



Composition: Paracetamol 500mg
Description: White powder with bitter taste
Pharmacodynamics:
Paracetamol has an analgesic and antipyretic effects. It alleviates pain by inhibiting the prostaglandin synthesis of the brain. Therefore block the synthesis of prostaglandin. However, it will not alleviate any pain that arises from smooth muscle spasm in hollow viscera. It reduces fever by inhibiting the action of endogenous pyrogen on the hypothalamic heat-regulating centers to increase dissipation of body heat.
Pharmacokinetic:
Paracetamol is rapidly and completely absorbed from the gastro-intestinal system. The plasma concentration reaches a peak in ½ to 1 hour, and the plasma half-life is about 1 to 4 hours. Paracetamol is metabolized in the liver. The hydroxylated motabolites are responsible for methemoglobin formation and hepatotoxicity. About 3% of the absorbed paracetamol is excreted unchanged in the urine and about 80% in conjugated forms.
Indication: For relief of fever, headache and mild pain.
Dosage: Adult: 1 - 2 sachets. Maximum 8 sachets daily. Children 1-4 year: 1/3 sachets. Maximum 2 sachets daily. Children 5-10 year: 1/2 sachets. Maximum 3 sachets daily. Take with warm water every 4 hours per day.
Route of Administration: Oral
Contraindication:
Nephropathy, Hypersensitivity to Paracetamol.
Warning and Precaution:
This preparation contains Paracetamol. Do not take any other paracetamol containing medicines at the same time. Paracetamol should be given with care to patients with impaired kidney or liver functions. Chronic use should be avoided.
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.
Drug Interaction:
Caution should be taken when Paracetamol are administered concurrently with these medications.
- Paracetamol may increase Chloramphenicol concentrations.

-Prolonged use or high doses of Paracetamol may increase the effects of oral anticoagulant (eg. Warfarin).
-Paracetamol absorption is increased by drugs which increase gastric emptying (eg. Metoclopramide)
-Paracetamol absorption is decreased by drugs which decrease gastric emptying (eg. Propantheline or narcotic analgesics, Pethidine).
-Paracetamol toxicity may be increased by the concomitant use of enzyme inducing agents (eg. alcohol or Phenytoin).
Pregnancy and Lactation:
Use in Pregnancy:
Paracetamol has been taken by large number of pregnant women and women of childbearing age without any proven increase in frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.
Use in Lactation:
Paracetamol is excreted in breast milk in less than 1% of the dose ingested by lactating women. Therefore, maternal ingestion of therapeutic doses does not present a risk to the baby.
Side effect:
Side effects of Paracetamol are usually milk, skin rashes and allergic reactions occur occasionally. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.
Symptoms and Treatment of Overdose:
Symptoms: Nausea, vomiting, anorexia and abdominal pain, acute renal failure may develop. In severe poisoning hepatic failure may proceed to encephalopathy, coma and death.
Treatment: Remove the ingested drug by activated charcoal orally or N-acetylcysteine 150mg per kg body weight as a 20% solution given intravenously over 15 minutes followed by I.V.infusion of 50mg per kg in 500ml of dextrose injection over the next 4 hours and then 100mg per kg in one liter of dextrose injection over the next 16 hours.
Storage: Store below 30°C.
Protect from light and moisture.
Keep out of reach of children.
Shelf Life: Please refer to the packaging.
Dosage Form: Powder
Packing Size: 24 sachets x 1g

140mm(W) x 200mm(H)

Komposisi: Paracetamol 500mg
Deskripsi:
Serbuk yang berwarna putih dengan sedikit rasa pahit.
Farmakodinamik:
Sila rujuk kepada penerangan Bahasa Inggeris.
Farmakokinetik:
Sila rujuk kepada penerangan Bahasa Inggeris.
Indikasi:
Untuk melegakan demam, sakit kepala dan kesakitan ringan.
Cara Penggunaan:
Dewasa: 1-2 bungkus. Maksima 8 bungkus sehari.
Kanak-kanak 1-4 tahun: 1/3 bungkus. Maksima 2 bungkus sehari. 5-10 tahun: 1/2 bungkus. Maksima 3 bungkus sehari. Dimakan dengan air suam setiap 4 jam sehari.
Laluan Pemberian Ubat: Oral
Kontraindikasi:
Pesakit buah pinggang dan yang hipersensitif terhadap paracetamol.
Amaran dan Perhatian:
Ubat ini mengandungi Paracetamol. Jangan makan ubat lain yang mengandungi Paracetamol pada masa yang sama. Perlu diberikan dengan berhati-hati untuk pesakit yang mempunyai penjejasan pada buah pinggang atau hati. Penggunaan jangka panjang harus dielakkan.
Amaran alahan: Paracetamol boleh menyebabkan alahan kulit yang teruk. Simptom termasuk kemerahan kulit, lepuh atau ruam. Ini boleh menjadi tanda keadaan serius. Jika tindak balas ini berlaku, berhenti menggunakannya dan dapatkan bantuan perubatan dengan segera.
Interaksi dengan ubat lain:
Sila rujuk kepada penerangan Bahasa Inggeris.
Kehamilan dan Penyusuan:
Sila rujuk kepada penerangan Bahasa Inggeris.
Kesan Sampingan:
Sila rujuk kepada penerangan Bahasa Inggeris.
Symptom dan Rawatan untuk kelebihan Dos:
Sila rujuk kepada penerangan Bahasa Inggeris.
Penyimpanan:
Simpan di bawah 30°C
Lindungi daripada cahaya dan kelembapan.
Jauhkan daripada capaian kanak-kanak.
Tempoh Hayat: Sila rujuk kepada pembungkusan
Dos: Serbuk
Saiz Bungkus: 24 sachet x 1g

Date of revision: 16.4.2021

Manufactured by:
Syrikat Wen Ken Drug Sdn Bhd
24, Jalan lambak, Taman Johor, 81200 Johor Bahru, Johor.
Product Registration Holder:
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