

## **PACKAGE INSERT TEMPLATE FOR WATER FOR INJECTION**

### **Brand or Product Name**

*[Product name]* Water for Injection

### **Name and Strength of Active Substance(s)**

Water for Injection ...ml

### **Product Description**

*[Visual description of the appearance of the product (eg colour etc)]*

*eg A clear, colourless, odourless, sterile solution.*

### **Pharmacodynamics & Pharmacokinetics**

Since Water for Injection is only a diluents and vehicle used for the administration of other pharmaceutical products, pharmacokinetic and pharmacodynamic properties depend on the nature of the drug being added.

### **Indication**

As diluent and vehicle for administration of medicaments

### **Recommended Dosage**

The dosage administered will be dictated by the nature of the medicines to be added /additive used.

The administration rate will be dependent upon the dose regimen of the prescribed drug.

### **Mode of Administration**

For parenteral use. The directions for use related to the added medicinal product will dictate the appropriate volumes as well as the administration route.

### **Contraindications**

None known

The contraindications related to the medicine that has been added should be taken into account.

*Updated October 2011*

## **Warnings and Precautions**

Water for Injection is hypotonic and therefore it should not be administered as is. It should not be used for intravenous infusion, unless the isotonicity has been adjusted using an appropriate agent. When Water for Injection is used for dilution of hypertonic solutions, the final solution should be isotonic.

Haemolysis may occur after infusion of large volume of hypotonic solution of water for injections. When large volumes of solutions of water for injections are administered, electrolyte balance should be checked regularly.

## **Interactions with Other Medicaments**

None known

Possible clinical interactions of the medicines that are to be dissolved in or diluted with Water for Injection should be confirmed before use

## **Statement on Usage During Pregnancy and Lactation**

Water for Injections should only be used if expected benefit outweighs possible risk

Risks of use during pregnancy and lactation depend on the nature of the medicine that has been added

## **Adverse Effects / Undesirable Effects**

Administration of Water for Injection as it is (without the addition of solute) may result in cell damage due to haemolysis / hypotonic effects.

The product information and nature of the additive; any drug or substance used with Water for Injections must be consulted before use as it will determine the likelihood of any undesirable effects.

## **Overdose and Treatment**

No effects anticipated with the proposed use. Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile Water for Injections as diluent. The signs and symptoms of overdose will also be related to the nature of the medicinal product being added. In the event of accidental overdose, the treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the medicinal product administered.

## **Incompatibilities**

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

*Updated October 2011*

## **Instructions for use and handling**

Before addition of other medicines, please confirm that they are:  
-soluble and stable in water at the pH value of Water for Injection  
-compatible with each other

Discard any unused portion.

Use only if the solution is clear and free of any visible/ foreign particles and the container is not damaged.

Once opened should be used immediately. It is necessary that any medicine has been added and completely dissolved under aseptic conditions. Freshly prepared solutions are recommended to be used; otherwise they should be prepared under controlled aseptic conditions.

## **Storage Conditions**

*[ eg Store below.... °C ]*

## **Dosage Forms and Packaging Available**

*[Packaging type & pack size]*

## **Name and Address of Manufacturer**

*[ Name & full address of manufacturer ]*

## **Name and Address of Marketing Authorization Holder**

*[ Name & full address of marketing authorization holder ]*

## **Date of Revision of Package Insert**

*[ day/month/year ]*

*Updated October 2011*