

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

TOR-BAC ®

Bacteriostatic saline for injection

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains sodium chloride, 0.9% w/v

Excipients with known effect:

Each vial contains 9mg/ml (0.9% w/v) benzyl alcohol

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Sterile solution

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

This product is intended as a diluent for certain medications.

#### 4.2 Posology and method of administration

Parenteral use.

#### 4.3 Contraindications

Hypersensitivity to benzyl alcohol.

This medicinal product must not be administered to infants born recently or prematurely because it contains benzyl alcohol. It may provoke toxic and anaphylactoid reactions in children under 3 years of age, and so should not be used in infants and children up to 3 years of age.

#### 4.4 Special warnings and precautions for use

The solvent contains the preservative benzyl alcohol, which may cause anaphylactoid reactions.

Intravenous administration of the preservative benzyl alcohol has been associated with serious adverse events, and death in paediatric patients including neonates characterized by central nervous system depression, metabolic acidosis, gasping respirations, cardio-vascular failure and haematological anomalies (“gasping syndrome”).

The minimum amount of benzyl alcohol at which toxicity may occur is not known.

Use only if it is necessary and if there are no alternatives possible. If given in high volumes, should be used with caution and preferably for short term treatment in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

Premature and low-birth weight infants may be more likely to develop toxicity.

Benzyl alcohol containing products should not be used in pre-term or full-term neonates unless strictly necessary because of the risk of severe toxicity including abnormal respiration (“gaspingsyndrome”).

Benzyl alcohol can cross the placenta and has the potential for toxicity in the newborn. Medicines containing benzyl alcohol should therefore be avoided in pregnant women at or near term (see section 4.6).

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

Not applicable.

#### **4.6 Fertility, pregnancy and lactation**

Benzyl alcohol can cross the placenta (see section 4.4).

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

Not applicable.

#### **4.8 Undesirable effects**

Benzyl alcohol is contained in the diluent and has been reported to be associated with a fatal "gaspingsyndrome" in premature infants.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Not applicable.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Solvents and diluting agents, incl. irrigating solutions, ATC code: V07AB

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of this Summary of Product Characteristics.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Benzyl alcohol Ph. Eur.

Water for injections Ph. Eur.

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

2 years

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

Store below 25°C. Discard any remaining solution after use.

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

The product is presented in 5mL glass ampoules.

Number of ampoules per carton – 10 x 5ml

### **6.6 Special precautions for disposal**

Not applicable

## **7 TOR Generics Ltd**

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## **8 MARKETING AUTHORISATION NUMBER(S)**

Tba