SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

KOLDBLAST

[Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate and Caffeine Tablets]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Paracetamol BP	500 mg
Phenylephrine HCL BP	10 mg
Chlorpheniramine Maleate BP	2 mg
Caffeine BP	30 mg
Excipients	q.s.

3. PHARMACEUTICAL FORM

Uncoated Tablets for oral use

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Paracetamol is recommended for the treatment of headaches including migraine and tension headaches; also for backache, rheumatic and muscle pains, 'nerve pains', toothache, dysmenorrhoea, sore throat and for relieving the fever, aches and pains of colds and flu.

Phenylephrine is used for the temporary relief of stuffy nose, sinus, and ear symptoms caused by the common cold, flu, allergies, or other breathing illnesses (e.g. sinusitis, bronchitis). This medication works by decreasing swelling in the nose and ears, thereby lessening discomfort and making it easier to breathe.

Chlorpheniramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes / nose / throat / skin, cough, runny nose, and sneezing.

Caffeine Tablet recommended for the relief of migraine, headache, backache, rheumatic pain, period pains, dental pain, strains & sprains and sciatica.

4.2. Posology and method of administration

Method of administration: For oral use only

Adults, elderly and children over 12 years: One tablet every three to four hours. Do not exceed five tablets per day.

Children 6-12 years: 1 tablet twice in a day. Children under six years: Not recommended. Do not exceed the recommended dose or as directed by the physician.

4.3. Contra-indications

- Hypersensitivity to any of the ingredients of the formulation.
- Severe hypertension.
- In women during breast feeding.
- Active gastric or intestinal ulcer, bleeding or perforation.

4.4. Special warnings and special precautions for use

In case a hypersensitivity reaction occurs which is rare, TrustCold Tablet should be discontinued. TrustCold Tablet contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products. TrustCold Tablet should be used with caution in patients with renal or hepatic dysfunction, diabetes mellitus, hyperthyroidism, cardiovascular problems, epilepsy and closed angle glaucoma.

Use in Pregnancy and Lactation

Fertility

Chronic toxicity studies in animals have shown that high doses of paracetamol cause testicular atrophy and inhibition of spermatogenesis; the relevance of this finding to use in humans is not known.

Pregnancy

Although the occasional use of recommended doses of antihistamine, decongestant, and analgesic combinations during pregnancy is not likely to result in adverse effects on the fetus or newborn infant, the following information should be considered.

Small amounts of antihistamines are distributed into breast milk; use is not recommended in nursing mothers because of the risk of antihistamines causing excitement or irritability in infants. Also, antihistamines may inhibit lactation because of their anticholinergic action.

Problems in humans have not been documented. Although peak concentrations of 10 to 15 mcg per mL have been measured in breast milk 1 to 2 hours following maternal ingestion of a single

650-mg dose, neither paracetamol nor its metabolites were detected in the urine of the nursing infants. The half-life in breast milk is 1.35 to 3.5 hours.

Pediatric

Use of antihistamines is not recommended in newborn or premature infants. This age group may be at a higher risk than other age groups because of an increased susceptibility to anticholinergic effects, such as CNS excitation, and an increased tendency toward convulsions.

In children taking antihistamines, a paradoxical reaction characterized by hyperexcitability may occur.

The use of Paracetamol in children is controversial. Many clinicians recommend that these medications not be given to children below 12 years of age. However, other clinicians advise that these medications may be given to children, provided that proper dosage can be achieved with the individual product.

Geriatric

Confusion, dizziness, sedation, hypotension, hyperexcitability, and anticholinergic side effects, such as dryness of mouth and urinary retention (especially in males), may be more likely to occur in geriatric patients taking antihistamines. If the anticholinergic side effects occur and continue or are severe, medication should probably be discontinued.

Interactions

Clinically significant drug interactions may occur on concomitant administration of TrustCold Tablet with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents and methyldopa, reserpine and veratrum alkaloids.

