

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Woodward's Gripe Water - Alcohol Free & Sugar Free

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Terpeneless Dill Seed Oil 2.3mg/5ml  
Sodium Hydrogen Carbonate 52.5mg/5ml

#### Excipients with known effects:

Sodium	15.73 mg (0.684mmol)/5ml
Propylene Glycol	200 mg /5ml
Maltitol	950 mg /5ml
Parahydroxybenzoates and their esters*	

\*nipasept sodium contains Sodium ethyl p-hydroxybenzoate (E215), Sodium propyl p-hydroxybenzoate (E217) and Sodium methyl p-hydroxybenzoate (E219).

For a full list of excipients see 6.1.

### 3 PHARMACEUTICAL FORM

Oral solution

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the symptomatic relief of distress associated with wind in infants up to one year old.

#### 4.2 Posology and method of administration

For oral use

Adults & the Elderly: Not applicable

Children:	1 - 6 months old	-	One 5ml spoonful
	6 - 12 months old	-	Two 5ml spoonsful
	Under one month old	-	Not to be used

Children aged 1 year and over: Do not use.

These doses may be given during or after each feed or up to six times in 24 hours.

### 4.3 Contraindications

Should not be used where impaired kidney function or hypersensitivity to hydroxybenzoates exists.

Hypersensitivity to dill seed oil, sodium hydrogen carbonate (sodium bicarbonate) or to any excipients in the product.

Patients with metabolic or respiratory alkalosis, hypocalcaemia, or hypochloraemia.

### 4.4 Special warnings and precautions for use

If symptoms persist, medical advice should be sought.

Keep all medicines out of the sight and reach of children.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Label must include equivalent sentences of:

This medicine contains hydroxybenzoate derivatives (E215, E217 and E219) which may cause allergic reactions (possibly delayed).

This medicinal product contains 15.73 mg sodium per 5 ml, equivalent to 0.8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This product is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

Do not use in children under 1 month.

This medicine contains 200 mg propylene glycol in each 5 ml which is equivalent to 200 mg/5 ml. Talk to your doctor or pharmacist before giving your child this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

This medicine contains maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. May have a mild laxative effect. Calorific value 2.3 kcal/g maltitol.

Maximum Daily Dose:

Sodium:	188.76 mg (8.21 mmol)
Propylene glycol for child aged 6 – 12 months**:	2400 mg
Propylene glycol for child aged 1 – 6 months***:	1200 mg
Maltitol liquid:	11.4 g

\*\* (343 mg/kg/day based on weight of 7 kg for a 6 month old)

\*\*\* (300 mg/kg/day based on weight of 4 kg for a 1 month old)

This medicine contains parahydroxybenzoates and their esters\* which may cause allergic reactions (possibly delayed).

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

A time-interval of 2 hours should be considered between intake of this product and the administration of other medicinal products.

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

Not applicable

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

Not applicable

#### **4.8 Undesirable effects**

Adverse events which have been associated with dill seed oil and sodium bicarbonate are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ( $\geq 1/10$ ); Common ( $\geq 1/100$  and  $< 1/10$ ); Uncommon ( $\geq 1/1000$  and  $< 1/100$ ); Rare ( $\geq 1/10,000$  and  $< 1/1000$ ); Very rare ( $< 1/10,000$ ); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
Immune System Disorders	Not known	Hypersensitivity

#### **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**

Symptoms following overdose are rare and are generally due to the effects of sodium hydrogen carbonate. These may include diarrhoea, metabolic alkalosis, hypokalaemia

and hypernatraemia. In the event of severe overdosing, medical advice should be sought immediately.

Symptoms of hypernatraemia may include drowsiness and irritability, pyrexia and tachypnoea, muscle weakness and arrhythmia. In more severe instances of acute sodium overload, signs of dehydration and convulsions may occur.

The treatment of metabolic alkalosis consists of correction of fluid and electrolyte balance.

The treatment of hypernatraemia includes repair of any dehydration present and gradual reduction of the plasma sodium. The alkalosis, if present, will respond usually to the treatment of hypernatraemia. At all times intensive monitoring of the electrolytes, and patients circulatory and central nervous system are necessary.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Sodium Hydrogen Carbonate has a well-established antacid action. Dill Seed Oil is a widely used aromatic carminative especially for use in the treatment of flatulence in children.

### **5.2 Pharmacokinetic properties**

Not applicable

### **5.3 Preclinical safety data**

Not applicable

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Glycerol

Propylene glycol

Maltitol Liquid

Nipasept (Sodium Methyl Parahydroxybenzoate, Sodium Ethyl Parahydroxybenzoate, Sodium Propyl Parahydroxybenzoate)

Disodium Edetate

Purified water

### **6.2 Incompatibilities**

None known

**6.3 Shelf life**

18 months unopened

14 days after opening

**6.4 Special precautions for storage**

Do not store above 25°C

**6.5 Nature and contents of container**

Clear, soda-lime-silica Type III pharmaceutical grade glass bottle with an expanded polyethylene wadded cap containing 150ml of product.

**6.6 Special precautions for disposal**

None

**7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) limited

103-105 Bath Road

Slough

Berkshire

SL1 3UH

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0698

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

30/11/1999

**10 DATE OF REVISION OF THE TEXT**

14/10/2025