

1. NAME OF THE MEDICINAL PRODUCT

Betasil Herbal Cough Syrup

Strength

Tolu Solution BP 0.56ml, Capsicum Tincture BPC 0.25ml, Creosote BPC '59 66.65mg, Anise Oil BP 13.89mg and Liquorice BP 25.00mg

Pharmaceutical Form

Oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative Declaration

Tolu Solution, Capsicum Tincture, Creosote, Anise Oil and Liquorice

Quantitative Declaration

Each 5ml contains: Tolu Solution BP 0.56ml, Capsicum Tincture BPC 0.25ml, Creosote BPC '59 66.65mg, Anise Oil BP 13.89mg and Liquorice BP 25.00mg

Excipient(s) with Known Effects

Sugar Syrup..... 0.215ml per 5ml

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

A greyish-brown liquid with a burning odour of creosote and a sweet taste followed by a burning sensation.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Betasil Herbal Cough Syrup is an antitussive that relieves dry irritating coughs and promotes expulsion of bronchial secretion. It also has demulcent effect that soothes the throat. It also has demulcent effect that soothes the throat.

Betasil Herbal Cough Syrup is used for the treatment of coughs and bronchitis and for symptomatic relief from colds and catarrh. It is especially effective in the treatment of persistent dry coughs and coughs which occur at night.

4.2 Posology/Dosage and Method of Administration

Posology/Dosage

Dosage:

Adults: 5mls every four hours.

Children: 5-14 years: 2.5ml every four hours.

To prevent coughs that occurs during the night take a dose half an hour before retiring to bed.

Method of Administration

Oral administration

4.3 Contraindications

There are no known contra-indications to the use of Betasil Herbal Syrup at the recommended dosage.

4.4 Special Warnings and Precautions for Use

Special Warnings

Do not exceed the recommended dosage.

Keep out of reach of children.

Precautions

If symptoms persist, medical advice should be sought.

Keep the medicine out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, Pregnancy and Lactation

Pregnancy

No clinical data on the effect of use during pregnancy.

Betasil Herbal Syrup should be used with caution during pregnancy.

Lactation

No clinical data on the effect of use during lactation.

Betasil Herbal Syrup should be used with caution during lactation.

4.7 Effects on Ability to Drive and use Machines

Does not affect the ability to drive and use machines

4.8 Undesirable 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.

4.9 Overdose

None known

Pharmacotherapeutic group: Expectorants; Combinations

ATC code: R05CA08

Mechanism of Action

The active pharmaceutical ingredients used in the manufacture of Betasil Herbal Cough Syrup are all herbal ingredients. They have no chemical properties. The following are the properties of the ingredients:

Tolu Solution

Tolu balsam is a sap-like substance that comes from the *Myroxylon balsamum* tree. It is a brownish, sticky, semisolid mass. An essential oil is also distilled from the balsam. The balsam contains a fairly large amount of benzyl and cinnamyl esters of benzoic and cinnamic acid (benzyl benzoate, benzyl cinnamate).

Tolu balsam contains ingredients that help break up congestion. Tolu Solution is extracted from the Tolu Balsam.

Tolu balsam is used as medicine. People take it for cough, bronchitis, and swollen airways. Some people inhale tolu balsam to treat hoarseness and croup.

Capsicum Tincture

Capsicum (also known as peppers) is a genus of flowering plants in the nightshade family *Solanaceae*. Its species are native to the Americas, where they have been cultivated for thousands of years.

The fruit of most species of *Capsicum* contains capsaicin (methyl-n-vanillylnonenamide), a lipophilic chemical that can produce a strong burning sensation (pungency or spiciness) in the mouth of the unaccustomed eater. Most mammals find this unpleasant, whereas birds are unaffected. The secretion of capsaicin protects the fruit from consumption by insects and mammals, while the bright colors attract birds that will disperse the seeds.

Capsicum has both anti-Irritant Properties and antioxidant Properties. It has the ability to ease upset stomach, ulcers, sore throats, spasmodic and irritating coughs, and diarrhea. *Capsicum* is a rich source of Vitamin A and C, which are both powerful antioxidants. These antioxidants help in fighting free radicals in the body and help in treating heart diseases, osteoarthritis, bronchial asthma, cataract etc.

Creosote

Creosote is a category of carbonaceous chemicals formed by the distillation of various tars and pyrolysis of plant-derived material, such as wood or fossil fuel. They are typically used as preservatives or antiseptics.

