Panadol SmPC

Panadol Original Tablets

Summary of Product Characteristics Updated 24-Jun-2025 | Haleon UK Trading Limited

1. Name of the medicinal product
Panadol Original Tablets**2. Qualitative and quantitative composition**
Each tablet contains Paracetamol Ph Eur 500.0 mg**3. Pharmaceutical form**
Tablet
White, film-coated capsule shaped tablet with a triangular logo debossed on one side and a break line on the other.**4. Clinical particulars4.1 Therapeutic indications**
Panadol Original Tablets is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu. Also recommended for the symptomatic relief of pain due to non-serious arthritis.**4.2 Posology and method of administration**
Adults, the elderly, and children aged 16 years and over:
One or two tablets up to four times daily as required.
Children:
Aged 10 - 15 years: One tablet up to four times daily as required.
Not suitable for children under 10 years of age. Children should not be given Panadol Original Tablets for more than 3 days without consulting a doctor.
These doses should not be repeated more frequently than every four hours nor should more than four doses be given in any 24 hour period.
Oral administration only.**4.3 Contraindications**
Hypersensitivity to paracetamol or any of the other constituents.**4.4 Special warnings and precautions for use**
Contains paracetamol. Do not use with any other paracetamol-containing products.
Underlying liver disease increases the risk or paracetamol related liver damage.
Patients who have been diagnosed with liver or kidney impairment must seek

medical advice before taking this medication.
Do not exceed the stated dose.
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.
Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Use with caution in patients with glutathione depletion due to metabolic deficiencies.
If symptoms persist, medical advice must be sought.
Contains no animal derived ingredients.
Keep out of the sight and reach of children.
Pack Label:
Talk to a doctor at once if you take too much of this medicine even if you feel well.
Do not take anything else containing paracetamol while taking this medicine.
Patient Information Leaflet:
Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.**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 absorption reduced by colestyramine. 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.
Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks

factors (see section 4.4).**4.6 Pregnancy and lactation**
Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy if clinically needed, however, as with any medicine it should be used at the lowest effective dose for the shortest possible time.
Paracetamol is excreted in breast milk but not in a clinically significant amount in recommended dosages. Available published data do not contraindicate breastfeeding.**4.7 Effects on ability to drive and use machines**
None.**4.8 Undesirable effects**
Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class and frequency.
The following convention has been utilised for the classification of the undesirable effects: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).
Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.
Post marketing data

Body SystemUndesirable effectFrequency Blood and lymphatic system disordersThrombocytopenia
AgranulocytosisVery rareImmune system disordersAnaphylaxis
Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema. Very rare cases of serious skin reactions have been reported.Very rareMetabolism and nutrition disordersHigh anion gap metabolic acidosis*Not knownRespiratory, thoracic and mediastinal disordersBronchospasm**Very rareHepatobiliary disordersHepatic dysfunctionVery rare

*Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.
** There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

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 MHRA Yellow Card in the Google Play or Apple App store.**4.9 Overdose**

Paracetamol overdose may cause liver failure which may require 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 (see below).

Risk factors

If the patient

a, Is on long term treatment with carbamazepine, phenobarbitone, 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 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, 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. Pharmacological properties5.1 Pharmacodynamic properties**

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however to be on a selective basis.**5.2 Pharmacokinetic properties**

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.**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 particulars6.1 List of excipients**

Maize starch, potassium sorbate, purified talc, stearic acid, polyvidone, starch pregelatinised, hypromellose, triacetin and carnauba wax.**6.2 Incompatibilities**

None.**6.3 Shelf life**

48 months.**6.4 Special precautions for storage**

None.**6.5 Nature and contents of container**

The tablets are packed into either:

PVC (250µm or 300µm) / aluminium foil 30µm blister strips

or

PVC (250µm or 300µm) / aluminium foil 20µm /8µm PET blister strips in an outer

cardboard cartons, containing 4, 6, 8, 12 or 16 tablets, or in a cardboard/PVC wallet containing 16 tablets.**6.6 Special precautions for disposal and other handling**

Not applicable.**7. Marketing authorisation holder**

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
United Kingdom**8. Marketing authorisation number(s)**

PL 44673/0081**9. Date of first authorisation/renewal of the authorisation**

29.05.84**10. Date of revision of the text**

03.03.2025

Company Contact Details

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