148.5mm

210mm

ActiMol Tablet 500 mg

pharmaniaga®

DESCRIPTION
White, round flat bevelled edge with Pharmaniaga icon on one side and breakline on the other.

COMPOSITION
Each tablet contains Paracetamol 500mg.

PHARMACODYNAMICS
Pharmacotherapeutic group:
Other analgesics and antipyretics, Anilides

ATC code N02B E01

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however to be on a selective basis.

PHARMACOKINETICS
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses. Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 30% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 - 100% of the drug may be recovered in the urine within the first day. However, practically no paracetamol is excreted unchanged and the bulk is excreted after hepatic conjugation.

INDICATIONS
For the relief from fever
For the relief from mild to moderate pain including : headache, migraine, backache, musculoskeletal pain, myalgia and neuralgia, dysmenorrhea, pain of osteoarthritis, toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from cold, influenza and sore throats.

CONTRAINDICATIONS
Hypersensitivity to paracetamol or any of the /other ingredients/ components of the product.

Severe and active hepatic impairment.

ADVERSE REACTIONS
Adverse reactions of paracetamol are rare and usually mild, though hematological reactions have been reported.

Body system	Adverse reactions	Frequency
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis	Very rare
	Cutaneous hypersensitivity reactions including skin rashes and angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.	Unknown
Respiratory, thoracic and mediastinal disorders	Bronchospasm*	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

*There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

WARNINGS AND PRECAUTIONS
This preparation contains PARACETAMOL. Do not take any other PARACETAMOL containing medicines at the same time.

Allergy alert:
Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of serious conditions. If these reactions occur, stop use and seek medical assistance right away.

- Keep out of reach of children.
- Do not take if allergic to paracetamol.
- Patients should contact their health care provider if symptoms persist (if the pain lasts for more than 10 days, if there is redness or fever lasts more than 3 days).
- Paracetamol should be given with care to patients with impaired kidney or liver function.
- Large doses should be avoided in patients with hepatic impairment. Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- It should be given with care to patients with alcohol dependence.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be initiated when necessary.
- Patients should be advised to consult their doctor if their headaches become persistent.
- Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.
- Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis.
- Use with caution in patients with glutathione depletion due to metabolic deficiencies.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
It is unlikely to impair a patient's ability to drive or to use machinery.

INTERACTION WITH OTHER MEDICAMENTS
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

PREGNANCY AND LACTATION
Use in pregnancy:
- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses placenta, paracetamol should be used at the lowest effective dose for the shortest possible time as a minor analgesic/antipyretic in pregnancy.

Use in lactation:
- Excreted in breast milk.
- Available published data do not contraindicate breastfeeding.

RECOMMENDED DOSAGE
Adults and children aged 12 years and over :

attn	customer **Pharmaniaga Manufacturing Berhad**		date **09.11.2021**
1 colours	spot colour: **PMS 285**		**Please Chop & Sign For Approval**
size description	**148.5 x 210mm** **Actimol 500mg Leaflet- Front**	material finishing	**60g Simili**
FocusPrint SDN BHD	t: 603-8766 6030 f: 603-8766 6033 (Factory) website: www.focusprint.com.my		
artwork prepared by: cynthia yap	email: graphic@focusprint.info (graphic Dept)		**date:**

IMPORTANT ! **Please note that this colour print is for visual purpose only. Output colour might differ in actual production.**

ARTWORK LOG

Version no.	Date	Reason for Change
01	26.02.16	- New artwork received.
02	01.03.16	- Amend PRP no.
03	10.05.16	- Amend text.
04	13.05.16	- Amend text.
05	16.05.16	- Amend text.
06	16.05.2016	- Amend text.
07	11.04.2018	- Amend text.
08	16.04.2018	- Amend text.
09	30.04.2018	- Amend PRP
10	14.06.2019	- Add in the new packing in Presentation
11	29.07.2019	- Amend text and PRP no.
12	08.10.20201	- Amend text and PRP no.
13	09.11.20201	- Amend text and PRP no.

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500mg or 1g paracetamol, taken every 4-6 hours as required up to a maximum of 4g daily.

Children 6 - 11 years :
250mg - 500mg every 4 to 6 hours as required. Maximum daily dose : 60mg/kg presented in divided doses of 10-15mg/kg throughout 24 hour period.

Children should not be given paracetamol for more than 3 days without consulting a doctor.

These doses should not be repeated more frequently than every four hours nor should more than four doses be given in any 24 hour period.

OVERDOSAGE

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors
If the patient
a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes; or
b) Regularly consumes ethanol in excess of recommended amounts; or
c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms:
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia,cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Treatment:
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patient, should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be accordance with established treatment guideline.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed further with the non-pharmaceutical interventions or a liver unit.

ROUTE OF ADMINISTRATION

Oral

STORAGE CONDITIONS

Store below 30°C. Protect from light and moisture.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION

In boxes of 1 blister x 10 tablets, 2 blisters x 10 tablets, 3 blisters x 10 tablets, 10 blisters x 10 tablets, 50 blisters x 10 tablets and 100 blisters x 10 tablets.

Date of Revision : 8th October 2021

PRODUCT REGISTRATION HOLDER/MANUFACTURER:

PHARMANIAGA MANUFACTURING BERHAD (198001006232)
No. 11A, Jalan P/1, Kawasan Perusahaan Bangi,
43650 Bandar Baru Bangi, Selangor Darul Ehsan.

PRP 0267.6/ BRP 0267.1 081021

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