SIDE EFFECTS / ADVERSE REACTIONS:
Incidence rare – Bloody or cloudy urine or difficult or painful urination or sudden decrease in amount of urine, skin rash, hives, or itching (allergic reaction). Unexplained sore throat and fever or unusual bleeding or bruising (blood dycrasias), unusual tiredness or weakness (anaemia), yellowing of eyes or skin (hepatitis).
Sign of overdose – may appear shortly after ingestion and persist for 24 hours – Diarrhoea. Loss of appetite, nausea or vomiting, stomach cramps or pain, unusual increase in sweating.

Cutaneous hypersensitivity reaction including skin rashes,angioedema,Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE
Empty stomach via induction of an emesis or gastric lavage. Activated charcoal my interfere with absorption of orally administered acetyleysteine (antidote used to protect against paracetamol induced hepatotoxicity) and decrease its efficacy. Although activated charcoal is recommended if ingestion of other substances in addition to paracetamol is confirmed or suspected, its removal by gastric lavage may be advisable before the antidote is given.

STORAGE CONDITIONS AND USER INSTRUCTIONS
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
Store in a dry place, below 30°C.
Protect from light.
For Suspension: Shake well before use

Warning:
This preparation contains PARACETAMOL. Do not take other Paracetamol containing medicines at the same time.

PACKING / PACK SIZES:
For Paracil Suspension 120 mg: Plastic bottles of 60 ml, 100 ml, 120 ml,
For Paracil Suspension 250 mg: Plastic bottles of 60 ml, 100 ml, 120 ml
For Paracil Tablet 500 mg: Blister pack of 10's, 10 x 10's/Box, 100 x 10's/Box,.2x10's/Box and 15x10's/Box

SHELF LIFE:
Suspension: 3 years
Tablet: 4 years

Manufacturer and Registration Holder:
SM PHARMACEUTICALS SDN BHD (218620-M)
Lot 88, Sungai Petani Industrial Estate
08000 Sungai Petani,
Kedah Darul Aman,
Malaysia.

26.08.2025

SM PHARMACEUTICALS SDN. BHD.

PARACIL
(PARACETAMOL SUSPENSION AND TABLET)

DESCRIPTION:
Suspension: A red colour, strawberry flavour, slightly viscous, uniform and free flowing, homogeneous suspension.
Contains Methyl Paraben 10 mg and Propyl Paraben 3.75 mg as preservatives.

Tablet: A white, round shaped with flat face and break line on one side tablet.

Contains Methyl Paraben 1.965 mg and Propyl Paraben 0.330 mg as preservatives.

COMPOSITION:

Paracil Suspension 120 mg =	Each 5 ml contains 120 mg Paracetamol
Paracil Suspension 250 mg =	Each 5 ml contains 250 mg Paracetamol
Paracil Tablet 500 mg =	Each tablet contains 500 mg Paracetamol

PHARMACOKINETICS:
Analgesic – inhibits prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action 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 – produced antipyresis by acting centrally on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action involves inhibition of prostaglandin synthesis in the hypothalamus.

PHARMACODYNAMICS
For Tablet:
Absorption: Rapid and almost complete following oral administration; may be decreased if taken following a high-carbohydrate meal. The rate and extent of absorption from the suppository dosage form may vary depending on the composition of the base.
Protein binding: Not significant with doses producing plasma concentrations below 60 mcg per ml; may reach moderate levels with high or toxic doses.
Metabolism: Approximately 90 to 95% of a dose is metabolized in the liver, primarily by conjugation with glucuronic acid, sulfuric acid, and cysteine. An intermediate metabolite, which may accumulate in overdosage after the primary metabolite pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half-life: 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly and in the neonate, and may be somewhat shortened in children.
Time to peak concentration: 0.5 to 2 hours.
Peak plasma concentration: 5 to 20 mcg per ml (with doses up to 6.50 mg).
Duration of action: 3 to 4 hours.
Excretion: Renal; primarily as conjugates.3% of a dose may be excreted unchanged.

