

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Tablets

Actavis Paracetamol 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet contains: 500mg Paracetamol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White uncoated capsule shaped tablet with a breakline on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pain, aches and pains, symptomatic relief of rheumatic aches and pains and of influenza, feverishness and feverish colds.

4.2 Posology and method of administration

For oral administration.

Adults, the elderly and children over 16 years:

Single dose 0.5 g - 1 g (one to two tablets) every 4-6 hours.

Maximum daily dose 4 g (8 tablets) in divided doses.

Children 12-15 years of age:

One to one & half tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children 10-12 years of age:

One tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children 6-10 years of age:

Half a tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 6 years of age:

Not recommended.

Dosage instruction

- 1 - Dose should not be repeated more frequently than 4 hour intervals.
- 2 - Not more than 4 doses should be administered in any 24 hour period.
- 3 - Dosage should not be continued for more than 3 days without consulting a doctor.

4.3 Contraindications

Hypersensitivity to paracetamol and/or other constituents.

4.4 Special warnings and precautions for use

Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment.

Although the hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease; however, there have been reports of severe hepatotoxicity including fatalities, in chronic alcoholics who have taken Paracetamol in amounts within the recommended therapeutic range (See section 4.8).

Published reports suggest that Paracetamol toxicity could occur in some individuals whilst taking the recommended daily dose of Paracetamol.

Care should be taken when paracetamol is prescribed to patients with liver diseases, and in those on potentially hepatotoxic effects.

Increase in the level of transaminases has been occasionally, and temporarily observed as a result of taking the recommended daily dose of paracetamol.

High anion gap metabolic acidosis has been reported to be associated with therapeutic ingestion of Paracetamol.

Do not exceed the stated dose.

If symptoms persist consult your doctor.

Keep out of the reach and sight of children

Do not take with any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Contains Lactose: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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

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.

Chronic alcohol intake could enhance the hepatotoxicity of paracetamol overdose.

Acute alcohol intake may diminish an individual's ability to metabolise large doses of Paracetamol, the plasma half-life of which can be prolonged.

Paracetamol may decrease busulfan clearance when used in combination.

May interact with chloramphenicol causing increased plasma levels.

4.6 Fertility, pregnancy and lactation

A large amount of data on pregnant women indicate neither malformative, nor foeto/ neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy 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 published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including, skin rashes, drug fever and mucosal lesions, anaphylactic reactions, angioedema, urticaria, Stevens-Johnson Syndrome and cases of fixed drug eruption have been reported. 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 necessarily casually related to paracetamol.

The development of severe hepatotoxicity, including fatalities, has been reported in chronic alcoholics, who have taken paracetamol in amounts within the daily-recommended doses.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

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 (see below).

Risk factors

If the patient

a, Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b, Regularly consumes ethanol in excess of recommended amounts.

Or

c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdose 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, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

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, see BNF overdose section.

Treatment with activated charcoal should be considered if 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 a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Analgesic and Antipyretic

ATC code: N02BE01

Paracetamol is an effective analgesic and antipyretic agent but has only weak anti-inflammatory properties. Its mechanism of action is not fully understood, as it is only a weak inhibitor of prostaglandin bio-synthesis, but it has been suggested that it is more effective against enzymes in the CNS than those in the periphery. The drug has no effect on the cardiovascular and respiratory systems and it does not cause gastric irritation or bleeding like salicylates.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half life varies from about 1 to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione, may accumulate following paracetamol overdose and cause liver damage.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone BP

Lactose BP

Starch (Maize) BP

Magnesium Stearate BP

Sodium Starch Glycollate BP

Colloidal Anhydrous Silica BP

6.2 Incompatibilities

None known

6.3 Shelf life

4 Years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Child-resistant blister packs of 16, 24, 32, 48, 96 and 100 tablets.

PVC/aluminium IPVC 250/20/15 micron

Glassine paper 41g/sqm/Adehesive lacquer 2.5g/sqm/Aluminium foil (9 micron)/ Heat seal coating 7.0g/sqm/PVC 250 micron

Bottle Packs of 25, 50 and 100.

Plastic tub: 1000.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Fourrts (UK) Pharmacare Ltd

First Floor,

2 Victoria Road,
Harpenden,
Hertfordshire,
A15 4EA,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 39484/0038

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

11/11/1981 / 26/05/2004

10 DATE OF REVISION OF THE TEXT

28/11/2025