4.5. Interactions with other Drug products and other forms of interaction

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance not necessarily inclusive:

» Alcohol or

» CNS depression–producing medications, other (concurrent use may potentiate the CNS depressant effects of either these medications or antihistamines)

» Anesthetics, hydrocarbon inhalation, such as:

Chloroform

Cyclopropane

Enflurane

Halothane

Isoflurane

Methoxyflurane

Trichloroethylene, or

» Digitalis glycosides

» Anticholinergics or other medications with anticholinergic activity or Antihistamines, other (anticholinergic effects may be potentiated when these medications are used concurrently with antihistamines; patients should be advised to report occurrence of gastrointestinal problems promptly, since paralytic ileus may occur with concurrent therapy)

» Antidepressants, tricyclic, or

Maprotiline (concurrent use with antihistamines may potentiate the CNS depressant effects of these medications or the antihistamine contained in these combinations.)

» CNS stimulation–producing medications, other (concurrent use with pseudoephedrine may result in additive CNS stimulation to excessive levels, which may cause unwanted effects, such as nervousness, irritability, insomnia, or possibly convulsions or cardiac arrhythmias)

Doxapram (concurrent use may increase the pressor effects of either doxapram or sympathomimetic amines)

» Monoamine oxidase (MAO) inhibitors, including furazolidone and

procarbazine (concurrent use with antihistamines may prolong and intensify the anticholinergic and CNS depressant effects of Antihistamines; concurrent use is not recommended)

Ototoxic medications (concurrent use with antihistamines may mask the symptoms of ototoxicity such as tinnitus, dizziness, or vertigo)

For paracetamol-containing combinations (in addition to the interactions listed for other ingredients)

» Alcohol, especially chronic abuse of, or

Hepatic enzyme inducers or

Hepatotoxic medications, other (risk of hepatotoxicity with single toxic doses or prolonged use of high doses of paracetamol may be increased in alcoholics or in patients regularly taking other hepatotoxic medications or hepatic enzyme inducers)

(Chronic use of barbiturates or primidone has been reported to decrease the therapeutic effects of paracetamol, probably because of increased metabolism resulting from induction of hepatic microsomal enzyme activity; the possibility should be considered that similar effects may occur with other hepatic enzyme inducers).

Anticoagulants, coumarin- or indandione-derivative (concurrent chronic, high-dose administration of paracetamol may increase the anticoagulant effect, possibly by decreasing hepatic synthesis of procoagulant factors; anticoagulant dosage adjustment based on increased monitoring of prothrombin time may be necessary when chronic, high-dose paracetamol therapy is initiated or discontinued; however, this does not apply to occasional use or to chronic use of doses below 2 grams per day of paracetamol)

Anti-inflammatory drugs, nonsteroidal (NSAIDs), or

Aspirin or other salicylates (prolonged concurrent use of paracetamol with a salicylate is not recommended because chronic, high-dose administration of the combined analgesics significantly increases the risk of analgesic nephropathy, renal papillary necrosis, end-stage renal disease, and cancer of the kidney or urinary bladder; also, it is recommended that for short-term use, the combined dose of paracetamol plus salicylate not exceed that recommended for paracetamol or a salicylate given alone)

(Diflunisal may increase the plasma concentration of paracetamol by 50%, leading to increased risk of hepatotoxicity)

(Prolonged concurrent use of paracetamol with other NSAIDs may also increase the risk of adverse renal effects; it is recommended that patients be under close medical supervision while receiving such combined therapy)

» Zidovudine (paracetamol may competitively inhibit the hepatic glucuronidation and decrease the clearance of zidovudine; zidovudine may also inhibit the hepatic glucuronidation of paracetamol; concurrent use should be avoided because the toxicity of either or both medications may be potentiated)

Acidifiers, urinary, such as:

Ammonium chloride

Ascorbic acid

Potassium or sodium phosphates (acidification of the urine by these medications decreases excretion of salicylate, leading to increased salicylate plasma concentrations)

Alcohol or

» Anti-inflammatory drugs, nonsteroidal (NSAIDs), other (risk of gastrointestinal side effects, including ulceration and gastrointestinal blood loss, may be increased when these agents are used concurrently with aspirin or sodium salicylate; also, concurrent use of aspirin or sodium salicylate with other NSAIDs may increase the risk of severe gastrointestinal side effects without providing additional symptomatic relief and is therefore not recommended)