For Suspension:
Absorption: Rapid and almost complete following oral administration; may be decreased if taken following a high-carbohydrate meal.
Protein binding: Not significant with doses producing plasma concentrations below 60 mcg per ml for per ml; way reach moderate levels with high or toxic doses.
Metabolism: Approximately 90 to 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulfuric acid, and cysteine. An intermediate metabolite, which may accumulate in overdosage after the primary metabolic path-ways become saturated, is hepatotoxic and possibly nephrotoxic.
Half-life: 1 to 4 hours; does not change with renal failure but nay be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly and in the neonate, and may be somewhat shortened in children.
Time to peak concentration: 0.5 to 2 hours.
Peak plasma concentration: 5 to 20 mcg per ml (with doses up to 6.50 mg).
Time to peak effect: 1 to 3 hours.
Duration of action: 3 to 4 hours.
Excretion: Renal; primarily as conjugates. 2% of a dose may be excreted unchanged

INDICATIONS:
1. Relief of fever and discomfort associated with the common cold and flu.
2. Relief of teething pain, toothache and earache.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:
For Paracil Suspension 120 mg:

Children: (3 months – 1 year) 60 to 120 mg
(1/2 teaspoon to 1 teaspoon)
(1 – 5 years) 120 to 240 mg (1 teaspoon to 2 teaspoon)
(6 – 12 years) 240 to 480 mg (2 teaspoon to 4 teaspoon)
(Maximum dose 2 grams daily),

To be given 3 to 4 times daily.

For Paracil Suspension 250 mg:

Children: 250 to 500 mg (6 – 12 years) (1 teaspoon to 2 teaspoon)
3-4 times daily (Maximum dose 2 grams daily)

Adult: 500 to 1000 mg (2 teaspoon to 4 teaspoon)
To be given 3 to 4 times daily

For Paracil Tablet 500 mg:

Adults – 500mg to 1g (1 to 2 tablets) every 4 to 6 hours up to a maximum of 4g daily (Maximum daily dose is 8 tablets).

Children (6 to 12 years) – up to 500mg (1 tablet).

(These doses may be given 3 to 4 times daily as required).

Route of administration: For Oral use

CONTRAINDICATIONS:
Drug Interactions – Combination containing any of the following medications, depending on the amount present may also interact with this medication.
Alcohol or hepatic enzyme-including agents or hepatoxic medications, other – risk of hepatoxicity with single toxic doses or prolonged use high doses paracetamol may be increased in chonic alcoholics or in patient regularly taking other hepatotoxic medications or hepatic enzyme-inducing agents. Chronic use of barbiturates or primadone has been reported to decrease the therapeutic effects of paracetamol, probably because in increased metabolism resulting from induction of hepatic microsomal enzyme activity; the possibility should be considered that similar effect may occur with hepatic enzyme inducing medications.
Anticoagulants, coumarin or indandione-derivative – concurrent chronic, high dose administration of paracetamol may increase the anticoagulant factors; anticoagulant dosage adjustment based on increased monitoring of prothrombin time may be necessary when chronic, high dose paracetamol therapy in initiated or discontinued; however, this does not apply to occasional use or to chronic use of doses below 2 grams per day of paracetamol.

PRECAUTIONS / WARNINGS:
Paracetamol should be given with care to patients with impaired kidney or liver function. Paracetamol should also be given with care to patients taking other drugs that affect the liver.
Cross – sensitivity
Patients sensitive to aspirin may not be sensitive to acetaminophen: however, mild bronchospastic reactions with acetaminophen have been reported in some aspirin-sensitive asthmatics (lee than 5% of those tested).

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

PREGNANCY AND LALACTATION:
Fertility – chronic toxicity studies in animals have shown that high doses of paracetamol cause testicular atrophy and inhibition of spermatogenesis; the relevance of this finding to use in humans is not known.
Pregnancy – Problems in humans have not been documented: however, controlled studies have not been done. Risk-benefit must be considered because paracetamol crosses the placenta.
Breast-feeding.
Problems in humans have not been documented; however, risk-benefit must be considered. Although peak concentrations of 10 to 15mcg maternal ingestion of a single 650mg dose, neither paracetamol nor its metabolites were detected in the urine of the nursing infants. The half-life in breast milk is 1.35 to 3.5 hours.