

# ACTAL PLUS TABLET

Sodium Polyhydroxyaluminium Mono-Carbonate Hexitol Complex/ Simethicone/ Magnesium Hydroxide (333mg/25mg/152mg)

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### 1. What ACTAL PLUS Tablet is used for?

ACTAL PLUS Tablet is used for the relief of pain and flatulence (wind) associated with gastric hyperacidity (excessive acid), heartburn, peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus) and indigestion.

### 2. How ACTAL PLUS Tablet works

ACTAL PLUS Tablet rapidly neutralizes hyperacidity of gastric contents. Aluminium hydroxide contributes in acid neutralization. Magnesium hydroxide contributes to immediate acid neutralization. The antiflatulent, simethicone reduces the surface tension of the bubbles present in the stomach to relieve gastric distress resulting from retention of gas.

### 3. Before you take ACTAL PLUS Tablet

#### When you must not take ACTAL PLUS Tablet

- Do not take ACTAL PLUS Tablet if you are a hypophosphataemia (low level of phosphorus in the blood) patient.

- ACTAL PLUS Tablet is an antacid. Antacids should preferably not be taken at the same time as other medicines as they may impair their absorption. Antacids may also damage enteric (intestinal) coatings designed to prevent dissolution in the stomach. The complete list of interactions is stated under section <Taking other medicines>.
- If you have known hypersensitivity to the active ingredient and any other component of the preparation.

#### Before you start to take ACTAL PLUS Tablet

Before you take ACTAL PLUS Tablet, talk to your doctor or pharmacist. There are a few precautions to be noted:

- Safety in pregnancy and lactation is not established.
- Antacids should preferably not be taken at the same time as other drugs as they may impair their absorption. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach.
- In general, aluminium salts are not well absorbed from the gastrointestinal tract. Therefore, systemic effects (adverse effect of a medical treatment that affects the body as a whole, rather than one part) are rare in patients with normal renal (kidney) function.
- Care is necessary in patients with chronic renal impairment. Diseases such as:
  - osteomalacia (bone softening)
  - adynamic bone (causing a loss of strength or function of the bone)
  - encephalopathy (disorder of the brain)

- dementia (loss the ability to think)
- microcytic hypochromic anaemia (red blood cells are smaller and paler than normal); have been associated with aluminium accumulation in such patients given large doses of aluminium hydroxide as a phosphate-binding agent. Similar side effects have also been associated with the aluminium content of dialysis fluid.

#### Taking other medicines

Antacids interact with many other medicines both by alterations in gastric acidity and emptying, and by formation of complexes that are not absorbed. Interactions can be minimized by giving the antacid and any other medications 2 to 3 hours apart.

The complete list of interactions is stated below:

- ACE Inhibitors: antacids reduce absorption of fosinopril
- Analgesics: excretion of aspirin increased in alkaline urine; antacids reduce absorption of diflunisal
- Anti-arrhythmics: excretion of quinidine reduced in alkaline urine (may occasionally increase plasma concentrations)
- Antibacterials: antacids reduce absorption of azithromycin, cefpodoxime, ciprofloxacin, isoniazid, nitrofurantoin, norfloxacin, ofloxacin, pivampicillin, rifampicin, and most tetracyclines
- Antiepileptics: antacids reduce absorption of gabapentin and phenytoin
- Antifungals: antacids reduce absorption of itraconazole and ketoconazole
- Antiplatelet Drugs:

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dipyridamole patient information leaflet advises avoidance of antacids.

- Antimalarials: antacids reduce absorption of chloroquine and hydroxychloroquine
- Antipsychotics: antacids reduce absorption of phenothiazines
- Bisphosphonates: antacids reduce absorption
- Iron: magnesium trisilicate reduces absorption of oral iron
- Lithium: sodium bicarbonate increases excretion (reduced plasma-lithium concentration)
- Mycophenolate Mofetil: antacids reduce absorption of mycophenolate mofetil
- Penicillamine: antacids reduce absorption

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

## 4. How to take ACTAL PLUS Tablet

### How much to take

Gastric Hyperacidity:

Suck and chew 1 to 2 tablets, half an hour to one hour after each meal and at bed time.

Heartburn:

Suck and chew 1 to 2 tablets, half an hour to one hour after each meal and at bed time.

Indigestion:

Suck and chew 1 to 2 tablets, half an hour to one hour after each meal and at bed time.

Peptic Ulcer:

Suck and chew 2 to 4 tablets, half an hour to one hour after each meal and at bed time.

ACTAL PLUS Tablet should be sucked and chewed before swallowed.