» Alkalizers, urinary, such as:

Carbonic anhydrase inhibitors

Citrates, or

Antacids, chronic high-dose use, especially calcium- and/or magnesium-containing or sodium bicarbonate (alkalinization of the urine by these agents increases excretion of salicylate [from aspirin], leading to decreased salicylate plasma concentrations, reduced effectiveness, and shortened duration of analgesic action)

(carbonic anhydrase inhibitors may also increase the risk of salicylate intoxication in patients receiving large doses of aspirin or sodium salicylate, because metabolic acidosis induced by carbonic anhydrase inhibitors may increase penetration of salicylate into the brain; the increased

risk of severe metabolic acidosis and salicylate toxicity must be considered if acetazolamide is used to produce forced alkaline diuresis in the treatment of aspirin overdose)

» Anticoagulants, coumarin- or indandione-derivative, or

» Heparin or

» Thrombolytic agents, such as:

Alteplase (tissue-type plasminogen activator, recombinant)

Anistreplase

Streptokinase

Urokinase (effects of coumarin- or indandione-derivative anticoagulants may be increased because of displacement by aspirin or sodium salicylate from protein-binding sites)

(Concurrent use with combinations containing aspirin is not recommended because aspirin-induced inhibition of platelet function may lead to prolonged bleeding time and hemorrhage in patients receiving anticoagulant or thrombolytic therapy)

(The potential occurrence of gastrointestinal ulceration or hemorrhage during salicylate therapy, especially aspirin, may cause increased risk to patients receiving anticoagulant or thrombolytic therapy)

Anticonvulsants, hydantoin (aspirin may decrease metabolism of hydantoin anticonvulsants, leading to increased serum concentrations and to increased therapeutic and/or toxic effects of the anticonvulsant; adjustment of hydantoin dosage may be necessary)

» Antidiabetic agents, oral, or

Insulin (hypoglycemic effects of these medications may be increased by large doses of aspirin or sodium salicylate; dosage adjustments may be necessary; potentiation of oral antidiabetic agents may partially be caused by displacement from serum proteins; glipizide and glyburide, because of their nonionic binding characteristics, may not be affected as much as the other oral agents; however, caution in concurrent use is recommended with all of these agents)

Antiemetics, including antihistamines and phenothiazines (antiemetics may mask the symptoms of aspirin- or sodium salicylate–induced ototoxicity, such as dizziness, vertigo, and tinnitus)

Bismuth subsalicylate (repeated ingestion of large doses as for traveler's diarrhea may produce substantial plasma salicylate concentrations; concurrent use with large doses of analgesic salicylates may increase the risk of salicylate toxicity)

» Cefamandole or

» Cefoperazone or

» Cefotetan or

» Plicamycin (these medications may cause hypoprothrombinemia and/or inhibition of platelet aggregation; concurrent use with aspirin may increase the risk of bleeding because of additive

inhibition of platelet aggregation and/or the potential occurrence of gastrointestinal ulceration or hemorrhage during therapy with aspirin)

Laxatives, cellulose-containing (concurrent use may reduce the salicylate effect because of physical binding or other absorptive hindrance; medications should be administered 2 hours apart)

» Methotrexate (aspirin or sodium salicylate may displace methotrexate from its binding sites and decrease its renal clearance, leading to toxic plasma concentrations of methotrexate; if these medications are used concurrently, methotrexate dosage should be decreased, the patient observed for signs of toxicity, and/or methotrexate plasma concentration monitored; also, it is recommended that salicylate therapy be discontinued 24 to 48 hours prior to, and not resumed for at least 12 hours following, administration of a high-dose methotrexate infusion)

Ototoxic medications, other especially

» Vancomycin (concurrent or sequential administration of these medications with aspirin or sodium salicylate should be avoided because the potential for ototoxicity may be increased, especially with long-term, high-dose use or overdose of salicylates; hearing loss may occur and may progress to deafness even after discontinuation of the medication; these effects may be reversible, but usually are permanent) (concurrent use of furosemide with high doses of aspirin or sodium salicylate may lead to salicylate toxicity because of competition for renal excretory sites)

