1.0. Name of the Medicinal Product:

Broxydex Cough Syrup

2.0. Qualitative and quantitative composition:

Each 10ml contains

Bromhexine Hydrochloride BP	8mg
Dextromethorphan Hydrobromide BP	10mg
Ammonium Chloride BP	100mg
Menthol BP	5mg

3.0. Pharmaceutical form:

Syrup

4.0. Clinical particulars:

4.1 Therapeutic indication:

Broxydex cough syrup is used for symptomatic treatment of irritating cough and cough associated with bronchitis, pulmonary congestion where retention of tenacious and viscid mucous secretions is a problem.

Bromhexine hydrochloride creates an environment in the bronchial to remove sticky mucus thus promoting expectoration without excessive straining.

Bromhexine hydrochloride and ammonium chloride maintain the integrity of the mucociliary blanket to bring out the secretion in a normal physiological manner.

Dextromethorphan Hydrobromide is a non-narcotic cough suppressant.

Ammonium chloride produces a mild irritation of the mucus lining of the stomach and this reflex increases the respiratory tract fluid relieving dryness and success of the respiratory passage.

Menthol acts as a demulcent and a soothing agent.

4.2 Posology and method of administration:

Adult: 10ml, 3 – 4 times a day.

Children: 5– 12 years: 5ml, 3 -4 times a day.

2 – 6 years: 2.5ml, 3 – 4 times a day or as directed by the physician.

4.3 Contraindications:

Dextromethorphan should not be used in patients receiving monoamine inhibitors. It is contraindicated in patients with peptic ulcer.

Bromhexine is contraindicated in the first trimester of pregnancy.

4.4 Special warnings and precautions for use

Dextromethorphan should be used with caution in sedated patients, in patients confined in supine position.

Dextromethorphan hydrobromide occasionally causes slight drowsiness, dizziness and gastrointestinal disturbances.

4.5 Fertility, pregnancy and lactation:

It is not known whether Dextromethorphan is excreted in human milk. Caution should be exercised when dextromethorphan administered to a nursing mother.

4.6 Effects on ability to drive and use machines:

Dextromethorphan hydrobromide occasionally causes slight drowsiness, dizziness and gastrointestinal disturbances.

4.7 Undesirable effects:

Dextromethorphan hydrobromide occasionally causes slight drowsiness, dizziness and gastrointestinal disturbances. The drug is relatively well tolerated with minor and infrequent side effects. Rarely it causes nausea and epigastria discomfort.

4.8 Overdose and Treatment:

Dextromethorphan may produce central excitement and mental confusion. Very high doses may produce respiratory depression. One case of toxic psychosis (hyperactivity, marked visual and auditory hallucination) after ingestion of 300mg of Dextromethorphan has been reported.

Bromhexine treatment above 60mg/day may cause gastric irritation.

Treatment of overdose with Dextromethorphan is essentially symptomatic and supportive. Only in cases of extreme over dosage or individual sensitivity do vital signs including respiratory, pulse, blood pressure, temperature and ECG need to be monitored. Activated charcoal orally or by lavage may be given or sodium/ magnesium sulphate orally can be used as cathartic. Attention should be given to the re-establishment of adequate respiratory exchange through provision of patient airway and assisted or controlled ventilation. Diazepam may be used to control convulsion. Acidosis and electrolyte losses should be corrected.

5.0. Pharmacological properties:

5.1 Pharmacodynamic properties:

Dextromethorphan is an antitussive agent and unlike its isomer, it has no analgesic or additive properties. The drug acts centrally and elevates the threshold for coughing. It is about equal to codeine in depressing the cough reflex. In therapeutic dosage Dextromethorphan does not inhibit ciliary activity. Bromhexine increases the expectorant of sputum in bronchitis patients, increases the output of water into respiratory tract fluid and depolymerises the mucopolysaccharides in the mucous. It is also claimed to act on bronchial glands to liberate lysosomal enzymes from the mucous secreting cells which digest the mucopolysaccharide fibres. Thus, Bromhexine is extremely useful in restoring the mucociliary equilibrium. Beside this, it has been attributed to have mild antitussive effect. Bromhexine increases sputum volume by stimulating the mucous glands of the respiratory tract and promoting ciliary clearance of sputum. Bromhexine further reduces sputum viscosity by breaking down the tenacious network of mucopolysaccharides fibres in mucous sputum which are mainly responsible for sputum sickness. Bromhexine creates an environment in the bronchial tree conducive to the removal of sticky mucus thus promoting expectoration without excessive straining. Ammonium chloride produces mild irritation of the

mucus lining of the stomach and this vagovagal reflex increases the respiratory tract fluid relieving dryness and success of the respiratory passage.
Menthol acts as a demulcent and a soothing agent.

5.2 Pharmacokinetic properties:

Dextromethorphan is rapidly absorbed from the gastrointestinal tract and exerts its effect in 15 to 30 minutes. The duration of action after oral administration is approximately 3 to 6 hours. Dextromethorphan is metabolizing primarily by liver enzymes undergoing O-demethylation, N-demethylation and partial conjugation with glucuronic acid and sulphate. Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and about 85% to 90% of the dose excreted in urine mainly as metabolite. Bromhexine is highly bound to plasma proteins. Administration of Bromhexine hydrochloride by mouth to healthy subjects produced peak plasma concentration after about 1 hour and only small amounts were excreted unchanged in the urine with the half-life of about 6 – 5 hours.

5.3 Preclinical safety data

Long term animal studies have not been performed to assess the carcinogenic potential of Dextromethorphan. There is no animal or human data concerning the carcinogenic and mutagenic effector impairment of fertility by these drugs.

6.0. Pharmaceutical particulars:

6.1 List of excipients

Propylene Glycol
Benzoic Acid
Sugar
Liquid Glucose
S0dium Benzoate
Sodium Saccharine
Mixed Fruits Essence
Vanilla Essence
Tartrazine Brilliant Blue

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

100ml per bottle.
The oral cough syrup are filled capped and packed in 100ml transparent pet bottles/ pack

Each pack contains a dosage cup.

6.6 Special precautions for disposal and other handling

No special requirements.

7.0.Applicant / Manufacturer:

Olpharm Nigeria Limited
13, Agbaoku Street, Awosika bus-stop,
Opebi Ikeja,
Lagos.