### Sodium Alginate Sodium Bicarbonate Calcium Carbonate

### GAVISCON

250 mg/ 133.50 mg/ 80 mg Chewable Tablet

# 1. WHAT IS SODIUM ALGINATE, SODIUM BICARBONATE, CALCIUM CARBONATE (GAVISCON) CHEWABLE TABLETS AND WHAT IS IT USED FOR?

This product belongs to a group of medicines called 'reflux suppressants', which form a protective layer on top of the stomach contents to prevent stomach acid escaping from the stomach where it works into the food pipe causing pain and discomfort. Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate (Gaviscon) Chewable Tablets is used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), which may occur, for example, following meals or during pregnancy, and in patients with symptoms related to oesophagitis.

This medicine starts working after 3 to 4 minutes of use.

This medicine is indicated for adults and children aged 12 years and above.

# 2. BEFORE USING SODIUM ALGINATE, SODIUM BICARBONATE, CALCIUM CARBONATE (GAVISCON) CHEWABLE TABLETS

### Do not take this product if:

You know you are allergic to any of the ingredients as very rarely difficulty in breathing and skin rashes have occurred (see further information for full ingredients list).

### Take special care before treatment with this product:

Talk to your doctor or pharmacist before taking this medicine if you:

- are on a low salt diet due to kidney problems or heart failure
- have high calcium levels in your blood
- have calcium deposition in the kidney
- have kidney stones

This medicine contains 63.16 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 3.2 % of the recommended maximum daily dietary intake of sodium for an adult. This medicine also contains 3.2 mnol of calcium per 4 tablet dose. The maximum recommended daily dose of this medicinal product contains 1012 mg sodium (found in table salt). This is equivalent to 50.6% of the adult recommended maximum daily dietary intake for sodium. Please also talk to your doctor regarding these salt contents if you suffer or have suffered from significant kidney or heart disease, as certain salts could interfere with these diseases. Talk to your pharmacist or doctor if you need this product on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

This medicine contains 3.75 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

#### Taking Other Medicines:

Do not take this product within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines. This is especially important if you are taking antihistamines, antibiotics (tetracyclines and quinolones such as norfloxacin), iron preparation, antifungals such as ketoconazole, digoxin and beta blockers (for heart conditions), penicillamine (commonly for rheumatoid arthritis), glucocorticoid (for inflammatory and autoimmune disorders), neuroleptics (for mental illness), thyroid hormones, chloroquine (for malaria), estramustine (for prostate cancer) and bisphosphonates (for osteoporosis).

#### Pregnancy and breast-feeding:

You can take this product if you are pregnant or breast - feeding. As with all medicines, the treatment duration should be limited as much as possible.

## 3. HOW TO TAKE SODIUM ALGINATE, SODIUM BICARBONATE, CALCIUM CARBONATE (GAVISCON) CHEWABLE TABLETS

For oral administration, Chew thoroughly before swallowing.

Adults, including the elderly and children 12 years and over: When symptoms occur take two to four tablets after meals and at bedtime, up to four times a day.

Children under 12 years: Should only be taken on medical advice.

If you forget a dose, it is not necessary to double the dose next time, just carry on taking as before.

If you take too much of this product you may feel bloated and experience some abdominal discomfort. It is unlikely to cause you any harm, but please consult your doctor or pharmacist.

After taking Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate (Gaviscon) Chewable Tablets:

If symptoms persist after 7 days consult your doctor.

#### 4. POSSIBLE SIDE FEFFCTS

Very rare (less than 1 in 10,000) chance of an allergic reaction to the ingredients. Symptoms of this may include skin rash, itching, difficulty breathing, dizziness, or swelling of the face, lips, tongue or throat. If you experience these or any other side-effects stop taking the product and consult your doctor immediately.

# 5. HOW TO STORE SODIUM ALGINATE, SODIUM BICARBONATE, CALCIUM CARBONATE (GAVISCON) CHEWABLE TABLETS

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date shown on the pack. Do not store above 30°C.

#### 6. FURTHER INFORMATION

Sodium Alginate, Sodium Bicarbonate, Calcium Carbonate (Gaviscon) Chewable Tablets are circular tablets with an off white to cream, slightly motted appearance.

Each chewable tablet contains 250 mg sodium alginate, 133.5 mg sodium bicarbonate and 80 mg calcium carbonate as the active ingredients. The other ingredients are mannitol, macrogol 20,000, copovidone, aspartame, peppermint flavouring, magnesium stearate and acesulfame potassium.

These tablets do not contain sugar or gluten.

For suspected adverse drug reaction, report to the FDA: <u>www.fda.gov.ph</u>. Seek medical attention immediately at the first sign of any adverse reaction.

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Manufactured by: Reckitt Benckiser Healthcare (UK) Limited Dansom Lane, Hull HU8 7DS UK

Imported by: Reckitt Benckiser Healthcare (Phils) Inc.

3/F Mead Johnson Bldg. 2309 Don Chino Roces Ave. Ext.,

Makati City, Philippines, 1231