» Platelet aggregation inhibitors, other (concurrent use with combinations containing aspirin is not recommended because of the increased risk of hemorrhage resulting from additive inhibition of platelet aggregation, the potential occurrence of gastrointestinal ulceration or hemorrhage during aspirin therapy, and the hypoprothrombinemic effect of large doses of aspirin)

(Plicamycin may cause hypoprothrombinemia as well as inhibition of platelet aggregation; concurrent use of plicamycin with aspirin may be especially hazardous)

» Probenecid or

» Sulfinpyrazone (concurrent use of aspirin or sodium salicylate is not recommended when these medications are used to treat hyperuricemia or gout, because uricosuric effects of probenecid or sulfinpyrazone may be decreased by doses of aspirin or sodium salicylate that produce serum salicylate concentrations above 50 mcg per mL; also, probenecid may decrease renal clearance and increase plasma concentrations of salicylate, thereby increasing the risk of toxicity)

(Sulfinpyrazone may decrease salicylate excretion and/or displace salicylate from its protein binding sites, possibly leading to increased salicylate concentrations and toxicity)

(Concurrent use of sulfinpyrazone with aspirin may increase the risk of gastrointestinal ulceration or hemorrhage; also, concurrent use of sulfinpyrazone with aspirin may increase the risk of bleeding at sites other than the gastrointestinal tract because of additive inhibition of platelet aggregation)

Salicylic acid (topical) (concurrent use with salicylates may increase the risk of salicylate toxicity if significant quantities are absorbed)

Vitamin K (requirements for this vitamin may be increased in patients receiving high doses of aspirin or sodium salicylate)

» Zidovudine (aspirin may competitively inhibit the hepatic glucuronidation and decrease the clearance of zidovudine leading to potentiation of zidovudine toxicity; the possibility must be considered that aspirin toxicity may also be increased; concurrent use of the 2 medications should be avoided)

4.6. Pregnancy and lactation

Fertility, Pregnancy and Lactation:

Although the occasional use of recommended doses of antihistamine, decongestant, and analgesic combinations during pregnancy is not likely to result in adverse effects on the fetus or newborn infant, the following information should be considered.

Small amounts of antihistamines are distributed into breast milk; use is not recommended in nursing mothers because of the risk of antihistamines causing excitement or irritability in infants. Also, antihistamines may inhibit lactation because of their anticholinergic action.

Problems in humans have not been documented. Although peak concentrations of 10 to 15 mcg per mL have been measured in breast milk 1 to 2 hours following maternal ingestion of a single 650-mg dose, neither paracetamol nor its metabolites were detected in the urine of the nursing infants. The half-life in breast milk is 1.35 to 3.5 hours.

4.7. Effects on ability to drive and use machines

It is advisable not to drive or operate machinery when on treatment with Koldblast Tablet.

4.8. Undesirable effects

Koldblast is generally well tolerated and adverse events are rare. Hypersensitive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness and nausea. Use of sympathomimetics has been associated with fear, anxiety, restlessness, tremor, weakness, dysuria, insomnia, hallucinations and convulsions. Chlorpheniramine in TrustCold Tablet may cause sedation.

4.9 Overdose

Recommended treatment of overdose consists of the following:

For Paracetamol-containing combinations

• Emptying the stomach via induction of emesis or gastric lavage.

• Administering activated charcoal. However, activated charcoal may interfere with absorption of oral acetylcysteine (antidote used to protect against paracetamol-induced hepatotoxicity); removal

of activated charcoal via gastric lavage may be advisable prior to acetylcysteine administration.

• For excessive hypertensive effect. An alpha-adrenergic blocker, such as phentolamine, may be administered.

• The cardiac state should be monitored and serum electrolytes measured.

