

**1. NAME OF THE MEDICINAL PRODUCT**

Water for Injections B.P. 2ml, 5ml, 10ml & 20ml.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 1ml of solution contains 1ml of Water for Injections B.P.

**3. PHARMACEUTICAL FORM**

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 : For S.C., I.M. or IV. injection, or as appropriate to the reconstituted drug.  
Dosage : In accordance with the particular situation for which Water for Injections B.P. is being used.

**4.3. Contra-Indications**

None known.

**4.4. Special Warnings and Special Precautions for Use**

None.

**4.5. Interactions 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.

**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. Pre-clinical 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 B.P. should not be mixed with any other agents unless their compatibility has been established.

#### **6.3. Shelf Life**

3 years.

#### **6.4. Special Precautions for Storage**

Do not store above 25°C.

#### **6.5. Nature and Content of Container**

2ml, 5ml, 10ml and 20ml hermetically sealed translucent plastic ampoules, polypropylene Ph.Eur., packed in cardboard cartons to contain 10, 20, 50 and 100 ampoules.

#### **6.6. Instructions for Use, Handling and Disposal**

For S/C, I/M or I/V Injection or as appropriate to the reconstituted drug.  
If only part of an ampoule is used, discard the remaining solution.  
Use as directed by the physician.  
Keep out of reach of children.

**7.     MARKETING AUTHORISATION HOLDER**

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

**8.     MARKETING AUTHORISATION NUMBER**

PL 2848/0152.

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

Date of first authorization : 10/10/91.

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

August 2001