



SmPC (Summary of Product Characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Krishat Gripe Water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Sodium Bicarbonate BP 50mg

Terpene less Dill oil BP 2.14mg

Ginger Tincture 0.368ml

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Krishat Gripe water is indicated in the relief of:

- Intestinal gas (flatulence)
- Digestive upsets
- Colic
- Discomfort of teething
- Hiccups
- Wind and griping pains

4.2 Posology and method of administration

Posology

For new born babies: 2.5ml

1 to 6 months: 5ml

6 months to 1year: 10ml

1year and above : 10ml-15ml

It can be given during or after each feed or up to six times in 24 hours.

Method of administration Oral
administration only.



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4.3 Contraindications

Contraindicated in pregnancy and hypersensitivity to Krishat Gripe water.

4.4 Special warnings and precautions for use

Hypersensitivity to Krishat Gripe Water is a contraindication. In addition, Krishat Gripe water should not be used

if you have the following conditions:

- Allergic reactions
- Congestive heart failure
- Decreased amount of urine or no urine
- Difficulty in respiration
- Exposure to estrogen
- Fluid retention
- Hypertension
- Kidney problems
- Liver problems
- Low blood levels of calcium

4.5 Interaction with other medicinal products and other forms of interaction.

Aspirin, Barbiturates, Cytochrome P450 3A4, Lithium, Memantine, Prednisone, Quinidine, Salicylates

4.6 Pregnancy and Lactation

Pregnancy:

It's unsafe to use dill in medicinal amounts if you are pregnant. Dill seed can start menstruation and that might lead to a miscarriage.

Using ginger during pregnancy is controversial. There is some concern that ginger might affect fetal sex hormones. There is also a report of miscarriage during week 12 of pregnancy in a woman who used ginger for morning sickness. However, studies in pregnant women suggest that ginger can be used safely for morning sickness without harm to the baby. The risk for major malformations in infants of women taking ginger does not appear to be higher than the usual rate

of 1% to 3%. Also there doesn't appear to be an increased risk of early labor or low birth weight. There is some concern that ginger might increase the risk of bleeding, so some experts advise against using it close to your delivery date. As with any medication given during pregnancy, it's important to weigh the benefit against the risk. Before using ginger during pregnancy, talk it over with your healthcare provider.

Lactation:

If given too soon after birth, gripe water may hinder breast-feeding and delay milk supply.



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4.7 Effects on ability to drive and use machines

If you experience drowsiness, dizziness, hypotension or a headache as side-effects when using Gripe Water Solution medicine then it may not be safe to drive a vehicle or operate heavy machinery.

4.8 Undesirable effects

Undesirable effects are skin rashes, breathing problems, swelling of the eyes and lips. Congestive heart failure, hyperosmolar syndrome, hypervolemic hyponatremia, and hypertension due to increased sodium.

4.9 Overdose

Symptoms

Symptoms following overdose are rare and are generally due to the effects of sodium hydrogen carbonate. These may include diarrhoea, metabolic alkalosis and hyponatremia. In the event of severe overdosing, medical advice should be sought immediately. Symptoms of hyponatremia may include drowsiness and irritability, pyrexia and tachypnoea. In more severe instances of acute sodium overload, signs of dehydration and convulsions may occur.

Treatment

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Krishat Gripe water is a liquid given to infants with colic, gastrointestinal discomfort, teething pain, reflux and other stomach ailments. Krishat Gripe water helps relieve the pain and discomfort associated with trapped wind in children who are under one year of age. It contains two main ingredients: sodium bicarbonate and Terpenes less dill seed oil. Sodium bicarbonate neutralizes excess acid. Terpenes less Dill seed oil warms and relaxes your baby's tummy and breaks down trapped air bubbles which are passed out as wind.

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

No additional data of relevance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, Sorbitol 70%, Sodium Methyl Paraben, Sodium propyl paraben, Sodium



KRISHAT PHARMA INDUSTRIES LIMITED
KM 15, LAGOS-IBADAN EXPRESSWAY, OPP. ORIENTAL FOODS,
IBADAN, OYO, NIGERIA

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Metabite sulphite, Dioctyl sodium sulfosuccinate, Sodium EDTA, Sodium Benzoate, Propylene Glycol, Bronopol, Caramel Colour & Flavour.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C, Protect from light and moisture.

6.5 Nature and contents of container

100 ml transparent round PET bottle with ROPP aluminum cap. In a carton with insert.

200 ml transparent flat PET bottle with ROPP aluminum cap. In a carton with insert.

6.6 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirement.

7 MANUFACTURER

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8. Applicant

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