• Administering acetylcysteine. It is recommended that acetylcysteine administration be instituted as soon as possible after ingestion of an overdose has been reported, without waiting for the results of plasma paracetamol determinations or other laboratory tests. Acetylcysteine is most effective if treatment is started within 10 to 12 hours after ingestion of the overdose; however, it may be of some benefit if treatment is started within 24 hours. For oral administration, the recommended adult dose of acetylcysteine is 140 mg per kg of body weight (mg/kg) initially, then 70 mg/kg every 4 hours for 17 doses. Each dose should be diluted to a 5% solution with cola or other soft drinks prior to administration because of acetylcysteine's unpleasant odor and its irritating or sclerosing properties. Consult the manufacturer's prescribing information for a table showing quantities of acetylcysteine (20% solution) and diluent needed to prepare a 5% solution containing the required initial dose and subsequent doses for patients weighing up to 109 kg. Any dose vomited within 1 hour of administration must be repeated. If necessary, the antidote may be given (diluted with water) via duodenal intubation.

• Determining plasma paracetamol concentration at least 4 hours following ingestion of the overdose. Determinations performed prior to this time are not reliable for assessing potential hepatotoxicity. Initial plasma concentrations above 150 mcg per mL at 4 hours, 100 mcg per mL at 6 hours, 70 mcg per mL at 8 hours, 50 mcg per mL at 10 hours, 20 mcg per mL at 15 hours, 8 mcg per mL at 20 hours, or 3.5 mcg per mL at 24 hours postingestion indicate possible hepatotoxicity and the need for completing the full course of acetylcysteine treatment. If the initial determination indicates a plasma concentration below those listed at the times indicated, cessation of acetylcysteine therapy can be considered. However, some clinicians advise that more than one determination should be performed to ascertain peak absorption and half-life of paracetamol prior to considering discontinuation of acetylcysteine.

• Instituting hemodialysis or hemoperfusion to remove paracetamol from the circulation may be beneficial if acetylcysteine administration cannot be instituted within 24 hours following ingestion of a massive paracetamol overdose. However, the efficacy of this treatment in preventing paracetamol-induced hepatotoxicity is not known.

• Performing liver function tests at 24-hour intervals for at least 96 hours postingestion if the plasma paracetamol concentration indicates potential hepatotoxicity. If no abnormalities are detected within 96 hours, further determinations are not needed.

• Monitoring renal and cardiac function and administering appropriate therapy as required.

• Instituting supportive treatment, including maintaining fluid and electrolyte balance, correcting

hypoglycemia, and administering vitamin K_1 (if prothrombin time ratio exceeds 1.5) and fresh frozen plasma or clotting factor concentrate (if prothrombin time ratio exceeds 3).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Koldblast Tablet contains a clinically proven analgesic-antipyretic Paracetamol with decongestant Phenylephrine and an antihistamine Chlorpheniramine maleate. Paracetamol produces analgesia by elevation of the pain threshold and antipyretic effect through action on the hypothalamic heat regulating center. Paracetamol is equal to aspirin in analgesic and antipyretic effectiveness, and it is unlikely to produce many of the side effects associated with aspirin and aspirin containing products. Sympathomimetic decongestants reduce the nasal congestion due to increased nasal blood flow associated with colds and influenza. Phenylephrine is sympathomimetic vasoconstrictor that has been used as a decongestant. It is a relatively selective alpha-adrenoceptor agonist. The majority of the sympathomimetic action is due to direct stimulation of the adrenoceptors and relatively little is due to an indirect effect via release of noradrenaline. Its presser action is weaker than that of noradrenaline but of longer duration. At therapeutic doses, it does not cause significant stimulation of the central nervous system. Chlorpheniramine in Koldblast Tablet provides prompt relief of itchy watery eyes, runny nose, sneezing, itching of the nose or throat due to respiratory allergies.

5.2 Pharmacokinetic Properties

Absorption:

Antihistamines:

Well absorbed from the gastrointestinal tract after oral administration.

Sympathomimetic amines:

Most sympathomimetic amines (except phenylephrine) are well absorbed from the gastrointestinal tract after oral administration. Phenylephrine has reduced bioavailability (about 38%) from gastrointestinal tract because of first pass metabolism by monoamine oxidase in the stomach and liver.

Analgesics:

Acetaminophen (Paracetamol): Rapid and almost complete; may be decreased if acetaminophen is taken following a high-carbohydrate meal.

Protein binding:

Acetaminophen: Not significant with usual analgesic doses.

