



## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **PRODUCT SUMMARY**

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

Water for Injections BP.

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

Each ml contains 100% Water for Injections Ph. Eur.

#### **3. PHARMACEUTICAL FORM**

Sterile injection.

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

Water for Injections BP is used as a solvent and diluent for injectable medicines.

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

Water for Injections BP is administered by Intravenous Injection.  
Dosage for Adults (including the elderly) and Children:- as required, by intravenous injection.

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

None known.

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

None known.

##### **4.5 Interactions with other medicinal products and other forms of interactions**

None known.

**4.6 Pregnancy and lactation**

None known.

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

None known.

**4.8 Undesirable effects**

None known.

**4.9 Overdose**

None known.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Water for Injections BP is used as a solvent and diluent for injectable medicines.

**5.2 Pharmacokinetic properties**

Not Applicable.

**5.3 Preclinical safety data**

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

**6. Pharmaceutical Particulars**

**6.1 List of excipients**

None.

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

60 months.

**6.4 Special precautions for storage**

Do not store above 25° C.

**6.5 Nature and contents of container**

Type I clear glass ampoules, 2ml, 5ml, 10ml and 20ml packed in cardboard cartons to contain 10 ampoules.

Type II clear glass vials, 1ml, 2ml, 10ml, 20ml, 30ml, 50ml, 100ml and 200ml, with a bromobutyl rubber stopper. Plastic outer cap and inner aluminium ring packed in cardboard cartons to contain either 10 vials or 25 vials.

**6.6 Instructions for use, handling and disposal**

Use as directed by a physician. Only to be used as a diluent.

**ADMINISTRATIVE DATA**

**7. MARKETING AUTHORISATION HOLDER**

hameln pharmaceuticals ltd  
Gloucester  
UK

**8. MARKETING AUTHORISATION NUMBER**

PL 01502 / 0003R

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

27th June 1986/ 6<sup>th</sup> May 2005

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

21<sup>st</sup> June 2004