

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Hydrogen Peroxide 6% (20 Vol) BP  
Purico 6% w/v Solution  
Hydrogen Peroxide 6% w/v Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 60 mg of Hydrogen Peroxide BP, equivalent to 6% w/v (20 vol)

## 3 PHARMACEUTICAL FORM

For cutaneous or oromucosal use  
Solution

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

As a gargle or mouthwash.  
As mild disinfectant for minor cuts, wounds and skin ulcers.

### 4.2 Posology and method of administration

#### Posology

#### As a gargle or mouthwash:

Dilute one part of peroxide to five parts of water. Rinse the mouth for two to three minutes. This may be repeated up to three times daily.

As mouthwash or gargle the product is suitable for adults, elderly and children over 12. Due to the risk of swallowing it should only be used by younger children under the instruction of a doctor.

#### As disinfectant:

Use as required. Dress the wound with a wound dressing soaked in a solution of equal parts of peroxide and water. As disinfectant this product is suitable for use by adults, children and elderly.

### **4.3 Contraindications**

Hypersensitivity to active substance or to any of the excipients listed in section 6.1.

Not for use in closed body cavities or on surgical wounds due to the risk of oxygen released into the circulation causing gas embolism.

Not for use as a disinfection agent for surgical instruments (particularly endoscopes) and as an enema.

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

For external use only.

Not for use in closed body cavities or on surgical wounds due to risk of oxygen released into the circulation causing gas embolism.

Avoid normal skin.

Product bleaches fabric.

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

None known.

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

No effects during pregnancy or breastfeeding are anticipated, since systemic exposure to hydrogen peroxide is negligible

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

Not relevant.

### **4.8 Undesirable effects**

Cases of gas embolism, sometimes resulting in cardiac arrest, have been reported when hydrogen peroxide has been instilled in closed body cavities or deep surgical wounds.

Strong solutions of hydrogen peroxide produce irritating burns on the skin and mucous membranes with a white eschar. The pain disappears after about one hour.

Continued use of the product as a mouthwash may cause reversible hypertrophy of the papillae of the tongue.

#### 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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **4.9 Overdose**

Accidental ingestion may cause sore throat, gastric disturbances and vomiting. Sudden evolution of oxygen may cause injury by acute distension of the stomach and internal bleeding. Water may be given to drink. Ingestion of large volumes can lead to gas embolism following evolution of oxygen in the stomach.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Antiinfectives and antiseptics for local oral treatment, ATC code: A01AB02

Pharmacotherapeutic group: Other antiseptics and disinfectants, D08AX01

Hydrogen Peroxide readily releases oxygen when applied to tissues. The effect lasts only as long as the oxygen is being released and is of short duration. The antimicrobial effect of the liberated oxygen is reduced in the presence of organic matter. It is used to cleanse wounds and ulcers in concentrations of up to 6%.

Adhering and blood-soaked dressings may be released by the application of a solution of hydrogen peroxide. A 1.5% solution has been used as a mouthwash in the treatment of acute stomatitis and as a deodorant gargle.

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

None.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium acid pyrophosphate E450 (stabiliser)

Phenacetin

Water

### **6.2 Incompatibilities**

Incompatible with reducing agents including organic matter and oxidisable substances and with alkalis, iodides, permanganates, and other stronger oxidising agents. Its decomposition is increased by metallic salts, light, agitation, heat and metals.

**6.3 Shelf life**

3 Years

**6.4 Special precautions for storage**

Do not store above 25°C. Keep the container tightly closed to protect from light and moisture

**6.5 Nature and contents of container**

Opaque containers and lids 100ml, 175ml, 200ml and 2000ml

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Crescent Pharma Limited  
Key House, Sarum Hill,  
Basingstoke,  
RG21 8SR  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 20416/0571

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

04/02/2009

**10 DATE OF REVISION OF THE TEXT**

25/06/2024