SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GERDICID® Chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 10 mg of famotidine,165 mg of magnesium hydroxyde and 800 mg of calcium carbonate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short-term symptomatic treatment of heartburn or acid regurgitations in adults and adolescents from 16 years old.
GERDICID is a combination of three active substances:

- Famotidine, H_2-receptors antagonist, reducing the production of acid in the stomach.
- Magnesium hydroxide and calcium carbonate, antacids, neutralising the acidity in the stomach.

4.2 Posology and method of administration

For adults and adolescents from 16 years old:

- In case of heartburn and acid regurgitation, chew one tablet
- Prevention: chew one tablet 1 hour prior to the meal
- Do not exceed two tablets per day

The treatment duration is limited to 2 weeks (see section 4.4 Precautions for use).

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Severe renal failure

4.4 Special warnings and precautions for use

Warnings:
It is recommended to patients to seek medical advice in case of:

- Symptoms associated with weight loss,
- Difficulty swallowing or persistent abdominal discomfort,
- Digestive troubles occuring for the first time or if these symptoms have recently changed,
- Known hypercalcaemia, as this product contains calcium,
- Known hypophosphateamia, as this product may worsen this condition,

- Known hypercalciuria, or history of renal calculi or nephrocalcinosis.
- In case of renal failure, this product should be taken under medical supervision and monitoring of serum mangesium and calcium should be undertaken.
- In case of hepatic or renal impairment, this medicine should only be taken under medical supervision and monitoring of serum magnesium and calcium should be undertaken.
- This medicine contains lactose. Its use is not recommended in people suffering from lactose intolerance.

Precautions for use:
If symptoms persist after 15 days of continuous treatment or get worse, an etiologic survey must be done and the conduct of the treatment should be re-evaluated.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids interact with some other medicines taken orally.

Association needing precautions for use:
A decrease absorption of some medicines administered concomitantly is observed.
As a precaution, it is recommended to take antacids separately from other medicines.
In general, space out the doses more than 2 hours apart (see list below). However 4 hours should be left between the administration of the product and administration of quinolones.
The absorption of certain NSAIDs, sulphonylurea antidiabetic agents and the oral anticoagulant dicoumarol can be enhanced by concomitant administration with the product.

- Atenolol, metoprolol, propranolol, sotalol
- Chloroquine,
- Tetracyclines,
- Diflunisal,
- Digoxin,
- Diphosphinate,
- Estramustine (due to the presence of calcium salts)
- Fexofenadine
- Iron (salts)
- Sodium fluoride
- Glucocorticoïdes (described for prednisolone and dexamethasone)
- Indomethacin
- Sodium polystyrene sulphonate resin
- Ketoconazole
- Lansoprazole
- Phenothiazine neuroleptics
- Penicillamine
- Phosphorus (supplements)
- Thyroxin
- Gabapentin
- Benzodiazepines

Association to be taken into account
- **Salicylates**: antacids increase the renal excretion of salicylates by alkalinization of the urine.
- **Probenecid** inhibits the tubular secretion of famotidine and thereby increases the plasma concentrations of famotidine.
- During concomitant use with **cardiac glycosides**, hypercalcaemia can increase the risk of digitalic toxicity (risk of dysrhytmia). Patients should be monitored with regard to ECG and calcium levels.
- **Thiazide diuretics** may cause hypercalcaemia due to decreased renal elimination of calcium. Since the product is only intended for short-term use there is no requirement to monitor calcium in the plasma.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data on a limited number of exposed pregnancies indicate no adverse effects of famotidine on pregnancy or on health of the fetus/newborn child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects of famotidine with respect to pregnancy, embryonal/fetal development, parturition or postnatal development.

Data on a limited number of exposed pregnancies indicate no adverse effects of magnesium hydroxyde or calcium carbonate on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available. Animal studies with magnesium hydroxyde are insufficient. With calcium carbonate ossification abnormalities have been described after long-term treatment at high doses. The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

Lactation
Famotidine is secreted via breast milk. There is a possibility of famotidine affecting the infant's gastric acid secretion. Magnesium salts may enter breast milk and cause diarrhoea. Therefore GERDICID should be avoided during breast feeding.

4.7 Effects on ability to drive and use machines

Although it is not expected, if dizziness appears, patients must not drive or use machines.