Do not take more than 8 tablets in a

24 hour period or use the maximum dosage for more than 2 weeks, except under the supervision of a physician.

### When to take ACTAL PLUS Tablet

The administration depends on your condition. It is important to take your medicine at the right time. Talk to your doctor or pharmacist for further information.

### How long to take it

The administration depends on your condition. Talk to your doctor or pharmacist for further information.

### If you forget to take ACTAL PLUS Tablet

Tell your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

### If you take too much (overdose)

Large doses can cause intestinal obstruction. Excessive doses, even normal doses in patient with low-phosphate diets may lead to phosphate depletion accompanied by increased resorption (the process by which something is re-absorbed) and urinary excretion of calcium with the risk of renal rickets (a disorder which leads to softening and weakening of the bones) in the young or bone softening in the older patients.

In order to reduce the constipating effects, aluminium hydroxide is often given with a magnesium-containing antacid, such as magnesium oxide or magnesium hydroxide.

Aluminium hydroxide is poorly absorbed and unlikely to cause serious symptoms following overdose. Hence, there is no specific treatment or antidote (a drug or substance that counteracts or neutralizes the effects of a

poison) for overdose.

Excessive ingestion of magnesium may lead to hypermagnesemia (high level of magnesium in the blood) even without kidney dysfunction. The overdose of magnesium hydroxide may induce diarrhea, which is followed by excessive magnesium loss.

As simethicone is not absorbed into the body, there is no likelihood for an overdose.

If you take more ACTAL PLUS Tablet than you should, tell your doctor or pharmacist.

## 5. While you are taking ACTAL PLUS Tablet

### Things you must do

Tell all the doctors, dentists and pharmacists that are treating you that you are taking ACTAL PLUS Tablet.

### Things you must not do

Do not take more than 8 tablets in a 24 hour period or use the maximum dosage for more than 2 weeks, except under the supervision of a physician. For further information, please refer to your doctor or pharmacist.

### Things to be careful of

This medicine or the stomach discomfort itself may affect your ability to drive or use machines. If the tablets or the discomfort make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

## 6. Side Effects

ACTAL PLUS Tablet contains aluminium hydroxide, magnesium hydroxide and other ingredients. Aluminium hydroxide, like other aluminium compounds, is astringent and may cause constipation; large doses can cause

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intestinal obstruction. Magnesium hydroxide may cause diarrhea, an effect that is dose-dependent. Hypermagnesaemia may occur, usually in patient with renal impairment. Although oral administration of simethicone is generally well tolerated when used as directed, the following adverse reactions have been observed on rare occasions: diarrhea (mild), nausea, regurgitation (sensation of acid backing up into the throat or mouth which can produce a sour or bitter taste, and you may experience a “wet burp” or even vomit some contents of your stomach), vomiting, bloating, heartburn, and constipation.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→ Reporting).

## 7. Storage and Disposal of ACTAL PLUS Tablet

### Storage

- Keep out of reach of children.
- Do not use ACTAL PLUS Tablet after the expiry date which is stated on the pack after ‘Exp’.
- Store your ACTAL PLUS Tablet below 30°C.

### Disposal

- If your doctor or pharmacist tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

medicines no longer required. These measures will help to protect the environment.

## 8. Product Description

### What ACTAL PLUS Tablet looks like

ACTAL PLUS Tablet is a mint-flavoured chewable tablet. It is round, flat, yellow tablet with ‘ACTAL’ marking on both sides. Free from foreign matter, no chipping and capping.

### Ingredients

Active ingredient:

- a) 333.0mg of sodium polyhydroxyaluminium monocarbonate hexitol complex which is equivalent to 200.0mg of aluminium hydroxide.

b) Magnesium hydroxide

c) Simethicone

The other ingredients are saccharin, refined sugar, mannitol, dextrose monohydrate, sodium saccharin, povidone K-25, FD&C Yellow No. 6, D&C Yellow No.10, purified talcum, magnesium stearate, peppermint oil and purified water.

### MAL number

MAL13085057XC

### Packing Particulars

- 20 tablets: 10 chewable tablets x 2 blister strips
- 120 tablets: 10 chewable tablets x 12 blister strips

## 9. Manufacturer

Pharmaniaga Manufacturing Berhad (60016-D),  
11A, Jalan P/1 Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

## 10. Product Registration Holder

A. Menarini Singapore Pte.Ltd. (994247-T),  
Level 2, No. 10 Jalan Bersatu 13/4, 46200 Petaling Jaya, Selangor.

## 11. Date of Revision

26/05/2014