1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT AND THE INTERNATIONAL NON PROPRIETARY NAME OF PRINCIPLE(S) ACTIVE INGREDIENT(S)

Betas Gripe Water

International Nonproprietary Name of Principle Active Ingredients Sodium Bicarbonate and Terpenless Dill Seed Oil

1.1 Pharmaceutical Form

Liquid

1.2 Strength

Each 5ml contains Sodium Bicarbonate 50mg and Terpenless Dill Seed Oil 2.15mg

1.3 Presentation

A colourless to pale straw liquid odour and taste of dill seed oil.

1.4 Administrative Route

Oral Administration

2. QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCES AND EXCIPIENTS

2.1 Qualitative Composition

Active Substances

Sodium Bicarbonate and Terpenless Dill Seed Oil

Excipients

Sodium Propyl Para benzoate, Rectified Spirit, Sugar Syrup and Purified Water

2.2 Quantitative Composition

Component and quality standard (and grade, if applicable)	**Function**	**Strength (Label Claim)**			
		Each 5ml contains Sodium Bicarbonate 50mg and Terpenless Dill Seed Oil 2.15mg			
		Quantity per 5ml	**%**	**Quantity per 2000L**	**%**
Liquid					
Active Ingredient(s)					
Sodium Bicarbonate BP	Active	50.000mg	1.000	20.000Kg	1.000
Terpenless Dill Seed Oil BP	Active	2.150mg	0.043	0.860Kg	0.043
Excipients					
Sodium Propyl Para benzoate BP	Antimicrobial Preservative	2.500mg	0.050	1.000Kg	0.050
Rectified Spirit BP	Solvent	250.000mg	5.000	100.00Kg	5.000
Sugar Syrup BP	Sweetener	1.125ml	22.500	450.000L	22.500
Purified Water BP	Vehicle	Q.s. to 5ml	Q.s. to 100%	Q.s. to 2000L	Q.s. to 100%

Total		**5ml**	**100%**	**2000L**	**100%**

3. PHARMACOLOGICAL CLASS

3.1 Therapeutic Class

Therapeutic group: Ordinary Salt Combinations and Antiflatulents

ATC Code: A02AF02

3.2 Therapeutic Indications

Betas Gripe Water is used for relief of gripe, excess acid and flatulence, invaluable during teething.

3.3 Dosage and Administrative Route

Dosage

New born infants: 2.5ml

1 - 6 months: 5ml

6 months - 2 years: 10ml

2 years and over: 10ml – 15ml

Above doses should be given during or after feeding as required up to a maximum of 8 times daily.

Administrative Route

Oral Administration

3.4 Contraindications

There are no known contraindications to the use of Betas Gripe Water but it is generally recommended that Sodium Bicarbonate should not be administered to patients with metabolic or respiratory alkalosis.

However, patients with hypersensitivity should avoid taking Sodium Bicarbonate.

Betas Gripe Water should not be used where impaired kidney function or hypersensitivity to hydroxybenzoates exists.

3.5 Side Effects

No adverse effects have been reported. However, it is possible for patients with hypersensitivity to one of the ingredients to exhibit general allergic symptoms or in the most severe case an anaphylactic reaction.

3.6 Precautions and Warnings

Do not exceed the recommended dosage.

3.7 Precautions for Use during Pregnancy and Lactation

The safety of Sodium Bicarbonate during pregnancy and lactation has not been established but its use during these periods is not considered to constitute a hazard.

3.8 Precautions when Driving

Does not affect the ability to drive and use machines

3.9 Interaction with other Drugs and other Forms of Interaction

The effect of oral Bicarbonate compounds in raising intra-gastric pH may reduce or increase the rate and/or extent of absorption of a number of medicines. Alkalinisation of the urine leads to increased renal clearance of acidic drugs such as salicylates, tetracyclines and barbiturates. Conversely, it prolongs the half life of basic drugs.

Sodium Bicarbonate enhances lithium excretion.

3.10 What to do in case of Overdose

Symptoms following overdose are rare and are generally due to the effects of Sodium Bicarbonate. These may include diarrhoea, metabolic alkalosis and hypematraemia. 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.

Treatment of Sodium Bicarbonate Overdose

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.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic Properties

Sodium Bicarbonate

Sodium Bicarbonate is a systemic alkalizer which increases plasma bicarbonate, buffers excess hydrogen ion concentration, and raises blood pH, thereby reversing the clinical manifestations of acidosis. It is also a urinary alkalizer, increasing the excretion of free bicarbonate ions in the urine, thus effectively raising the urinary pH. By maintaining analkaline urine, the actual dissolution of uric acid stones may be accomplished.

Sodium Bicarbonate has antacid properties and neutralises gastric acid with the production of carbon dioxide. Any bicarbonate ions not involved in that reaction are absorbed and in the absence of a deficit of bicarbonate in the plasma, are excreted in the urine, which is rendered alkaline and there is an accompanying diuresis.

Terpenless Dill Seed Oil

Dill seed oil is a widely aromatic carminative especially for use in the treatment of flatulence in children.

Dill plant has shown appetite-stimulating property. The extracts exhibit a marked decrease in total gastric acid together with an increase in pH values. As the fruit of dill has an antispasmodic effect on the smooth muscles of the gastrointestinal tract.

4.2 Pharmacokinetic Properties

Sodium Bicarbonate causes neutralisation of gastric acid with the production of carbon dioxide. Any bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine that is rendered alkaline and there is an accompanying diuresis.

4.3 Preclinical Safety Data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

5. PHARMACEUTICAL PARTICULARS

5.1 Duration of Stability for Reconstituted Forms if necessary before and after reconstitution of the product

Not Applicable

5.2 Storage Conditions

Store in a cool dry place below 30^0C away from direct light

5.3 Nature of Primary Packaging

The primary pack is 60ml amber coloured PET bottle. The secondary pack is chipboard unit carton

5.4 Shelf Life

36 months

5.5 Registration for a Poisons List

Not Applicable

6. MANUFACTURING SITE ADDRESSES

Name: BETA HEALTHCARE INTERNATIONAL LTD

Address: Plot No. LR 209/6554, Mogadishu Road, Off Lung Lunga, Industrial Area, Nairobi

P.O. BOX 42569-00100 GPO Nairobi

Country: KENYA

Telephone: +254 20 2652042/89

Telefax: +25420556198 / 2944

E-Mail: info@ke.betashelys.com

7. DATE OF REVISION OF THE TEXT

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