

PARACETAMIN

Composition and ingredients: **Oral solution:** Each 5 ml of Oral solution contains: Paracetamol 160 mg. **Drops:** Each 1 ml of the dropper contains: Paracetamol 100mg

Mechanism of action:

Analgesic effect: Paracetamol may act by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain-impulse generation.

Antipyretic effect: paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss.

In the treatment of mild to moderate pain including headache, backache, migraine, neuralgia, toothache, sore throat, period pain, aches and pain, symptomatic relief of rheumatic pain, muscular pain and pains of cold & influenza, fever, feverish colds and post-immunisation fever.

Contraindications:

Hypersensitivity to Paracetamol or any of the components.

Warnings and precautions:

In the elderly, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is lower than in adults.

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Patients should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as redness, blisters, or rash occurs or if existing skin symptoms worsen the patient should stop use and seek medical assistance right away.

If sore throat is severe, persists for more than 2 days or is accompanied or followed by fever, headache, rash, nausea, or vomiting, the patient should consult the doctor promptly.

The patient shouldn't take this drug with any other paracetamol-containing product.

If symptoms persist for more than 3 days or get worse the patient should consult the doctor.

The patient should consult the doctor at once if he takes too much of paracetamol, this is because too much paracetamol can cause delayed, serious liver damage.

This medicine shouldn't be given to the child for more than 3 days without consulting to the doctor or pharmacist.

Due to the presence of sucrose and sorbitol, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Ethyl, Propyl and Methyl parahydroxybenzoate may cause allergic reactions.

Caution is advised if paracetamol is administered concomitantly with flucoxacinil due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Drug Interactions:

Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, it should be taken within one hour if maximal analgesia is required.

Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone.

Warfarin: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Chloramphenicol: Increased plasma concentration of chloramphenicol.

Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

Patients who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

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.

The use of drugs that induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptives, may increase the extent of metabolism of paracetamol, resulting in reduced plasma concentrations and a faster elimination rate.

Caution should be taken when paracetamol is used concomitantly with flucoxacinil as concurrent intake, especially in patients with risks factors.

Pregnancy and lactation:

Studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of the doctor regarding its use. paracetamol can be used during pregnancy if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available data do not contraindicate breast feeding.

Undesirable effects:

Oral Solution & Drops

Adverse effects of paracetamol are rare. Very rarely hypersensitivity, angioedema and anaphylactic reactions including skin rash may occur. Very rare cases of serious skin reactions have been reported.

There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not causally related to paracetamol.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods.

Nephrotoxicity following therapeutic doses of paracetamol is uncommon.

Capillary necrosis has been reported after prolonged administration.

Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.

Dosage and method of administration: Tablets: For (325 mg):

Age	Dosage
Adults And Children 12years And Over	Take 2 Tablets Every 4-6 Hours While Symptoms Last,not More Than 12 Tablets In 24 Hours
children 6 to 11 years	take 1 tablet every 4-6 hours while symptoms last not more than5 tablets in 24 hours
children under 6 years	do not use

For tablets (500 mg or 1000 mg) and capsule 500 mg:

Adults, the elderly and over 15years: 2 tablets/Capsules 500mg or 1 tab 1000 mg every 4 hours to a maximum of 8 tablets/capsules for 500 mg and 4 for 1000 mg tablets in 24 hours. Do not take for more than 3 days without consulting your doctor.

These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

Children 10 – 15 years: One tablet/capsule 500 mg every four to six hours when necessary to a maximum of four doses in 24 hours. Do not take for more than 3 days without consulting your doctor. Under 10 years of age: shouldn't be given.

For 650 mg:

Adults: 2 tablets every 8 hours. Do not take more than 6 tablets in 24 hours.

Do not use more than 10 days unless directed by a doctor.

Under 18 years: ask a doctor.

For 665 mg: Adults and children aged 12 years and over:

Take 2 caplets three times a day, every six to eight hours as needed. Do not take more than 6 caplets in 24 hours.

Not recommended in children under 12 years.

For 1000 mg Sustained release tablets:

Take the drug as directed by the doctor, do not take more than recommended, and keep a gap of a minimum 4 hours between two consecutive doses.

Syrup or suspension:

For 240 mg/5ml: This product is suitable for children 5-12 years of age.

A dose of 10-15 mg/kg to be repeated.

