

PARANEXT™

(USP Specification)

Paracetamol

(USP Specification)

120mg/ 5ml & 250mg/ 5ml Suspension

COMPOSITION

PARANEXT 120mg/ 5ml Suspension: Each 5ml contains:

Paracetamol 120mg

(USP Specification)

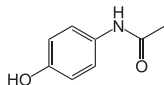
PARANEXT 250mg/ 5ml Suspension: Each 5ml contains:

Paracetamol 250mg

(USP Specification)

DESCRIPTION

PARANEXT (Paracetamol), also known as acetaminophen, is a medication used to treat fever and mild to moderate pain. At a standard dose, paracetamol only slightly decreases body temperature; it is inferior to ibuprofen in that respect, and the benefits of its use for fever are unclear. Paracetamol Molecular Formula is $C_8H_9NO_2$, and has structural formula:



CLINICAL PARTICULARS

Mechanism of Action:

Paracetamol has a central analgesic effect that is mediated through activation of descending serotonergic pathways. Debate exists about its primary site of action, which may be inhibition of prostaglandin (PG) synthesis or through an active metabolite influencing cannabinoid receptors.

Pharmacokinetics:

Absorption:

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion.

Distribution:

It distributes rapidly and evenly throughout most tissues and fluids and has a volume of distribution of approximately 0.9L/kg. 10 to 20% of the drug is bound to red blood cells.

Metabolism:

Paracetamol is metabolized primarily in the liver, mainly by glucuronidation and sulfation, and the products are then eliminated in the urine. Only 2–5% of the drug are excreted unchanged in the urine. Glucuronidation by UGT1A1 and UGT1A6 accounts for 50–70% of the drug metabolism.

Excretion:

Excreted in the urine mainly as the glucuronide and sulphate conjugates.

Less than 5% is excreted as unchanged paracetamol.

Special Population:

Elderly Patients:

Paracetamol, on its own or in combination with other analgesics, is widely used to treat pain associated with acute and chronic conditions. It is considered safe enough to have a GENERAL SALES LICENSE (GSL) for use by "adults, elderly and children over 16 years" and has few listed cautions or contraindications.

Hepatic Impairment:

Detoxification of NAPQI by conjugation with hepatic glutathione may be impaired in the setting of malnutrition, recent fasting or advanced cirrhosis wherein the synthesis of glutathione may be impaired. Therefore, these patients may theoretically be at higher risk of paracetamol toxicity.

Renal Impairment:

Paracetamol is the analgesic of choice for elderly patients or those with impaired renal function.

Polymorphism:

Paracetamol shows polymorphism and exists in three forms. These are monoclinic (Form I, stable), orthorhombic (Form II, metastable) and Form III (unstable and not yet characterized). Most of the paracetamol drug samples belong to monoclinic form which is the most stable polymorph.

THERAPEUTIC INDICATIONS

Paracetamol is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine, toothache, neuralgia, colds and influenza, sore throat, backache, rheumatic pain and dysmenorrhea.

DOSEAGE AND ADMINISTRATION

Usual Pediatric Dose for Fever:

Oral/Rectal:

<=1 month: 10 to 15 mg/kg/dose every 6 to 8 hours as needed.

>1 month to 12 years: 10 to 15 mg/kg/dose every 4 to 6 hours as needed (Maximum: 5 doses in 24 hours)

Fever:

4 months to 9 years: Initial Dose: 30 mg/kg (Reported by one study (n=121) to be more effective in reducing fever than a 15 mg/kg maintenance dose with no difference regarding clinical tolerance.)

>=12 years: 325 to 650 mg every 4 to 6 hours or 1000 mg every 6 to 8 hours.

Usual Pediatric Dose for Pain:

Oral/Rectal:

<=1 month: 10 to 15 mg/kg/dose every 6 to 8 hours as needed.

>1 month to 12 years: 10 to 15 mg/kg/dose every 4 to 6 hours as needed (Maximum: 5 doses in 24 hours)

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SIDE EFFECTS OF PARACETAMOL

Side effects from paracetamol are rare but can include:

An allergic reaction, which can cause a rash and swelling, flushing, low

blood pressure and a fast heartbeat – this can sometimes happen when paracetamol is given in hospital into a vein in your arm. Blood disorders, such as thrombocytopenia (low number of platelet cells) and leukopenia (low number of white blood cells). Liver and kidney damage, if you take too much (overdose) – this can be fatal in severe cases. Speak to a pharmacist or doctor if you develop any troublesome side effects that you think could be caused by paracetamol.

CONTRAINDICATIONS

- Don't take paracetamol if you are allergic to it.
- Acute liver failure.
- Liver problems.
- Severe renal impairment.
- A condition where the body is unable to maintain adequate blood flow called shock.

PREGNANCY

Pregnancy Category A – Both Paracetamol and Caffeine have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations.

PRECAUTIONS

Taking quantities of paracetamol that are higher than is recommended (or directed by a medical doctor) is not advisable. No more than 4 000mg (or 4 grams) of paracetamol should be taken in a 24-hour period (this applies to adults).

DRUG INTERACTIONS

- Acenocoumarin. Paracetamol increases the anticoagulant effect of acenocoumarin.
- Alcohol. Both paracetamol and alcohol can increase the risk of hepatotoxicity.

DISEASE INTERACTION

- Alcoholism
- Liver disease
- PKU(Phenylketonuria)

OVERDOSES OF PARACETAMOL

Taking too much paracetamol, known as an overdose, can be very dangerous.

If you've taken more than the recommended maximum dose, go to your nearest accident and emergency (A&E) department as soon as possible.

It can be helpful to take any remaining medicine and the box or leaflet with you to A&E if you can.

Some people feel sick, vomit or have abdominal (tummy) pain after taking too much paracetamol, but often there are no obvious symptoms at first. Go

to A&E even if you're feeling well.

TREATMENTS OF OVERDOSE

Intravenous acetylcysteine is the antidote to treat paracetamol overdose and is virtually 100% effective in preventing liver damage when given within 8 hours of the overdose

STORAGE:

Store below 30°C. Protect from light.

HOW SUPPLIED

PARANEXT 120 mg/ 5ml Suspension: 60ml & 100ml Bottle.

PARANEXT 250 mg/ 5ml Suspension: 60ml Bottle.

TO BE SOLD ON THE PRESCRIPTION OF A REGISTERED MEDICAL PRACTITIONER ONLY.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Lactose & Gluten Free

پیرا نیکسٹ
(پیرا سیٹامول)

120 ملی گرام / 5 ملی لیٹر اور

250 ملی گرام / 5 ملی لیٹر سپینشن

خوراک و ہدایت

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فرم وخت کی جائے۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

دوا کو 30°C سے کم درجہ حرارت پر، روشنی سے محفوظ رکھیں۔

NEXT
PHARMACEUTICAL

Manufactured by:
NEXT Pharmaceutical Products (Pvt.) Ltd.
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