SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Paracetamol & Caffeine Tablets
Paracetamol and Caffeine 500 mg/50 mg Film-coated Tablets
Max Healthcare Pain Relief Extra 500mg/50mg Film-coated Tablets

2. Qualitative and quantitative composition

Paracetamol	500.0 mg
Caffeine	50.0 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet (Tablet)
White film coated capsule-shaped tablet with a break line

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the effective treatment of mild to moderate pain such as headache, migraine, neuralgia, backache, rheumatic and muscular pain, period pain and toothache. For the relief of the symptoms of coughs, colds and sore throats. For the reduction of fever in influenza.

4.2 Posology and method of administration

Posology: Oral.

Adults and children of 16 years and over: 1-2 tablets every 4-6 hours when necessary to a maximum of 4 doses in 24 hours. The tablets should be taken with a glass of water.

Children 12 to 15 years: 1 tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours. The tablets should be taken with a glass of water.

Elderly: No special dosage regimen required, but care should be taken to observe the contraindications, precautions and warnings, which may be particularly applicable to elderly persons.

Children: Not recommended for children less than 12 years old except under medical supervision.

4.3 Contraindications

Hypersensitivity to paracetamol and/or other constituents.

4.4 Special warnings and special precautions for use

Precautions: paracetamol should be used with caution in patients with severe renal disease or liver dysfunction. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

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.

Excessive intake of caffeine from coffee and tea should be avoided.

Keep out of the reach of children.

Warning: Do not exceed the stated dose.

If symptoms persist consult your doctor.

The label will say: Contains paracetamol. 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.
The leaflet (including label - leaflets) will say: 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

4.5 Interactions with other medicaments and other forms of interactions

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.

Metoclopramide/domperidone: The speed of absorption of paracetamol may be increased by metoclopramide or domperidone. Concurrent use need not be avoided.

Cholestyramine: The speed of absortion of paracetamol may be reduced by cholestyramine if given at the same time, but the reduction in absortion is small if given an hour later.

Caffeine: The effects of caffeine may be enhanced by isoniazid and meprobamate.
If taking other prescribed medicines a doctor should be consulted before taking the product.

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 Fertility, pregnancy and lactation

Paracetamol :

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 data do not contraindicate breast feeding for paracetamol.

Caffeine:

Caffeine crosses the placental barrier. Some animal studies have shown foetal malformations from caffeine, but no abnormalities have been observed in humans following administration during pregnancy. However, it is recommended that the product is only used during pregnancy on medical advice.

Care is advisable during lactation since caffeine passes into the maternal milk.

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 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 necessarily causally related to paracetamol. Caffeine may cause nausea, headache and insomnia.

Metabolism and nutrition disorders
High anion gap metabolic acidosis with frequency "Not known" (cannot be estimated from the available data)

Description of selected adverse reactions

High anion gap metabolic acidosis

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.

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, 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 PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an analgesic and antipyretic agent. Caffeine is a central nervous system stimulant.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and completely absorbed from the gastro-intestinal tract giving peak blood levels 40-60 minutes after ingestion. Paracetamol is metabolised by the liver and its metabolites excreted via the kidneys principally as the glucuronide and sulphate conjugates.
Caffeine is rapidly and completely absorbed from the gastro-intestinal tract and maximum plasma levels are usually attained between several minutes and one hour after ingestion. Caffeine is metabolised by the liver and excreted via the kidney.

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

Microcrystalline Cellulose
Maize Starch

Colloidal Anhydrous Silica
Sodium Starch Glycollate
Stearic Acid
Croscarmellose Sodium
Povidone
Hypromellose
Macrogol 400
Titanium Dioxide

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Precautions for storage

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

6.5 Nature and contents of container

CRC blisters consisting of 35 gsm Glassine (Pergamin) paper/9 micron soft temper aluminium foil with 250 micron/60 gsm PVC/PVdC.

CRC blisters consisting of 250 micron PVC/60gsm PVdC. Lidding foil: 20 micron hard aluminium foil / 15 micron PVC.

Pack sizes: 2, 8, 12, 16

Not all pack sizes are marketed.

6.6 Special precautions for disposal

No special precautions necessary.

7 MARKETING AUTHORISATION HOLDER

Max Remedies Ltd
William Nadin Way
Swadlincote
Derbyshire
DE11 0BB

8 MARKETING AUTHORISATION NUMBER(S)

PL 31308/0033

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/10/1992

10 DATE OF REVISION OF THE TEXT

07/05/2026