Do not give to your child more than 60 mg /kg presented in divided doses throughout 24 hours.

Do not give to your child more frequently than every 4 hours.

Do not give to your child more than four doses in any 24 hour period.

Do not give to your child for longer than 3 days without asking a doctor.

Weight	Age	Dose(ml)
18 - 20	5-6 Years	5.5
20 - 23	6-7 Years	6
23 - 25	7-8 Years	7
25 - 38	8-9 Years	7.5
28 - 32	9-10 Years	8.5
32 - 36	10-11 Years	10
36 - 41	11-12 Years	11

For 250 mg / 5ml:

Children under 6 years of age: shouldn't be given.

Children aged 6 to 12 years: 6-8 years: 5 ml 4 times daily.

8-10 years: 7.5 ml 4 times daily -10-12 years: 10 ml 4 times daily

Do not give more than 4 doses in any 24 hour period, Leave at least 4 hours between doses.

Children aged 12-16 years: 10-15 ml up to 4 times a day.

Adults and children over 16 years: 10-20 ml up to 4 times a day.

For 160 mg/5ml:

Children from 2-3 years of age : 5 ml every 4 hours while symptoms last , do not give more than 5 times in 24 hours. -Less than 2 years: ask a doctor.

For 120 mg / 5ml:

For the relief of fever after vaccinations at age (2, 3 and 4 months): 2.5 ml may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period, Leave at least 4 hours between doses. If the baby still needs this medicine two days after receiving the vaccine talk to the doctor.

For Pain and other causes of fever:

Babies less than 2 months of age: shouldn't be given.

Age (2 – 3 months): If the baby weighs over 4 kg and was born after 37 weeks: 2.5 ml If necessary, after 4-6 hours, give a second 2.5 ml dose. Leave at least 4 hours between doses. Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If the child is still feverish after two doses, talk to the doctor or pharmacist. Children aged 3 months – 6 years

Age 3 months – 6 months: 2.5 ml 4 times daily

Age 6 – 24 months: 5 ml 4 times daily -Age 2 – 4 years: 7.5 ml 4 times daily

Age 4 – 6 years: 10 ml 4 times daily

Do not give more than 4 doses in any 24 hour period, Leave at least 4 hours between doses.

For the 200 mg / 5ml:

Dosage interval depends should not be less than 6 hours. For complaints lasting more than 3 days, a doctor should be consulted. The total dose should not exceed 60 mg / kg body weight per day for children.

Body Weight (Age)	The Dose	Maximum Daily Dose
7-9 kg (Children from 6-12 months)	2.5 ml (100 mg)	400 mg paracetamol
10-12 kg (children of 1-2 years)	3.75ml (150 mg)	600 mg paracetamol
13-18 kg (children from 2-5 years)	5 ml (200 mg)	800 mg paracetamol
19-25 kg (children of 5-8 years)	7.5 ml (300)	1,200 mg paracetamol
26-32 kg (children from 8- 11 years)	10 ml (400 mg)	1,600 mg paracetamol
33-43 kg (Children of 11-12 Years)	12.5 ml (500 mg)	2,000 mg paracetamol
Other Dosage forms May be More Suitable for this Age Group		

Children under 6 months or under 7 kg: it is not recommended as the dose strength is not suitable.

For 500mg/5ml: Adults and young persons 16 years and over:

The Optimal dosage range is 500mg (5ml) to 1000mg (10ml) up to three to four times a day, as required, to a maximum of 4 g paracetamol/ day (40 ml paracetamol oral solution).

The dose should not be repeated more frequently than every four hours, and not more than four doses should be taken in any 24 hour period.

Elderly: in older people, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and Paracetamol clearance is lower than in young adults.

Paediatric Population:

Do not use this medicine in children and adolescents under 16 years.

Oral Drops: for 100mg/1ml:

Weight of the child	Age	Volume in ml	Paracetamol(mg)
5 kg	2-3 months	0.6 ml	60 mg
6 kg	4 months	0.9 ml	90 mg
7 -8 kg	5 - 8 months	1 ml	100 mg
9 kg	9-12 months	1.2 ml	120 mg
10 - 11 kg	13-18 months	1.5 ml	150 mg
12 - 13 kg	19-24 months	1.8 ml	180 mg

These doses can be repeated every 6-8 hours. If the desired effects are not achieved within 3-4 hours, the dose may be advanced every 4 hours.

