



## DR VAMIS GRIPE WATER (Dill Oil + Sodium Bicarbonate + Fennel Oil)

### Summary of Product Characteristics

#### 1. Name of the medicinal product

Dr Vamis Gripe Water

#### 2. Qualitative and quantitative composition

Each 5ml contains

Dill Oil 0.005ml

Sodium Bicarbonate 50mg

Fennel Oil 0.0007ml

For a full list of excipients see 6.1.

#### 3. Pharmaceutical form

Oral solution

A Clear colourless solution in a transparent bottle

#### 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 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 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.



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This medicine contains 200 mg propylene glycol in each 5 ml which is equivalent to 200 mg/5 ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them 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.

System Organ Class	Frequency	Adverse Events
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



## **DR VAMIS GRIPE WATER (Dill Oil + Sodium Bicarbonate + Fennel Oil)**

Symptoms following overdose are rare and are generally due to the effects of sodium hydrogen carbonate. 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 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, glass bottle with an expanded polyethylene wadded cap containing 200ml of product.



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6.6 Special precautions for disposal and other handling  
None

7. Marketing authorisation holder/MANUFACTURER

**TUYIL PHARMACEUTICAL INDUSTRIES LIMITED**  
NO 22, NEW YIDI ROAD ILORIN, KWARA STATE, NIGERIA