

GDN Fever & Pain Relief MYS Insert
Opsl 2: 70 (W) x 192 (H) mm

guardian

FEVER & PAIN RELIEF TABLET

Paracetamol 500mg

Name and strength of active pharmaceutical ingredient(s)
Paracetamol 500 mg

Product description
Plain tablet, round 1/2" in diameter, white, flat, beveled-edge, debossed with "GUARDIAN" logo insignia on one side and plain on the other side.

Pharmacodynamics
Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties.

Analgesic
The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (specifically cyclooxygenase (COX)-2) and, to a lesser extent, through a peripheral action by blocking pain impulse generation.

The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic
Paracetamol act centrally on the hypothalamic heat-regulating center to produce peripheral vasodilatation resulting in increase blood flow through the skin, sweating and heat loss. Paracetamol reduces fever by inhibiting the formulation and release of prostaglandins in the CNS and by inhibiting endogenous pyrogens at the hypothalamic thermoregulatory center.

Pharmacokinetics
Following oral administration paracetamol is rapidly absorbed.

Paracetamol absorption takes place mainly in the small intestine and therefore the rate of absorption is depending on the rate of gastric emptying. It has been shown that drugs which delay gastric emptying also delay the absorption of paracetamol whereas metoclopramide (a drug which increases the rate of gastric emptying) accelerates absorption of the analgesic through the total amount absorbed doses not increase.

The presence of food in the stomach has also been reported to reduce the rate of absorption of paracetamol. Alterations in gastric pH have no appreciable effect on paracetamol absorption. During absorption, the amount of paracetamol which is inactivated is negligible and it has been shown that paracetamol does not affect gastric mucosal permeability and does not produce mucosal bleeding.

Peak plasma concentrations are reached 1 hour after absorption. The plasma half life is 1 to 3 hours.

Paracetamol penetrates the brain and is present in breast milk of human.

Paracetamol is metabolized by the microsomal enzyme system of the liver. This metabolism is mainly to the glucuronide and sulphate conjugates, accounting for approximately 49% and 26% of the ingested dose respectively. About 4% is excreted as free paracetamol. Other minor pathways include the excretion is rapid and occurs via the urine.

Indication
Guardian fever & pain relief tablet is an analgesic and antipyretic agent which relieves fever, headache and muscular pain caused by cold and flu.

Recommended dose
Adults and children aged 12 years and above:
1 - 2 tablets, taken every 4 - 6 hours as required up to a maximum of 8 tablets daily.

Children 6 to 11 years:
0.5 - 1 tablet every 4 to 6 hours as required.

Maximum daily dose: 60 mg/kg presented in divided doses of 10 - 15 mg/kg throughout 24 hour period.

Route of administration
Oral.

Contraindication
Hypersensitivity to paracetamol or any of the other ingredients/components of the product.
Severe and active hepatic impairment.

Warning and precautions
This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

- 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 last 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 instituted when necessary.

Effect on Ability to Drive and Use Machines. It is unlikely to impair a patient's ability to drive or use machinery.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.

These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Interactions with other medications

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.

Statement on usage during pregnancy and lactation

Use in pregnancy:
• Considered to be the analgesic of choice in pregnant patients.
• Although it crosses placenta, paracetamol is considered to be safe in normal therapeutic doses for short-term use as a minor analgesic/antipyretic in pregnancy.

Use in lactation:
• Excreted in breast milk.
• Maternal ingestion of paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

Side effect

Skin rashes and other allergic reaction may occur occasionally and liver damage may occur when 10 g or more is consumed. In cases of accidental overdose, seek medical attention immediately, even if there is no symptom. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Overdose and treatment

Symptoms:
Toxic symptoms include vomiting, abdominal pain, hypotension, and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Treatment:
In case of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50 g activated charcoal and 500 ml-iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15 g Paracetamol or more has been ingested, administer one of the following antidotes;

Acetylcysteine 20% i.v.: Administer intravenously, 20% acetylcysteine immediately without waiting for positive urine test or plasma level results: initial dose of 150 mg/kg over 15 minutes, followed by continuous infusion of 50 mg/kg in 500 ml 5% glucose/dextrose over 4 hours and 100 mg/kg in 1L 5% glucose/dextrose over 16 hours;

OR

Oral Methionine: 2.5 g immediately followed by three further doses of 2.5 g at four hourly intervals. For a 3 year old child, 1 g methionine every four hours for doses has been used.

OR

Oral acetylcysteine 5%: 140 mg/kg as a loading dose, then 70 mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdose was taken, the antidote may be in ineffective.

Storage condition

Store at temperatures not exceeding 30°C

Pack Size:
4, 10, 30, 80, and 100 tablets

Date of Revision of Package Insert
May 2023

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Jawa Barat, Indonesia

GDXXXXXXX
PIN:00000xxx
879409+CAIGXXYY

PT Medifarma Laboratories		PRINT OUT ARTWORK	
Date	: Jul 26, 2023	AW Rev No. :	04
Descriptions	: --	Dimension :	70 x 192 mm
Item Code	: --	PRINT OUT :	100%
Remarks	: (31/05) - Revise text to Gotham bold and gotham book - Change text color from black 80% to black (100%) (28/06) - Change "cyclooxygenase" to "cyclooxygenase" - Change "dose" to "does" - Change "AGO/RC/6294" to "RC/00006294" (30/06) - Change "angiodema" to "angioedema" (10/07) - Change "GD350LR1W" to "GDXXXXXXX" (26/07) - Change "Patiens" to "Patients" - Change "Acetylcyteine" to "Acetylcysteine"		Colors Information :  Black 100%

APPROVED BY						
Director Own Brand Design	Commercial Own Brand Director	Design Team		Product Team	Local Product Team	Technical Team
Signature:	Signature:	Signature:	Signature:	Signature: 	Signature:	Signature:
Date:	Date:	Date:	Date:	Date: 20230711	Date:	Date:

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