SUMMARY OF PRODUCT CHARACTERISTICS

MAGNOMINT TABLETS

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1. Name of the medicinal product

a) Proprietary name of a medicine

Magnomint Tablets

b) Approved generic name(s)

Magnesium Trisilicate BP, Dried Aluminium Hydroxide Gel BP

2 Qualitative and quantitative composition

Each Tablet contains: Magnesium Trisilicate BP 250mg; Dried Aluminium Hydroxide Gel BP 125mg.

3 Pharmaceutical form Dosage form

Tablet

4 Clinical particulars

4.1 Therapeutic indication(s)

Magnomint is an antacid indicated for the relief of gastric hyperacidity, indigestion and heartburn.

4.2 Posology and method of administration

To be chewed and then swallowed 4-8 times a day preferably between meal or as directed by a doctor.

Adults and children over 12 years

2-4 tablets

Children 6 to 12 years

1-2 tablets

Do not take more than 32 tablets in any 24 hour period.

4.3 Contra-indications

Magnomint should not be used in patients who are severely debilitated or suffering from kidney failure or if there is severe abdominal pain and/or the possibility of bowel obstruction.

***4.4* Special warnings and precautions for use**

It is wise to avoid taking preparations containing antacids in the first trimester of pregnancy and during lactation. Antacids are known to interfere with the absorption of certain drugs including Tetracyclines, vitamins, ciprofloxacin, ketoconazole, chloroquine, hydroxychloroquine, chlorpromazine, and rifampicin. Most interactions can be avoided by taking Magnomint 2 hours before or after ingestion of other drugs.

4.5 Interactions

Antacids are known to interfere with the absorption of drugs such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, levothyroxine, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, rosuvastatin.

Polystyrene sulphonate

Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminum hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminum hydroxide).

Aluminium hydroxide and citrates may result in increased aluminum levels, especially in patients with renal impairment.

Urine alkalization secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of aluminum hydroxide and magnesium hydroxide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Maalox is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception. Caution should be exercised when prescribing to pregnant and lactating women.

Breast-feeding

Because of the limited maternal absorption, when used as recommended, aluminum hydroxide and magnesium salt combinations are considered compatible with lactation.

No effects on the breastfed newborns/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminum hydroxide and magnesium hydroxide is negligible.

4.7 Effects on the ability to drive and operate machinery

None stated.

4.8 Undesirable effects

Gastro intestinal side effects are uncommon. Occasional diarrhea or constipation may occur, if use is excessive.

4.9 Overdose

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4).

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids; aluminium compound combinations

ATC code: A02AB10

Maalox is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Gastro-intestinal side effects are thus rare with Maalox and this makes it especially suitable when long term therapy is necessary.

5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3 Preclinical safety data

Non-clinical data are limited and are considered insufficient with respect to repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6 Pharmaceutical particulars

6.1 List of excipients

- Starch.
- Sodium Benzoate.
- Potassium sorbate.
- Magnesium stearate.
- Sucrose.
- Sodium Saccharin.
- Peppermint Oil.
- Alcohol 90% Rectified Spirit.
- Sunset yellow FD &C Yellow 6 colour.

6.2 Incompatibilities - None known.

6.3Shelf-life -

- **In the original unopened container;** 48 months
- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

6.4 Special precautions for storage:

Magnomint Tablets should be stored below 25^{o}C, in a dry and dark place.

Keep out of the reach of children

6.5 Nature and composition of containers

Pack Size: 1000s, 10X10 BP, Magnomint Tablet Leaflets, Magnomint Tablet labels

6.6Instruction for use/handling

For internal use only

Restriction on sale / distribution:

General Sale

7 **Administrative data**

i. **Name and address of holder of a registration.**

Regal Pharmaceuticals Limited

Phone: 8564211/2/3/4

Fax: 8560946/8564093

Email: info@regalpharmaceuticals.com

Plot No.: 7879/18, Off Baba Dogo Road, Ruaraka,

P.O. Box 44421-00100, Nairobi, Kenya

8. **Registration number**. H93/294

ii. Date of first registration- 02/04/1993

DECLARATION BY AN APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority of the EAC Partners States.

I further agree that I am obliged to follow the requirements of the Partner States Legislations and Regulations, which are applicable to medicinal products.

I also consent to the processing of information provided by the EAC Partner States.

It is hereby confirmed that fees will be paid/have been paid according to the National/Community rules*

Name: DR. MANDERE JAMES ATEBE
Position in the company: COMPANY PHARMACIST

Signature: .....

Date: 24th July 2019

Official stamp:.....

* Note: If fees have been paid, attach proof of payment