Drugfield **PHARMACEUTICALS LIMITED**

SUMMARY OF PRODUCT CHARACTERISTICS

Buscomin® Paediatric Drops

1. NAME OF THE MEDICINAL PRODUCT

Buscomin® (Homatrophine Methybromide 2mg) Paediatric Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Homatrophine Methybromide 2mg

(For a full list of excipients, see section 6.1).

3. PHARMACEUTICAL FORM

Liquid preparation

4. Clinical particulars

4.1 Therapeutic indications

Buscomin® -Paediatric drops is indicated for the treatment of gastro-intestinal spasms and as an adjunct in the treatment of peptic ulcer.

4.2 Posology and method of administration

Buscomin® -Paediatric drops for infant doses are to be taken 10-15 minutes before feeding.

Dosage:
Doses according to age:

Up to 3months - 2-4 drops 3-4 times daily
3-6 months - 4-6 drops 3-4 times daily
6-12 months - 6-9 drops 3-4 times daily

4.3 Contraindications

Hypersensitivity to the drug or any component of the formulation. Myasthenia gravis, closed or narrow angle glaucoma.

4.4 Special warnings and precautions for use

Treatment with Buscomin in acute myocardial infarction, thyrotoxicosis, cardiac insufficiency should be done with care. Not to be dispensed or repeated without medical prescription.

If symptoms persist for more than two days consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant administration with other antimuscarinic drugs such as atropine, hyosine, antihistamines, butyrophenones, phenothiazine, and

tricylic antidepressants may cause potentiation of pharmacological responses.

4.6 Pregnancy and Lactation

The product should be used during pregnancy only if the possible benefit outweighs the possible risk to the unborn baby. No studies have been done in animals, and no well-controlled studies have been done in pregnant women. Homatropine should be given to a pregnant woman only if clearly needed.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Mydriasis, cycloplegia; prolonged use may lead to cardiovascular side effects such as bradycardia followed by relaxed tachycardia with palpitation, in high doses urinary urgency, difficulty and retention, constipation due to reduction in gut motility (paralytic ileus) may occur; dryness of mouth; difficulty in swallowing.

4.9 Overdose

Emesis of gastric lavage with 4% tannic acid solution. Administration of aqueous slurry of activated charcoal.

Supportive care:
Adequate hydration.

For anticholinergic overdose with severe life- threatening symptoms, physiostigmine 1-2mg (0.5mg or 0.02mg/kg for children) subcutaneous or intravenous may be given to reverse these effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Homatropine methylbromide belongs to the group of medicines called anti-muscarinics. Homatropine is used to treat duodenal or stomach ulcers or intestine problems. It can be used together with antacids or other medicine in the treatment of peptic ulcer. It may also be used to prevent nausea, vomiting, and motion sickness

5.2 Pharmacokinetic properties

Homatropine methylbromide belongs to the group of medicines called anti-muscarinics. Homatropine is used to treat duodenal or stomach ulcers or intestine problems. It can be used together with antacids or other medicine in the treatment of peptic ulcer. It may also be used to prevent nausea, vomiting, and motion sickness

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Paraben
Propyl Paraben
Sorbitol 70%
Citric Acid Monohydrate
Sodium Citrate
Aspartame
Strawberry Essence
Anise Oil
Purified Water
Talcum Powder
Hyflow Super
Ethanol 96%

6.2 Incompatibilities

None.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30^{o}C in tight container protected from light and moisture.

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

Buscomin® Paediatric Drops is presented in 15ml bottle with leaflet enclosed.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

Drugfield Pharmaceuticals Limited
Lynson Chemical Avenue Km38,
Lagos-Abeokuta Expressway
Sango-Otta, Ogun State, Nigeria
Tel: +2348033513989
Email:Info@drugfieldpharma.com