SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg Paracetamol

Paracetamol 500mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White, capsule shaped tablet with a break-line on one face.

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.

Symptomatic relief of influenza, feverishness, feverish colds.

4.2. Posology and method of administration

Posology

Adults, the elderly and children 16 years and over: One or two tablets to be taken up to four times daily. Maximum dose of 8 tablets in 24 hours.

Children 10 to 15 years of age: One tablet to be taken for every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 10 years of age: Not recommended. Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses of less than 500mg.

The dose should not be repeated more frequently than every 4 hours, and not more than 4 doses should be taken in any 24 hour period.

Dosage should not be continued for more than 3 days without consulting a doctor.

Method of administration

For oral administration.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other ingredients.

4.4 Special warnings and precautions for use

Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics (MOH medication-overuse headache) should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.

Care is advised in the administration of paracetamol to patients with alcohol dependency (see section 4.9), severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

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.

Do not exceed the recommended dose.

If symptoms persist, consult your doctor.

Keep out of the sight and reach of children.

The label will state the following warnings:

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine, even if you feel well.

The leaflet will state the following warnings:

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Do not take anything else containing paracetamol while taking this medicine.

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

Alcohol reduces liver capacity to deal with paracetamol.

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.

Colestyramine reduces absorption if given within one hour of paracetamol; and Metoclopramide and Domperidone accelerate absorption of paracetamol. May interact with chloramphenicol causing increased plasma levels.

Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

4.6 Fertility, pregnancy and lactation

A large amount of data on pregnant women indicate neither malformative, nor feto/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 literature do not contraindicate breast-feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia neutropenia, pancytopenia, leukopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

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. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Post marketing data:

Skin and subcutaneous disorders: Very rare cases of serious skin reactions have been reported.

Blood and lymphatic system disorders: Thrombocytopenia, agranulocytosis.

Immune system disorders: Anaphylaxis. Cutaneous hypersensitivityreactions including skin rashes, angioedema and Stevens Johnson syndrome/toxic epidermal necrolysis.

Respiratory, thoracic and mediastinal disorders: Bronchospasm*.

*There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Hepatobiliary disorders: Hepatic dysfunction.

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.

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

- Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts.
- 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 24 hours from ingestion should be discussed with the NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 10 to 60 minutes 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 unchanged as paracetamol. It is distributed in most body tissues. Paracetamol crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration.

The elimination half life varies from about 1 to 4 hours.

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 overdosage 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

Pregelatinised maize starch

Povidone

Stearic Acid

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

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

Tablet containers: Do not store above 25°C. Keep the container tightly closed. Store in the original container.

6.5 Nature and contents of container

Al/PVC blister strips (child resistant) enclosed in an outer carton containing 24 or 32

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None applicable.

7 MARKETING AUTHORISATION HOLDER

RIA Generics Ltd
36 Ingleby Way, Wallington, Surrey,
SM6 9LR, United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 36282/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/05/2009

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12/05/2021