

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE MEDICINAL PRODUCT**

Water for Injections BP 1.2ml, 2ml, 5ml, 10ml and 20ml glass ampoules.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Water for Injections BP/Ph. Eur. 1.2ml, 2ml, 5ml, 10ml and 20ml ampoules.

### **3. PHARMACEUTICAL FORM**

Solvent for parenteral use.

Clear, colourless, odourless, sterile solution intended for parenteral administration to human beings.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the reconstitution, dilution and making-up of appropriate drugs where Water for Injections is the diluent of choice, and for use as an irrigant.

#### **4.2 Posology and method of administration**

Route of administration: As appropriate to the reconstituted drug.

Dosage: In accordance with the particular situation for which Water for Injections BP is being used.

#### **4.3 Contra-indications**

None known.

#### **4.4 Special warnings and special precautions for use**

None known.

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

None known.

#### **4.6 Pregnancy and lactation**

May be used during this period.

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

None known.

#### **4.8 Undesirable effects**

None known.

#### **4.9 Overdose**

No effects anticipated with the proposed use.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Not applicable.

#### **5.2 Pharmacokinetic properties**

Not applicable.

#### **5.3 Preclinical safety data**

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

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Not applicable.

#### **6.2 Incompatibilities**

Water for Injections BP should not be mixed with any other agents unless their compatibility has been established.

#### **6.3 Shelf life**

5 years (60 months).

If only part of the contents of an ampoule is used, the remaining solution should be discarded.

#### **6.4 Special precautions for storage**

Keep the container in the outer carton in order to protect from light.

Do not store above 25°C.

#### **6.5 Nature and contents of container**

1.2ml, 2ml, 5ml, 10ml and 20ml clear glass ampoules, glass, type 1 Ph. Eur. borosilicate glass packed in cardboard cartons to contain 10 ampoules.

#### **6.6 Instructions for use/handling**

Not applicable.

**7. MARKETING AUTHORISATION HOLDER**

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

**8. MARKETING AUTHORISATION NUMBER**

PL 02848/5924R.

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

Date of first PL : 26 September 1986  
Date of last renewal : 08 February 1999

**10. DATE OF (PARTIAL) REVISION OF TEXT**

March 2008