Creosote was first discovered in its wood tar form in 1832, by Carl Reichenbach, when he found it both in the tar and in pyroligneous acids obtained by a dry distillation of beechwood.

The two main kinds recognized in industry are coal-tar creosote and wood-tar creosote. The coal-tar variety, having stronger and more toxic properties, has chiefly been used as a preservative for wood; coal- The wood-tar variety has been used for meat preservation, ship treatment, and such medical purposes as an anaesthetic, antiseptic, astringent, expectorant, and laxative, though these have mostly been replaced by modern medicines.

Aniseed Oil

Anise is an essential oil in clear glass vial. As with all spices, the composition of anise varies considerably with origin and cultivation method. These are typical values for the main constituents: Moisture: 9-13%, Protein: 18%, Fatty oil: 8-23%, Essential oil: 2-7%, Starch: 5%, N-free extract: 22-28% and Crude fibre: 12-25%

The main use of anise in European herbal medicine was for its carminative effect, as noted by John Gerard in his Great Herball, an early encyclopedia of herbal medicine.

It acts as decongestant or expectorant; it helps in the elimination of congestion in the respiratory tract.

Liquorice

- Licorice Root

Liquorice root (*Glycyrrhiza*, U.S.P.; Licorice Root) consists of the dried peeled root and peeled underground stem of *Glycyrrhiza glabra*, Linn. (N.O. Leguminosae), and other species. *Glycyrrhiza*, U.S.P., may be obtained from either *G. glabra* or *G. glandulifera*; the latter contains an amorphous bitter substance named glycyramarin.

Peeled Spanish liquorice root occurs in long cylindrical pieces, varying usually from 1 to 2 centimetres in thickness. Its surface is yellow in colour, and nearly smooth, but somewhat fibrous, owing to the exposure of the bast fibres caused by the peeling. The fracture is fibrous in the bark and splintery in the wood. A smoothed transverse section appears dense, and exhibits a yellow radiate wood, with large vessels, and very numerous medullary rays; it also exhibits a comparatively wide bark, containing numerous radially arranged yellowish groups of strongly thickened bast fibres, accompanied by small prismatic crystals of calcium oxalate; groups of sieve tissue are also numerous, the outer ones being collapsed.

There are different species of *Glycyrrhiza* such as *Pulvis Glycyrrhiza*. Each species is used all over the world for its medicinal benefits. This is specifically in Asia. It is known as licorice.

Licorice root, also known as Gan Cao and *Radix Glycyrrhizae*, is one of well-known herbs primarily used as a harmonizer in Chinese herbal formulas. By contrast, western clinical medicine uses it more as a moderator thanks to its anti-inflammatory, antispasmodic and antacid effects. It relieves cough significantly, makes expectoration easy, and prevents asthma to a certain extent. It also protects the inflamed mucous membranes of the throat and trachea.

Pharmacological Properties

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6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Black Powder,
- Keltrol Gum,
- Citric Acid,
- Sugar Syrup,
- Rectified Spirit
- Purified Water

6.2 Incompatibilities

None known

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

The primary pack is 100ml Amber coloured glass bottle sealed with aluminum ropp cap and labelled. The secondary pack is unit carton made of chipboard material.

6.6 Special Precautions for Disposal of a Used Medicinal Product or Waste Materials derived from such Medicinal Product and Other Handling of the Product

- There are no special precautions for disposal and other handling of Betasil Herbal Syrup.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Name: **ASPEN PHARMACARE NIGERIA LIMITED**

Address: **Plot 28, Infinity House, Ilupeju Bypass**

Country: **Nigeria**

Telephone: **+234 90 624 96814**

E-Mail: info@aspennigeria.com

8. DRUG PRODUCT MANUFACTURER

Name: **BETA HEALTHCARE INTERNATIONAL LTD**

Address: **Plot No. Nairobi/Block59/135, Mogadishu Road, Industrial Area, Nairobi**

P.O. BOX 42569-00100 Nairobi, Kenya

Country: **KENYA**

Telephone: **+254-20-2652042/89**

E-Mail: info@ke.aspenpharma.com

9. MARKETING AUTHORIZATION NUMBER

NAFDAC REG No. A7-1842

10. DATE OF FIRST REGISTRATION/RENEWAL OF REGISTRATION

Date of First Registration: 01st July 2015

Date of Renewal of Registration: 29th Nov 2028

11. DATE OF REVISION OF THE TEXT

October 2024