

1. NAME OF THE MEDICINAL PRODUCT

Woodward's Gripe Water.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Terpeneless Dill Seed Oil 2.14mg/5ml

Sodium Bicarbonate 50mg/5ml

Ginger Tincture 0.368ml/5ml

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.

4.2 Posology and method of administration

Posology

For oral use

Adults & the Elderly: Not applicable

Children:	Newborn infants	-	2.5ml
	1 - 6 months old	-	5ml
	6 – 1 year old	-	10ml
	2 years and above	-	10ml – 15ml

These doses may be given during or after each feed or up to 8 times in 24 hours.

Method of administration

For oral use

4.3 Contraindications

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

4.4 Special warnings and precautions for use

If symptoms persist, medical advice should be sought.

Keep all medicines out of the reach of children.

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

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Not applicable

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

None known

4.9 Overdose

Symptoms following overdose are rare and are generally due to the effects of sodium bicarbonate. These may include diarrhoea, metabolic alkalosis 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. In more severe instances of acute sodium overload, signs of dehydration and convulsions may occur.

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 bicarbonate 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. Ginger is a carminative.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Bicarbonate
Terpeneless Dill Seed Oil
Ginger Tincture
Nipasol M. Sodium
Refined Sugar
Deionized Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Clear bottle with ROPP aluminium screw cap containing 100ml and 148ml of product.

6.6 Special precautions for disposal and other handling

None

7. APPLICANT/MANUFACTURER

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