1. NAME OF THE MEDICINAL PRODUCT

GOOD MORNING COUGH SYRUP

Strength

Tolu Solution 0.56ml, Capsicum Tincture 0.25ml, Creosote 66.65mg, Anise Oil 13.89mg and Liquorice 25.00mg per 5ml syrup

Pharmaceutical Form

Syrup

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Qualitative Declaration

Tolu Solution BPC, Capsicum Tincture BPC, Creosote BPC' 59, Anise Oil BP and Liquorice BPC

Quantitative Declaration

Each 5ml syrup contains: Tolu Solution 0.56ml

Capsicum Tincture 0.25ml

Creosote 66.65mg

Anise Oil 13.89mg

Liquorice 25.00mg

Excipient(s) with Known Effects

White Refined Sugar ..... 3.33ml per 5ml

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

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

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

GOOD MORNING 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.

GOOD MORNING 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 and Method of Administration

Posology

Adults: 5mls every 4 hours.

Children: 5 - 14 years: 2.5ml every 4 hours.

Method of Administration

For oral administration

4.3 Contraindications

GOOD MORNING COUGH SYRUP is contraindicated in patients suffering from:

- Hypersensitivity to any of the ingredients used.
- Heart conditions.
- Hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, uterine fibroids or any other condition that might be made worse by exposure to estrogen.
- Hypertonia
- Hypokalemia

4.4 Special Warnings and Precautions for Use

Special Warnings

GOOD MORNING COUGH SYRUP contains Sugar Syrup. Patients who have intolerance to some sugars should consult with their contact your doctor before taking this medicinal product.

Do not exceed the stated doses.

- Surgery

Liquorice might interfere with blood pressure control during and after surgery. Anise might lower blood sugar levels. This might interfere with blood sugar control during and after surgery. Additionally, eucalyptus might affect blood sugar levels, there is concern that it might make blood sugar control difficult during and after surgery Stop taking GOOD MORNING COUGH SYRUP at least 2 weeks before a scheduled surgery.

- Patients with gastric ulcers

GOOD MORNING COUGH SYRUP should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract. In case of GI effects, the tablets should be discontinued.

- Patients with blood clotting disorders

Capsicum might slow blood clotting. Taking GOOD MORNING COUGH SYRUP along with medications that also slow blood clotting might increase the risk of bruising and bleeding.

- Patients with Hypertension

Liquorice might increase blood pressure. Taking GOOD MORNING COUGH SYRUP might reduce the effects of blood pressure medications. Monitor your blood pressure closely.

Precautions

- Pregnant women and lactating mothers should consult their physician or pharmacist before taking GOOD MORNING COUGH SYRUP.
- If symptoms persist consult your doctor.
- Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

- Estrogen

Liquorice seems to change hormone levels in the body. Taking GOOD MORNING COUGH SYRUP along with estrogen might decrease the effects of estrogen. (Refer to section 4.4)

- Diuretics

Liquorice can decrease potassium levels. Loop diuretics can also decrease potassium levels. Taking GOOD MORNING COUGH SYRUP and loop diuretics together might make potassium levels drop too low.

- Corticosteroids

Liquorice can decrease how quickly the body breaks down corticosteroids. This can increase the effects and side effects of corticosteroids.

- Warfarin

Warfarin is used to slow blood clotting. GOOD MORNING COUGH SYRUP might decrease the effects of warfarin. Decreasing the effects of warfarin might increase the risk of clotting. Be sure to have your blood checked regularly. The dose of your warfarin might need to be changed.

- Midazolam

Liquorice might increase how quickly midazolam is broken down by the body. This might decrease the effects of midazolam.

- Paclitaxel

Liquorice might increase how quickly the body breaks down paclitaxel. Taking GOOD MORNING COUGH SYRUP with paclitaxel might decrease the effects of paclitaxel.

- Methotrexate

Liquorice might decrease how quickly the body breaks down methotrexate. This might increase the effects and side effects of methotrexate.

- Diazepam

The body breaks down diazepam to get rid of it. Taking GOOD MORNING COUGH SYRUP with diazepam might slow down how quickly the body breaks down diazepam. This might increase the effects and side effects of diazepam.

- Fluoxetine

Anise Oil might reduce how well fluoxetine works. Taking GOOD MORNING COUGH SYRUP may affect how fluoxetine works.

- Aspirin

Capsicum might decrease how much aspirin the body can absorb. Taking GOOD MORNING COUGH SYRUP along with aspirin might reduce the effects of aspirin.

- Theophylline

Capsicum can increase how much theophylline the body can absorb. Taking GOOD MORNING COUGH SYRUP along with theophylline might increase the effects and side effects of theophylline.

4.6 Fertility, Pregnancy and Lactation

No clinical data on the effect of use on fertility, pregnancy and lactation. However, GOOD MORNING COUGH SYRUP should be used with caution.

Consult your doctor before taking GOOD MORNING COUGH SYRUP while breastfeeding.

4.7 Effects on Ability to Drive and use Machines

GOOD MORNING COUGH SYRUP does not affect the ability to drive and use machines.

4.8 Adverse 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

Although there are no data on cases of overdose, overdose is likely to increase side-effects. Thus, treatment should be symptomatic and as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group Expectorants

ATC code: R05CA10

Mechanism of Action

GOOD MORNING COUGH SYRUP is manufactured using the following active ingredients: Tolu Solution, Capsicum Tincture, Creosote, Anise Oil and Liquorice.

