National Agency for Food & Drug Administration & Control (NAFDAC)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Good morning cough tablets

Strength

Pulvis Glycyrrhiza 56.35mg, Menthol 11.25mg, Eucalyptus Oil 2.20mg, Kreostum 2.20mg, Oleum Menthe Piperitae 1.10mg, Oleum Anisi 1.10mg, Liquid Tolu 0.04ml and Capsicum Tincture 0.03ml per tablet

Pharmaceutical Form

Tablet

2. QUALITATIVE AND QUANTITAVE COMPOSITION

Qualitative Declaration

Pulvis Glycyrrhiza BP, Menthol BP, Eucalyptus Oil BP, Kreostum BPC, Oleum Menthe Piperitae BP, Oleum Anisi BP, Liquid Tolu BP and Capsicum Tincture BPC

Quantitative Declaration

Each tablet contains: Pulvis Glycyrrhiza 56.35mg
Menthol 11.25mg
Eucalyptus Oil 2.20mg
Kreostum 2.20mg
Oleum Menthe Piperitae 1.10mg
Oleum Anisi 1.10mg
Liquid Tolu 0.04ml
Capsicum Tincture 0.03ml

Excipient(s) with Known Effects

Brown Sugar ……566.667mg per tablet

Lactose …….....269.167mg per tablet

Magnesium Stearate …….....8.500mg per tablet

Light Magnesium Carbonate …….....5.667mg per tablet

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

A greyish-brown, circular tablet plain on one side and a “GMCT” imprint on the other.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Good morning cough tablets are indicated in adults as an antitussive for the treatment of dry irritating Coughs and promote expulsion of bronchial secretion.

Good morning cough tablets also has demulcent effect that soothes the throat.

4.2 Posology and Method of Administration

Posology

One tablet to be sucked slowly in the mouth every 2 to 3 hours or as directed by the physician.

Not recommended for children under 5 years.

Method of Administration

For oral administration

Good morning cough tablets should be sucked and not swallowed with water.

4.3 Contraindications

Good morning cough tablets 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 tablets contains Brown Sugar. Patients who have intolerance to some sugars should consult with their contact your doctor before taking this medicinal product.

Good morning cough tablets contains Lactose. Patients who are lactose intolerant should avoid 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 tablets at least 2 weeks before a scheduled surgery.

- Children

Eucalyptus Oil is likely unsafe for children to take eucalyptus Oil by mouth, apply it to the skin, or inhale it. Seizures and other nervous system side effects have been experienced in infants and children who were exposed to eucalyptus Oil. Infants and children should not take Good morning cough tablets.

- Patients with gastric ulcers

Good morning Tablets 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 Diabetes

Eucalyptus might lower blood sugar levels. Taking Good morning cough tablets along with diabetes medications might cause blood sugar to drop too low. Monitor your blood sugar closely.

- Patients with blood clotting disorders

Capsicum might slow blood clotting. Taking Good morning cough tablets 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 tablets 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 tablets.
- 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 tablets 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 tablets 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 tablets 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 tablets 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.

- Cyclosporine

Peppermint Oil might decrease how quickly the body breaks down cyclosporine. Taking Good morning cough tablets along with cyclosporine might increase the effects and side effects of cyclosporine.

- Diazepam

The body breaks down diazepam to get rid of it. Taking Good morning cough tablets 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 tablets may affect how fluoxetine works.

- Aspirin

Capsicum might decrease how much aspirin the body can absorb. Taking Good morning cough tablets along with aspirin might reduce the effects of aspirin.

- Theophylline

Capsicum can increase how much theophylline the body can absorb. Taking Good morning cough tablets 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 tablets should be used with caution.

Menthol passes into breast milk in small amounts. Consult your doctor before taking Good morning cough tablets while breastfeeding.

4.7 Effects on Ability to Drive and use Machines

Good morning cough tablets 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of this medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions.

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 and **ATC code:** R05CA10

Mechanism of Action

Good morning cough tablets is manufactured using the following active ingredients: Pulvis Glycyrrhiza, Menthol, Eucalyptus Oil, Kreostum, Oleum Menthe Piperitae, Oleum Anisi, Liquid Tolu and Capsicum Tincture.

Pulvis Glycyrrhiza, Eucalyptus Oil, Kreostum, Oleum Menthe Piperitae, Oleum Anisi and Capsicum Tincture have expectorant properties. Menthol acts as a pain reliever and Liquid Tolu is used as a decongestant to promote expulsion of bronchial secretion.

Pharmacodynamic Effects

- Pulvis Glycyrrhiza (Glycyrrhizic acid)

Pulvis Glycyrrhiza (Glycyrrhizic acid) 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.

- Oleum Anisi

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.

- Menthol

It is unclear how menthol actively suppresses Cough; however, studies suggest that menthol suppresses Cough by a reflex transduced through TRPM8-dependent activation of nasal trigeminal afferent neurons. The mechanism is still unknown.

- Kreostum (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.

- Oleum Menthe Piperitae (Peppermint)

Peppermint and its main active agent, menthol, are effective decongestants. Because menthol thins mucus, it is also a good expectorant, meaning it helps loosen phlegm and breaks up Coughs. It is soothing and calming for sore throats (pharyngitis) and dry Coughs.

- Liquid Tolu (Tolu Solution)

Tolu Solution is used as an expectorant. It works by thinning and loosening mucus in the airways, clearing congestion, and making breathing easier.

- Eucalyptus Oil

Eucalyptus Oil is used as a Cough suppressant. It controls airway mucus hypersecretion and asthma via anti-inflammatory cytokine inhibition. Eucalyptus Oil is an effective treatment for non-purulent rhinosinusitis. However, the mechanism of action is not available.

- 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.

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.

Oral Menthol administration has a faster metabolism (i.e., glucuronidation process) that occurs when the molecule is absorbed through the gastrointestinal tract leading to higher menthol glucuronide concentration as compared to topical administration of Menthol.

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

- Brown Sugar
- Lactose
- Tragacanth Gum
- Powdered Acacia
- Carmellose Sodium (Blanose)
- Rectified Spirit
- Magnesium Stearate
- Light Magnesium Carbonate
- Purified Talc Powder

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

Primary packaging: Aluminium strips.

Secondary packaging: Chipboard unit cartons.

Pack size(s); 10 x 10 tablets.

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

- 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. 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. A7-2363L

10. DATE OF FIRST REGISTRATION/RENEWAL OF REGISTRATION

Date of First Registration: 1st July 2017

Date of Renewal of Registration: 29th November 2025

11. DATE OF REVISION OF THE TEXT

October 2024