## 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

### SCHEDULING STATUS

**S0**

### PROPRIETARY NAME AND DOSAGE FORM

**WOODWARD'S CELEBRATED GRIPE WATER** (liquid)

### COMPOSITION

Each 5 ml of WOODWARD'S CELEBRATED GRIPE WATER contains:

| | |
|---|---|
| Sodium bicarbonate | 50,00 mg |
| Dill Seed Oil, Terpeneless | 2,15 mg |

*Excipients:*

Alcohol, extract for ginger tincture, flavour spirits, Nipasept sodium, purified water, sucrose.

*Preservatives:*

| | |
|---|---|
| Nipasept Sodium | 0,1 % *m/v* |
| Contains alcohol | 4,4 % *v/v* |
| Contains sugar: Sucrose | 1,0 g |

### CATEGORY AND CLASS

A 11.4.3 Antacids - Acid neutralizers

## PHARMACOLOGICAL ACTION

### Pharmacodynamic properties

Acid neutralizing action and carminative.

## INDICATIONS

To comfort infants with gripes.

## CONTRAINDICATIONS

It is generally recommended that sodium bicarbonate should not be administered to patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria.

## WARNINGS AND SPECIAL PRECAUTIONS

Do not administer more than the recommended dose of this product, except under the advice and supervision of a doctor. Consult your doctor if there is no improvement after 24 hours.

Use with care in patients with renal failure.

*Effects on ability to drive and use machines*

Not known.

*Excipients*

*Sucrose warning:*

WOODWARD'S CELEBRATED GRIPE WATER contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take WOODWARD'S CELEBRATED

GRIPE WATER.

**INTERACTIONS**

May interfere with the absorption of other medicines given concomitantly.

Alkalinisation of the urine by sodium bicarbonate leads to increased renal clearance of acidic medicines.

**HUMAN REPRODUCTION**

Not known.

**DOSAGE AND DIRECTIONS FOR USE**

**Babies up to 12 months of age:** 5 ml not more than 3 to 4 times per 24 hour period. Do not give this medicine to babies with a body mass less than 2,5 kg.

**SIDE EFFECTS**

*Side effects of sodium bicarbonate:*

Can cause stomach cramps and flatulence.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS**

**Symptoms**

Overdosage may result in hypernatraemia and systemic alkalosis with the following signs and symptoms: restlessness, thirst, pyrexia, oliguria, hypotension, hyperpnoea and fluid retention.

**Treatment**

Treatment consists mainly of appropriate correction of fluid and electrolyte balance.

Further treatment is symptomatic.

## IDENTIFICATION

A clear, colourless to pale straw-coloured liquid.

## PRESENTATION

75 ml, 100 ml and 150 ml are packed into a clear, round glass bottle and sealed with a white polypropylene screw-on cap with an expanded polyethylene (EXPE) liner. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

## STORAGE INSTRUCTIONS

Store at or below 25 °C away from direct sunlight.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

## REGISTRATION NUMBER

E/11.4.3/1551

## NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE**

Date of registration: 19 October 1993

Date of the most recent amendment to the professional information as approved by the Authority:

19 October 1993

Botswana: B9316060 S4

Zimbabwe: H.R. 79/16.1/1249

ZA_WCGWLIQ_9310_03