Chlorpheniramine: High (72%).

Diphenhydramine: Very high (98 to 99%).

Biotransformation:

Antihistamines: Hepatic; some renal.

Sympathomimetic amines:

Phenylephrine: Extensive, in the intestinal wall and in the liver. Sulfate conjugates are formed largely in the intestinal wall. Also, phenylephrine undergoes oxidative deamination by monoamine oxidase.

Pseudoephedrine: Incompletely metabolized in the liver; less than 1% by *N*-demethylation to the active metabolite norpseudoephedrine.

Analgesics:

Acetaminophen: Approximately 90 to 95% of a dose is metabolized in the liver, primarily by conjugation with glucuronic acid, sulfuric acid, and cysteine. An intermediate metabolite is hepatotoxic.

Aspirin: Largely hydrolyzed in the gastrointestinal tract, liver, and blood to salicylate, which is further metabolized, primarily in the liver.

Half-life:

Antihistamines:

Brompheniramine: 25 hours.

Chlorpheniramine: 21 to 27 hours.

Diphenhydramine: 1 to 4 hours.

Sympathomimetic amines:

Phenylephrine: 2.1 to 3.4 hours.

In children: Mean half-life of pseudoephedrine has been reported to be 4.6 hours.

Analgesics:

Acetaminophen:

1 to 4 hours; does not change with renal failure but may be prolonged in some forms of hepatic disease, in overdose, in the elderly, and in the neonate; may be somewhat shortened in children.

Onset of action:

Time to peak concentration:

Antihistamines:

Chlorpheniramine: 2 to 6 hours.

Sympathomimetic amines:

Phenylephrine: 0.75 to 2 hours (to achieve peak concentrations ranging from 0.9 to 298nanograms/mL, respectively).

Analgesics:

Acetaminophen: 0.5 to 2 hours.

Peak serum concentration:

Paracetamol: 5 to 20 mcg per mL with doses up to 650 mg.

Therapeutic plasma concentration:

Analgesic: 25 to 50 mcg per mL (2.5 to 5 mg per 100 mL); these concentrations are generally reached with doses of 325 to 650 mg.

Time to peak effect:

Antihistamines:

Chlorpheniramine: 6 hours.

Analgesics:

Acetaminophen: 1 to 3 hours.

Duration of action:

Antihistamines:

Ethanolamine derivatives: 6 to 8 hours.

Propylamine derivatives: 4 to 8 hours.

Pyrilamine: 8 hours.

Sympathomimetic amines:

Analgesics:

Acetaminophen: 3 to 4 hours

Elimination:

Antihistamines:

Renal. Most of the antihistamines studied are excreted as metabolites within 24 hours.

Sympathomimetic amines: Renal.

Phenylephrine:

2.6% of the administered oral dose is excreted unchanged. Eighty to 86% of unchanged phenylephrine and metabolites is recovered in the urine within 48 hours after oral administration.

Analgesics:

Acetaminophen:

Renal, as metabolites, primarily conjugates; 3% of a dose may be excreted unchanged.

In dialysis:

Hemodialysis: 120 mL per minute (for unmetabolized drug); metabolites also cleared rapidly.

Hemoperfusion: 200 mL per minute.

Peritoneal dialysis: <10 mL per minute.

5.3. Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Microcrystalline Cellulose

Maize Starch

Povidone

Sodium Methyl Hydroxybenzoate

Sodium Propyl Hydroxybenzoate

Erythrosine

Magnesium Stearate

Sodium Starch Glycolate

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 Months

6.4 Special precautions for storage

Storage below 30^{o}C, Protected from the sunlight.

Keep out of reach and sight of children.

6.5. Nature and contents of container

25 x 1 x 4 Tablets in Alu–Alu strip pack

6.6. Instruction for use and handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Basic Pharmaceuticals & Herbal Healthcare Ltd.

24, Odelola Street, Surulere, Lagos, Nigeria.

8. MARKETING AUTHORISATION NUMBER

NAFDAC Reg No.: B4-5930

9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

29th October, 2015

10. DATE OF REVISION OF THE TEXT

1st January, 2025