1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Maysedyl Expectorant Diphenhydramine Hydrochloride B.P 14mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5mls contains: Diphenhydramine hydrochloride BP 14mg

Ammonium chloride BP 135mg

Menthol BP 1.1 mg

Sodium citrate BP 57mg

3. PHARMACEUTICAL FORM

Oral Suspension

4. Clinical particulars

4.1 Therapeutic indications

Maysedyl Expectorant is a pleasantly tasting preparation for the relief of dry cough and other symptoms that accompany coughs, and colds such as runny nose, catarrh, nasal congestion and blocked sinuses.

Posology and method of administration

DOSAGE & ADMINISTRATION

Adults and Children aged 12 years and over:

One 10 ml dose of syrup 4 times a day.

Maximum daily dose: 40 ml syrup.

Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure

Do not exceed the stated dose.

Keep out of the reach and sight of children.

4.2 Contraindications

Maysedyl expectorant is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

Maysedyl expectorant is contraindicated in individuals with chronic or persistent

cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by the physician.

Maysedyl expectorant should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOI) or those patients who have received treatment with MAOIs within the last two weeks.

ADVERSE REACTION

Diphenhydramine may cause drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremor, convulsions or parasthesia.

Hypersensitivity reactions have been reported, in particular, skin rashes, erythema, urticaria and angiodema.

Adverse reactions to menthol at the low concentration present in Maysedyl expectorant are not anticipated

4.4 Special warnings and precautions for use

This product may cause drowsiness. If affected, individuals should not drive or operate machinery.

Subjects with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this product

This product contains diphenhydramine and therefore should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy.

4.5 Interaction with other medicinal products and other forms of interaction

This product contains diphenhydramine and therefore may potentiate the effects of alcohol, codeine, antihistamines and other CNS depressants. Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or other antihistamines (such as cetirizine, chlorpheniramine).

As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (eg, some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (eg, colic), urinary retention and headache.

4.6 Pregnancy and Lactation

Pregnancy

Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. Maysedyl expectorant should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 OVER DOSAGE:

Symptoms and signs

The symptoms and signs of overdose may include of overdose may include: severe drowsiness, seizures, widened pupils. In children, mental/mood changes (such as restlessness, irritability, hallucinations) may occur.. With massive doses, coma or cardiovascular collapse may follow.

Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe antichlolinergic symptoms.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Diphenhydramine acts as an inverse agonist at the H1 receptor, thereby reversing effects of histamine on capillaries, reducing allergic reaction symptoms. Diphenhydramine is a first-generation antihistamine, it readily crosses the blood-brain barrier and inversely agonizes the H1 CNS receptors, resulting in drowsiness, and suppressing the medullary cough center.The H1 receptor is similar to muscarinic receptors. Therefore, diphenhydramine also acts as an antimuscarinic; it is a competitive antagonist of muscarinic acetylcholine receptor, resulting in its use as an antiparkinson medication. Lastly, diphenhydramine acts as an intracellular sodium channel blocker, resulting in local anesthetic properties. The liver metabolizes

diphenhydramine via CYP450. It is excreted in the urine, unchanged, and has a half-life of 3.4-9.2h. Its time to peak, serum is 2 hours.

Menthol has mild local anaesthetic and decongestant properties

5.2 Pharmacokinetic properties

Absorption

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

Distribution

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

Metabolism and Elimination

Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

The Elderly

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

DIPHENHYDRAMINE HCl BP

AMMONIUM CHLORIDE BP

SODIUM CITRATE BP

LEVOMENTHOL CRYSTALS BP

GRANULATED SUGAR BP

CITRIC ACID MONOHYDRATE BP

GLYCEROL BP

ETHANOL 96 %

CARAMEL HT

BLACK CURRANT FLAVOR (NON COLOURED) BP

CARMOISINE RED BP

DEMINERALISED WATER

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30^0C. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of that month. The expiry date refers to the product in its original package that has been stored correctly.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

100ml Amber PET bottle with plastic screw cap and insert in a pack.

6.6 Special precautions for disposal <and other handling>

To be destroyed by NAFDAC enforcement unit.

7. <APPLICANT/MANUFACTURER>

May & Baker Nigeria, PLC

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Off Idiroko Road,

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