

ACTAL TABLET

Sodium Polyhydroxyaluminium Monocarbonate Hexitol Complex (360mg)

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1. What ACTAL Tablet is used for?

ACTAL Tablet is used for the relief of stomach discomfort such as indigestion, heartburn due to gastric hyperacidity (excessive acid) and peptic ulcer (an ulcer of the stomach, duodenum or lower end of esophagus).

2. How ACTAL Tablet works

ACTAL Tablet rapidly neutralizes hyperacidity of gastric contents.

3. Before you take ACTAL Tablet

When you must not take ACTAL Tablet

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

Before you take ACTAL 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 medicines 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 when 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: 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

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- 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 Tablet

ACTAL Tablet should be sucked and chewed before swallowed.

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 / 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 Tablet should be sucked and chewed before swallowed.

Do not take more than 4 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 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 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 overdosage.

Hence, there is no specific treatment or antidote (a medicine or substance that counteracts or neutralizes the effects of a poison) for overdosage.

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

5. While you are taking ACTAL Tablet

Things you must do

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

Things you must not do

Do not give ACTAL Tablet to anyone else, even if they have the same symptoms or condition as you.

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 Tablet contains aluminium hydroxide. Aluminium hydroxide, like other aluminium compounds, is astringent and may cause constipation; large doses can cause intestinal obstruction.

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 (Consumers → Reporting).

7. Storage and Disposal of ACTAL Tablet

Storage:

- Keep out of reach of children.
- Do not use ACTAL Tablet after the expiry date which is stated on the pack after 'Exp'.
- Store your ACTAL 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.

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8. Product Description

What ACTAL Tablet looks like

ACTAL Tablet is a round white mint flavoured tablets with 'ACTAL' markings on both sides. Free from foreign matter, no chipping and capping.

Ingredients

The active ingredient is sodium polyhydroxyaluminium monocarbonate hexitol complex which contains aluminium hydroxide. Each ACTAL tablet contains 360.0mg of sodium polyhydroxyaluminium monocarbonate hexitol complex which is equivalent to 216.0mg of aluminium hydroxide.

The other ingredients are corn starch, mannitol, purified talcum, magnesium stearate, sodium saccharin, peppermint oil and purified water.

MAL Number

MAL13085056XC

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