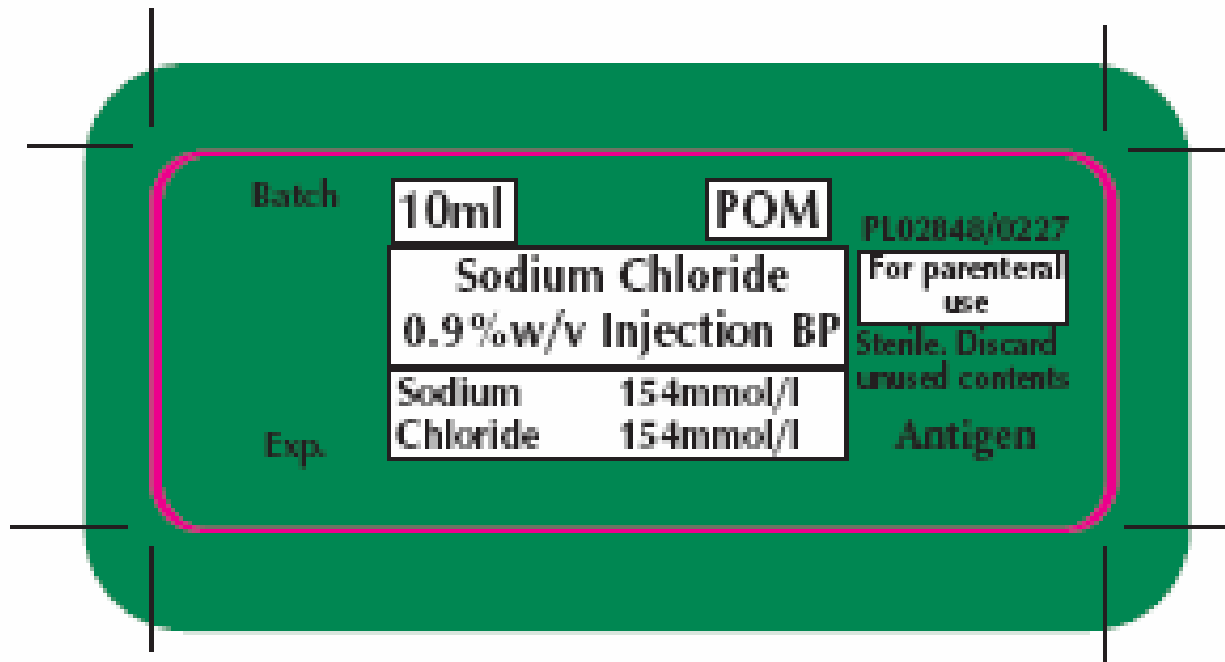


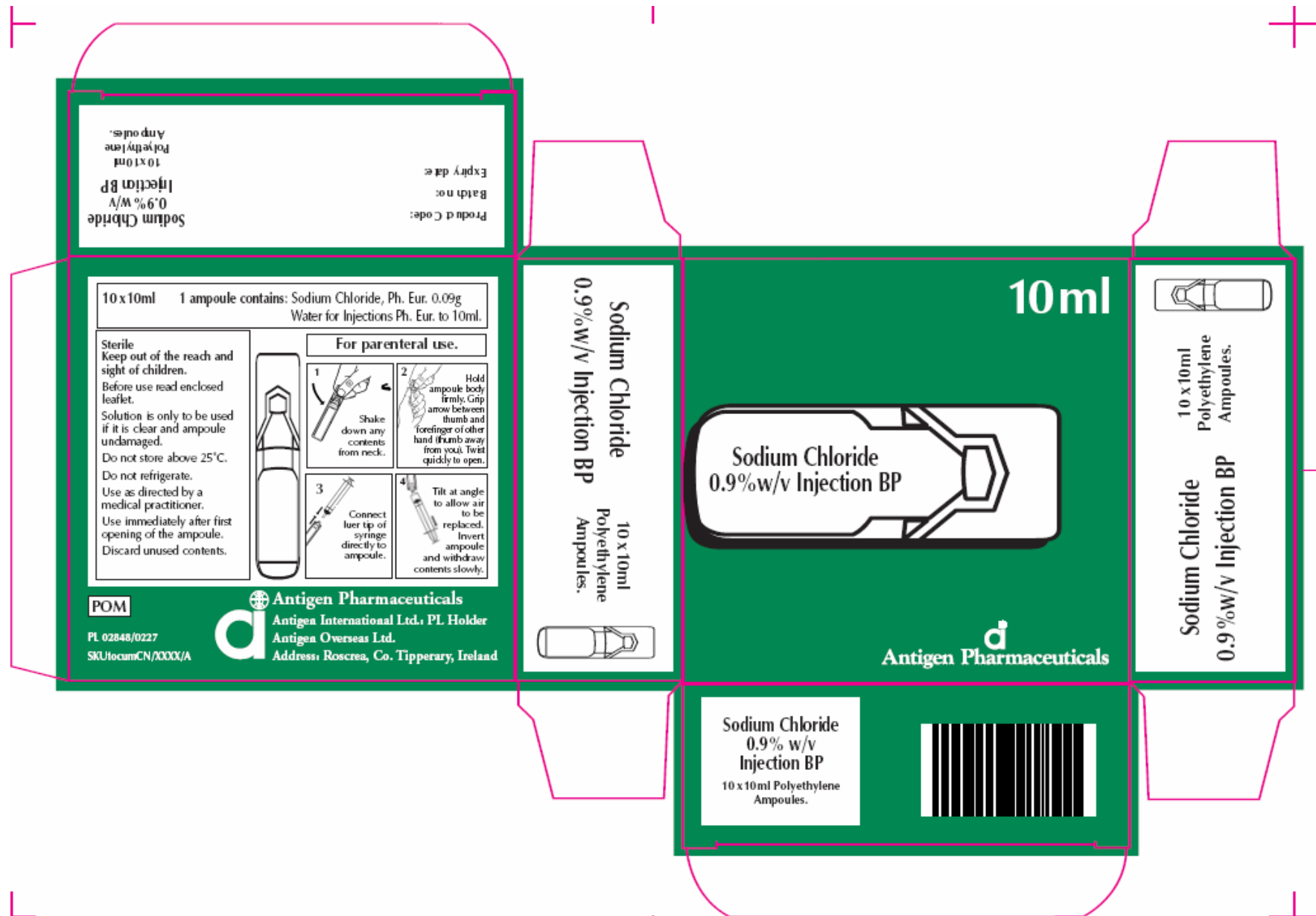
**Antigen Pharmaceuticals**  
Antigen-Oncology Ltd., Ph. Holder  
Address: Boreen, Co. Tipperary, Ireland.

**FCM**  
R. O'SHEA  
Antigen-Oncology Ltd.




21

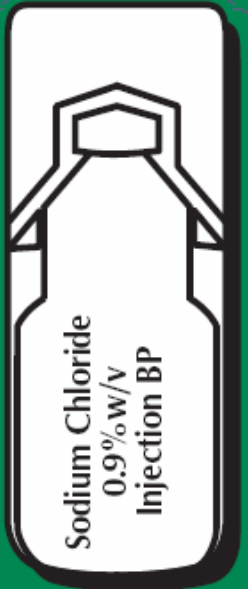




**Sodium Chloride 0.9% w/v Injection BP**  
100 x 10ml  
Polyethylene Ampoules.




**Antigen Pharmaceuticals**



**Sodium Chloride 0.9% w/v Injection BP**

**10ml**

**Sodium Chloride 0.9% w/v Injection BP**  
100 x 10ml  
Polyethylene Ampoules.




**Sodium Chloride 0.9% w/v Injection BP**  
100 x 10ml  
Polyethylene Ampoules.

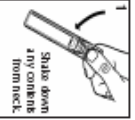

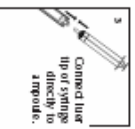

**Sterile**  
Keep out of the reach and sight of children.  
Before use read endorsed leaflet.  
Solution is only to be used if it is clear and ampoule undamaged.  
Do not store above 25°C.  
Do not refrigerate.  
Use as directed by a medical practitioner.  
Use immediately after first opening of the ampoule.  
Discard unused contents.

**For parenteral use.**

100 x 10ml  
1 ampoule contains  
Sodium Chloride, Ph. Eur. 0.09g  
Water for Injections Ph. Eur. 10.0ml



1. Break ampoule at score.
2. Tilt at angle to allow air to be displaced.
3. Connect the tip of syringe directly to ampoule.
4. Shake down any contents from neck.

**POW**  
Antigen Pharmaceuticals  
Antigen International Ltd, P.O. Box 144  
Antigen, Osney Mead, Oxford, OX2 0EL  
Address: Boreham, Co. Tipperary, Ireland

