# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% w/v Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solvent contains 9mg sodium chloride.

For excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for Injection

A clear, colourless, sterile aqueous solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For use as a solvent for freeze dried products.

### 4.2 Posology and method of administration

Usually 1ml as a solvent for injection.

### 4.3 Contraindications

None stated.

### 4.4 Special warnings and precautions for use

Each unit should be discarded after a single use.
Do not use if solution contains particles.

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

None stated.

### 4.6 Pregnancy and lactation

This solution does not present any hazard to pregnant women, to the foetus or to the breast-fed child.

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

None stated.

## 4.8 Undesirable effects

None stated.

## 4.9 Overdose

Administration of quantities which may have adverse effects (i.e. over 3 litres) is very unlikely when each unit contains 1ml of solution only.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Solutions of sodium chloride closely approximate the composition of the extracellular fluid of the body; more than 90% of the cation of the extracellular fluid is sodium and more than 60% of the anion is chloride. Furthermore a 0.9% solution of sodium chloride is approximately isotonic with body fluids. Thus an injection of 0.9% sodium chloride will not appreciably affect the osmotic pressure of the body or the chemical composition of the extracellular fluid. A 0.9% solution of sodium chloride is therefore the choice of solvent for many drugs which have to be administered parenterally. The solution has the added advantage of being nonirritating to tissue.

## 5.2 Pharmacokinetic properties

Not appropriate.

## 5.3 Preclinical safety data

No special particulars.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Hydrochloric acid
Sodium hydroxide
Water for injections

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

5 years.

## 6.4 Special precautions for storage

Do not store above 25°C.
Store the ampoule in the outer container.

Discard any remaining contents after a single use.

## 6.5 Nature and contents of container

1 ml clear Type I Ph. Eur. glass ampoule containing 1 ml of solution.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Only to be used if the solution is clear and does not contain particles.

## 7 MARKETING AUTHORISATION HOLDER

Organon Laboratories Limited
Cambridge Science Park
Milton Road
Cambridge, CB4 0FL
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA 261/29/1

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

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Date of last renewal: 20 September 2005

## 10 DATE OF REVISION OF THE TEXT

February 2006