YL PARACETAMOL 500MG TABLET

PRODUCT DESCRIPTION
White to off white uncoated round flat tablet with scoreline on 1 side and plain on another side.

COMPOSITION
Each uncoated tablet contains 500mg Paracetamol.

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 inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic
Paracetamol acts centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased 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 thermoregulator center.

PHARMACOKINETICS
Following oral administration paracetamol is rapidly absorbed.

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 relief from fever
-For the relief from mild to moderate 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 colds, influenza and sore throats.

CONTRAINDICATIONS

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

Severe and active hepatic impairment.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS

Adverse effects of paracetamol are rare and usually mild, although hematological reactions have been reported.

Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.

Body System	**Adverse Reaction**	**Frequency**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema. Very rare cases of serious skin reactions have been reported.	Very rare
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. Leave at least 4 hours between doses.
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed serious liver damage.

- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted 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 MACHINES
It is unlikely to impair a patient's ability to drive or 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 hepatotoxicity of paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants and alcohol.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolize large doses of paracetamol, the plasma half-life of which can be prolonged.

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

PREGNANCY AND LACTATION
Use in pregnancy:
- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses placenta, paracetamol is 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.

RECOMMENDED DOSAGE
Adults and children aged 12 years and over: 500mg or 1g paracetamol (1 or 2 tablets), taken every 4-6 hours as required up to a maximum of 4g (8 tablets) in 24 hours.

Children 6 - 11 years: 250mg or 500mg paracetamol (1/2 or 1 tablet), taken every 4 to 6 hours as required up to a maximum of 2g (4 tablets) in 24 hours.

Maximum 24 hours dose: 60mg/kg presented in divided doses of 10-15mg/kg throughout 24 hours period.
Children below 6 years: Not recommended.
Do not exceed the recommended dose.
The lowest effective dose and the shortest duration of treatment should be used.

OVERDOSAGE
Paracetamol Overdose may cause liver failure which may required 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.
Risk Factors,
If the patient

a) Is on term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St Johns wort or other drugs that include liver enzymes or
b) Regularly consumes ethanol in excess or 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, hemorrhage, hypoglycemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by joint pain, hematuria, and proteinuria, may develop even in the absence of sever liver damage. Cardiac arrythmias and pancreatitis have been reported.

Treatment:
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients 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 in accordance with established treatment guidelines.

Treatment with activated charcoal should be considered I 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 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 CONDITION
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.

PACK SIZE
Boxed tablets in ALU/PVC blisters, as 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.

PRODUCT REGISTRATION HOLDER:
Yanling Natural Hygiene Sdn. Bhd.
21, Jalan S.B. Jaya 11, Taman Industri S.B. Jaya, 47000 Sungai Buloh, Selangor, Malaysia.

MANUFACTURER
Yanling Natural Hygiene Sdn. Bhd.
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