For the 80 mg/0.8ml:

If needed, repeat dose every 4 hours while symptoms last, do not give more than 5 times in 24 hours, do not give for more than 5 days unless directed by a doctor.

Age(yrs)	Dose (ml)
Under 2 Years	the doctor should be consulted
2 - 3 Years	1.6 ml (0.8 + 0.8 ml)

Suppositories: For the suppository (80 mg):

Age	Dose
Under 6 months	Do not use unless directed by a doctor
6 to 11 months	Use 1 suppository every 6 hours (Maximum of 4 doses in 24 hours)
12 to 36 months	Use 1 suppository every 4 to 6 hours (Maximum of 5 doses in 24 hours)

For the suppository (120 mg):

This product does not contain directions or warnings for adult use.

Under 3 years: Do not use unless directed by a doctor.

3 to 6 years: Use 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours)

For the suppository (60 mg, 125 mg, and 250 mg).

Children under 3 months of age: One suppository (60 mg) is suitable for babies who develop a fever following immunisation at 2 months. Otherwise only use in babies aged less than 3 months on a doctor's advice.

Children 3 months to 1 year: 3 months (5 kg): 60mg (1 suppository)

year (10 kg): 120mg (2 suppositories)

Children 1 to 5 years: 1 year (10 Kg): 125mg (1 suppository)

5 years (20 Kg): 250mg (2 suppositories of 125 mg or 1 suppository of 250 mg)

Children 6 to 12 years: 6 years (20 Kg): 250mg (1 suppository)

12 years (40 Kg): 500mg (2 suppositories)

These doses may be repeated up to a maximum of 4 times in 24 hours.

The dose should not be repeated more frequently than every 4 hours.

For the suppository (325 mg): Do not use in children under 6 years.

Children 6-12 years: 1 suppository every 4 to 6 hours (maximum of 5 doses in 24 hours).

Adult and children 12 years and older: 2 suppositories every 4 to 6 hours (maximum of 6 doses).

For the suppository (500 mg): The recommended dose is:

Age	Number of Suppositories	Minimum Length of time between doses	Maximum number of suppositories in 24 hours
10 years to 12 years (body weight 30-40kg)	from 2-3 months	0.6 ml	60 mg
Adults + Children over 12 years	from 4 months	0.9 ml	90 mg

Children under 10 years of age: This product is not suitable for use in this age group.

For the suppository (650 mg): Adults and children 12 years and older: 1 suppository every 4 to 6 hours while symptoms last

Do not exceed 6 suppositories in any 24 hour period -Children under 12 years: ask a doctor.

For the suppository (1000 mg): Adults:

1 suppository every 4 to 6 hours up to a maximum of 4 suppositories in 24 hours.

The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in analgesic effect.

The product should not be used for more than 3 days, except on the advice of a doctor.

Only whole suppositories should be administered.

Hepatic impairment and mild renal impairment: In patients with hepatic impairment or renal impairment and Gilbert's syndrome, the dose must be reduced or the dose interval extended.

Severe Renal Insufficiency: a dose interval of at least 8 hours must be maintained.

Overdosage:

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: If the patient is on long term treatment drugs that induce liver enzymes or regularly consumes ethanol in excess amount or if the patient is on glutathione depleted. 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.

Treatment: Immediate treatment is essential in the management of Paracetamol overdose. Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol.

Storage conditions:

Store at a temperature below 25°C, away from heat and out of reach of children.

Packaging: Oral solution: Opaque glass bottle with a capacity of 100 ml.

Drops: Opaque glass bottle with a capacity of 30 ml with a dropper.

THIS IS A MEDICAMENT	
A medicament is a Product but Unlike any Other Products A medicament is a Product Which Affects Your health, and its Consumption Contrary to Instructions is Dangerous for you. Follow Strictly the Doctors' Prescription, the Method of use and the Instructions of the Pharmacist who Sold you the Medicament. The Doctor and the Pharmacist are Experts in Medicine, its Benefits and Risks. Do not by Yourself Interrupt the Period of Treatment Prescribed for you. Do not Repeat the Same Prescription Without Consulting your Doctor.	
Keep Medicaments out of Reach of children (Council of Arab Health Ministers) (Arab Pharmacists Association)	



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