SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of The Medicinal Product

1.1 Product Name : DEXANTA

1.2 Strength :
Each chewable tablet contains:
Aluminium hydroxide dried gel equivalent to aluminium hydroxide 200 mg
Magnesium hydroxide 200 mg
Simethicone 50 mg

1.3 Pharmaceutical Dosage Form : Chewable tablet

2. Quality and Quantitative Composition

2.1. Qualitative Declaration
Aluminium hydroxide dried gel equivalent to aluminium hydroxide
Magnesium hydroxide
Simethicone

2.2. Quantitative Declaration
Aluminium hydroxide dried gel equivalent to aluminium hydroxide 200 mg
Magnesium hydroxide 200 mg
Simethicone 50 mg

3. Pharmaceutical Form

Chewable tablet.
Green, round and flat beveled edge tablet, diameter 13 mm, peppermint odor, sweet astringent taste. Side I marked DEXA, side II with breakline.

4. Clinical Particulars

4.1 Therapeutic Indications
Symptomatic relief of hyperacidity, gastritis, gastric ulcers, and duodenal ulcers such as nausea, gastric pain, heartburn, flatulence, and fullness of the stomach.

4.2 Posology and Method of Administration
Adults
1 – 2 tablets, 3 – 4 times daily.

Children 6–12 years
½ – 1 tablet, 3 – 4 times daily.

4.3 Contraindications
Should not be used in patients with severe impaired renal function.

4.4 Special Warning and Precautions for Use
- Should not be used continuously for more than 2 weeks, unless directed by a physician.
- Should not be used in children under 6 years, unless directed by a physician.
- Should be used with caution for long-term therapy and in patients with low-phosphorus diet since it may reduce the blood phosphorus levels

4.5 Interaction with Other Medicinal Products and Other Forms of Interactions
DEXANTA may interact with certain drugs. Take DEXANTA at least 1–2 hours before or after other antiulcer drugs such as cimetidine or tetracycline antibiotic

4.6 Fertility, Pregnancy and Lactation
Not applicable.

4.7 Effects on Ability to Drive and Use Machines:
Not applicable.

4.8 Undesirable Effects
Constipation, diarrhea, nausea, vomiting. These symptoms will disappear when the drug is discontinued

4.9 Overdose
Large doses and prolonged use of this medicine may cause anorexia, malaise, muscle weakness, kidney stones, osteoporosis, hypotension, nausea, and vomiting. In case of overdose, get medical help or contact a physician.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties
Aluminium hydroxide and magnesium hydroxide combination are an antacid to neutralize stomach acid and decrease pepsin activity thus relieving upper stomach pain and discomfort. Otherwise, this combination may offer the advantage of balancing the constipating and the laxative qualities. Simethicone releases the gas trapped in the gastrointestinal tract and relieves from bloating.

5.2. Pharmacokinetic Properties
Not applicable.

5.3. Preclinical Safety Data
Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients:
Lactose, corn/maize starch, methylparaben, propylparaben, sodium cyclamate, saccharin sodium, eurocert tartrazine, FD&C blue no. 1 powder, peppermint flavor, talc, magnesium stearate, purified water

6.2 Incompatibilities:
Not applicable.

6.3 Shelf-life:
48 months

6.4 Special Precautions for Storage:
Store at temperatures below 30ºC, protect from light.

6.5 Nature and Contents of Container:
Box, 10 catch covers x 1 strip x 10 chewable 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:
Not applicable.

7. Applicant / Holder of Certificate of Product Registration:
Glorious Dexa Mandaya Ltd.
2nd Floor NIS Building, Plot B, Block H,
Elephant Cement Way,
Central Business District (CBD)
Ikeja, Lagos, Nigeria

8. Drug Product Manufacturer:
Manufactured by:
PT Beta Pharmacon
Kawasan Industri Suryacipta,
Jl. Surya Madya Kav I-18C,
Karawang-Indonesia

For:
PT Dexa Medica
Jl. Jend. Bambang Utoyo No. 138
Palembang-Indonesia

9. Date of Revision of the Text:
November 14, 2023