Liquorice, Capsicum Tincture, Creosote and Anise Oil have expectorant properties. Tolu Solution is used as a decongestant to promote expulsion of bronchial secretion.

Pharmacodynamic Effects

- 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 Solution is extracted from Tolu Balsam. It helps in the breakup of congestion thus people take it for cough and bronchitis. Others inhale to treat hoarseness and croup.

- Capsicum Tincture

Capsicum Tincture may reduce the severity and frequency of coughing attacks capsaicin's potential to "defunctionalize" nociceptors by depleting the mucosal neurotransmitter substance P.

- Creosote

Glyceryl guaiacolate is a derivative of guaiacol which is the chief constituent of creosote and takes its name from guaiac resin from which it was first isolated. Guaiacol acts as an expectorant, loosening bronchial secretions in the respiratory tract making them easy to be coughed out.

- Anise Oil

Anise Oil is used as an expectorant, that helps bring up phlegm.

Mechanism of action is not available.

During infection and inflammatory processes, the airway mucosa increases the mucus secretion. Mucus is made up of a polymeric matrix of large, oligomeric, gel forming glycoproteins, called mucins such as Muc5b and Muc5ac. Afterwards, mucus is cleared by ciliary movement and cough. During heavy infections, the activity of mucous cells seems to be reduced.

Expectorant remedies are those substances capable of decreasing the adhesivity of secretions and increasing the airway hydration, which is often altered during inflammation.

- Liquorice

Liquorice, also known as Licorice, is the common name of Glycyrrhiza glabra, a flowering plant of the bean family Fabaceae, from the root of which a sweet, aromatic flavouring is extracted.

Pulvis Glycyrrhiza which is powder of Liquorice Calyx can be found in the alpha and beta forms. The alpha form is predominant in the liver and duodenum and thus, it is thought that the anti-inflammatory liver effect of this drug are mainly due to the action of this isomer. Glycyrrhizic acid anti-inflammatory effect is generated via suppression of TNF alpha and caspase 3.

It also inhibits the translocation of NFkB into the nuclei and conjugates free radicals. Some studies have shown a glycyrrhizic-driven inhibition of CD4+ T cell proliferation via JNK, ERK and PI3K/AKT. The antiviral activity of glycyrrhizic acid includes the inhibition of viral replication and immune regulation. The antiviral activity of glycyrrhizic acid seems to be of a broad spectrum and be able to cover several different viral types.

5.2 Pharmacokinetic Properties

The active ingredients are well-documented pharmacopoeial ingredients.

Glycyrrhizic Acid is mainly absorbed after presystemic hydrolysis as Glycyrrhetic Acid. Glycyrrhizic Acid is mainly absorbed after presystemic hydrolysis and formation of glycyrrhetinic acid. Therefore, after oral administration of a dose of 100 mg of Glycyrrhizic Acid, this major metabolite appears in plasma in a concentration of 200 ng/ml while Glycyrrhizic Acid cannot be found. The finding of a minimal amount of Glycyrrhizic Acid in urine suggests the existence of a partial absorption in the gastrointestinal tract. The apparent volume of distribution of Glycyrrhizic Acid either in the central compartment and in steady-state are in the range of 37-64 ml/kg and 59-98 ml/kg, respectively. Glycyrrhizic Acid does not bind to any plasma proteins as it is not absorbed systemically. On the other hand, its main active metabolite, Glycyrrhetinic Acid presents a very large binding to serum proteins such as albumin. When orally administered, Glycyrrhizic Acid is almost completely hydrolyzed by intestinal bacteria for the formation of Glycyrrhetinic Acid, which is an active metabolite and can enter systemic circulation, and two molecules of glucuronic

acid. This metabolite is transported and taken in the liver for its metabolization to form glucuronide and sulfate conjugates.

The constant reabsorption of Glycyrrhetic Acid in the duodenum causes a delay in the terminal plasma clearance. The reported total body clearance of Glycyrrhizic Acid is reported to be in the range of 16-25 ml.kg/h.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to prescriber which are additional to that included in other sections of the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dry place below 30^0C. Protect from light.

6.5 Nature and contents of container

GOOD MORNING COUGH SYRUP is filled into 60ml amber coloured PET bottles and sealed with aluminium ropp cap and measuring cup and labelled. The filled, sealed and labelled bottles are packed in chipboard unit cartons together with paper literature inserts.

6.6 Special precautions for disposal and other handling

- Do not throw away any medicines you no longer use.
- Ask your pharmacist or medical facility how to properly dispose of any medicine you no longer use. These measures will help protect the environment.

7. MARKETING AUTHPROZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorization Holder

Name: **ARTEMIS LIFE SCIENCES NIGERIA LIMITED**

Address: **2EB, Aswan Market Osolo Way, Lagos**

Country: **Nigeria**

Manufacturing Site(s)

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

8. MARKETING AUTHORIZATION NUMBER

NAFDAC REG. No. A7 – 2366L

9. DATE OF FIRST REGISTRATION

Date of First Registration: 01 Jul 2017

Date of Renewal of Registration: 29 Nov 2025

10. DATE OF REVISION OF THE TEXT

October 2024

11. DOSIMETRY (IF APPLICABLE)

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Not Applicable