



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

BOND GRIPE WATER

**(Dill 0.00239ml, Sodium Bicarbonate 50mg, Sodium
Citrate 0.05mg & Ginger Tincture 0.00215ml)**

1. Name of the medicinal product

Bond Gripe Water

2. Qualitative and quantitative composition

Dill Oil

Sodium Bicarbonate,

Sodium Citrate &

Ginger Tincture

For a full list of excipients see 6.1.

3. Pharmaceutical form

Oral Suspension

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

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

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.

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

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

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 and

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

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

Methyl Paraben BP

Propyl Paraben BP

Sodium Benzoate BP

Granulated Sugar BP

Ethanol BP

Peppermint Oil BP

Talcum BP (For filtration)

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

A sealed 100ml flint glass bottle with Bond Gripe water label and containing a clear free flowing peppermint-flavoured colourless liquid

6.6 Special precautions for disposal and other handling

None

7. Marketing authorisation holder

Bond Chemical Industries Limited

8. Manufacturer
Bond
Chemicals
Industrial
Limited,
Mushin, Lagos.