4.8 Undesirable effects

The frequencies are classified as follows: very common ≥ 10 %, common ≥ 1% - < 10%, uncommon ≥ 0,1% - < 1%, rare ≥ 0,01% - < 0,1%, very rare, isolated cases < 0,01%.
•*Nervous system*
Common: headache, dizziness
•*Gastrointestinal tract*
Uncommon: nausea, diarrhoea, flatulence, dyspepsia, eructation, dry mouth, thirst.
•*Musculoskeletal, connective tissue and bone disorders*
Uncommon: paresthesia.
•*General disorders*
Uncommon: abdominal distension, abdominal pain, taste perversion.

Other side effects noted in isolated reports with higher dosages of famotidine in principle cannot be excluded.
There have been very rare reports of:

- Cutaneous: skin rashes, pruritus and urticaria, and, as with other H_2-antagonists, severe skin reactions (toxic epidermal necrolysis).
- Hypersensitivity reactions: anaphylaxis, angioneurotic oedema, bronchospasm.
- Hepatic disorders including hepatic cholestasis and such as raised laboratory values for transaminases, gamma-GT, alkaline phosphatase and bilirubin.
- Neurological disorders such as hallucinations: disorientation, confusion and insomnia, epileptic seizures, drowsiness and agitation and depression related states. These have been reported to be reversible on stopping medication.
- Blood disorders such as thrombocytopenia, leucopenia, agranulocytosis and pancytopenia.
- Musculoskeletal disorders, such as muscle cramps.
- Other such as impotence, reduced libido, breast tension.

The following side effects are generally attributed to antacids containing calcium and magnesium salts: change in stool frequency and consistence, bloating and fullness.

4.9 Overdose

Patients have tolerated doses up to 800 mg/day of famotidine for more than a year without development of significant adverse effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: H_2 antagonist/antacid, ATC code: A02BA53 Famotidine, combination

Famotidine reduces the acid and pepsin production, as well as the volume of basal, nocturnal and stimulated gastric secretion. Magnesium hydroxide and calcium carbonate have antacid properties by neutralisation mechanism.

5.2 Pharmacokinetic properties

Famotidine:
Famotidine obeys linear kinetics
Famotidine is rapidly absorbed with dose-related peak plasma concentration occurring at 1-3 hours after administration.
The mean bioavailability of an oral dose is 40-45 %. It is not modified when taken during meals. First-pass metabolism is minimal. Repeated doses do not lead to accumulation of the drug.
Protein binding in the plasma is relatively low (15-20 %). The plasma half-life after a single oral dose or multiple repeated dose (for 5 days) is approximately 3 hours.
Metabolism occurs in the liver, with formation of inactive metabolite, the sulfoxide.
Following oral administration, the mean urinary excrection of famotidine is 65-70 of the absorbed dose, 25 to 30 % as unchanged compound. Renal clearance is 250 to 450 ml/min, indicating some tubular excretion. A small amount may be excreted as the sulfoxide.

Calcium carbonate and magnesium hydroxide are converted to soluble chloride salts by gastric acid. Approximately 10 % of the calcium and 15-20 % of the magnesium is absorbed, and the remaining soluble chlorides are reconverted to insoluble salts, and are eliminated in the faeces. In individuals with normal kidney function the small amounts of calcium and magnesium that are absorbed are rapidely excreted by the kidneys.

5.3 Preclinical safety data

Pre-clinical data for famotidine rveal no specific hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

Only limited toxicology data are available for magnesium hydroxide and calcium carbonate. These data indicate no special hazard for humans under normal conditions of use. Ossification abnormalities have been described in animals treated with calcium carbonate at high doses or long periods.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, cellulose acetate, maize starch, magnesium stearate, sodium benzoate (E211), gum arabic, sucralose, hydroxypropylcellulose, hypromellose, crospovidone, spearmint and peppermint flavours.

6.2 Incompatibilities

No incompatibility known up to date.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep out of reach and sight of children.
Store in the original packaging, protect from light, heat and moisture.

6.5 Nature and contents of container

Pouch of four chewable tablets packaged in alu-alu strips.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

EXPHARLAB Ltd,
Ovado place, No. 387 Agege Motor Road,
Mushin, Lagos, Nigeria

8. CATEGORY OF DISTRIBUTION

☒ Over-the counter medicine ☐ Prescription only medicines

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Milan laboratories (India) Pvt. Ltd.
Jawhar Co-Op Industrial Estate Ltd.,
Kamothe, Panvel (Navi Mumbai), Maharashtra - 410209.
INDIA

10. DATE OF REVISION OF THE TEXT

08/2019