Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paraextra Hard CapsulesParacetamol 500mgCaffeine 32mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains paracetamol 500mg and caffeine 32mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsules, hard
Size 0, hard gelatin capsules with an opaque blue cap and an opaque yellow body imprinted on both sections with '500/32', containing a white, free flowing granule mix.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an analgesic and antipyretic agent. The capsules are recommended for use in short term management of headaches, migraine and tension headaches, backache, rheumatic pain, muscle pain, period pain, neuralgia, toothache and for relieving fever, aches and pains of colds and influenza including the pain of sore throat.

4.2 Posology and method of administration

Posology:
Adults (including the elderly):
1 to 2 capsules which may be repeated 4 hourly as necessary.
A maximum of 8 capsules in any 24 hour period.

Adolescents aged 12 to 15 years:
1 capsule which may be repeated every 4 to 6 hours. A maximum of 4 doses in any given 24 hour period.

Children:
Not recommended for children under 12 years of age.

Method of Administration: Oral.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

4.3 Contraindications

Use in children under 12 years.

Hypersensitivity to any of the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Paracetamol should be administered with caution under the following circumstances:

- Hepatic impairment
- Chronic alcoholism
- Renal impairment (GFR≤50ml/min)
- Gilbert's Syndrome (familial non-haemolytic jaundice)

- Concomitant treatment with medicinal products affecting hepatic function
- Glucose-6-phosphate dehydrogenase deficiency
- Haemolytic anaemia
- Glutathione deficiency
- Dehydration
- Chronic malnutrition
- Weight less than 50kg
- Elderly In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a physician or dentist and not at high doses. If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.Prolonged or frequent use is discouraged. Patients should be advised not to take other paracetamol containing products concurrently. Taking multiple daily doses in one administration can severely damage the liver; in such case medical assistance should be sought immediately.

- Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with hepatic or renal impairment must seek medical advice before taking this medication The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
- If symptoms persist, consult your doctor.
- Prolonged use without medical advice may be harmful.
- Do not exceed the stated dose.
- Immediate medical advice should be sought in the event of overdosage even if you feel well.
- Use only when clearly necessary.
- This medicine contains less than 1 mmol (23 mg) sodium per capsule, that is to say essentially "sodium free". Caution is advised if paracetamol is administered concomitantly with flucloxacillin 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. Cases of hepatic dysfunction/ failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, are chronic heavy users of alcohol or have sepsis.In patients with glutathione-depleted states the use of paracetamol may increase the risk of metabolic acidosis. Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol:

Warfarin - 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.

Flucloxacillin - Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

Caffeine:

Lithium - Caffeine can increase the elimination of lithium from the body. Concomitant use is therefore not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

This product is not recommended for use during pregnancy.

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.

Caffeine
Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.

Lactation

This product is not recommended for use during breast feeding.

Paracetamol

Paracetamol is excreted in breast milk but not in a clinically significant amount at recommended dosages.

Caffeine

Caffeine excreted in breast milk may potentially have a stimulating effect on breast fed infants but significant toxicity has not been observed.

4.7 Effects on ability to drive and use machines

Paraextra Hard Capsules has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse events 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 MedDRA System Organ Class. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be very rare (<1/10,000**).**

Paracetamol		
Immune system disorders	Rare Very Rare	 Hypersensitivity reactions, including skin rash may occur. There have been isolated reports of thrombocytopenia purpura, Anaphylaxis, Cutaneous hypersensitivity reactions including, among others, angioedema.
Skin and subcutaneous tissue disorders	Very Rare	Serious skin reactions (including severe cutaneous reactions such as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, and Acute Generalised Exanthematous Pustulosis) have been reported.
Respiratory, thoracic and mediastinal	Very Rare	Bronchospasm in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Very rare	Hepatic dysfunction

Caffeine		
Nervous system disorders	Not known	Dizziness, headache
Cardiac disorders	Not known	High doses of Caffeine can cause palpitations.
Psychiatric disorders	Not known	Insomnia, restlessness, anxiety and irritability, nervousness
Gastrointestinal disorders	Not known	Gastrointestinal disturbances

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects.

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 HPRA Pharmacovigilance, website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Paracetamol

Signs and symptoms:

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Immediate medical advice should be sought in the event of overdosage, even if symptoms of overdose are not present because of the risk of irreversible liver damage.
In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute pancreatitis have been reported.

Treatment:

Immediate treatment is essential in the management of paracetamol overdose. Despite lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. The antidote N-acetylcysteine should be administered as soon as possible in accordance with national treatment guidelines.

General supportive measures must be available.

Caffeine

Symptoms and signs of caffeine overdose:

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, anxiety, tremors and convulsions).

For clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic activity but it has no useful anti-inflammatory properties.
Caffeine is thought to increase the pain-relieving effect of paracetamol.

5.2 Pharmacokinetic properties

Absorption - Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion.
Caffeine is absorbed readily after oral administration and is widely distributed through the body.

Metabolism - Paracetamol is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed function oxidases in the liver may accumulate following overdosage and cause liver damage.

Caffeine is metabolised almost completely via oxidation, demethylation and acetylation.

Excretion - Less than 5% is excreted in the urine as unchanged paracetamol.
Caffeine is excreted in the urine as 1-methyluric acid, 1-methylxanthine and other metabolites with only 1% unchanged.

5.3 Preclinical safety data

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

Non-clinical safety data for paracetamol and caffeine have not revealed findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Magnesium Stearate
Sodium Laurilsulfate
Croscarmellose Sodium

Capsule Shell
Gelatin
Purified water
Erythrosine (E127)
Patent blue V (E131)
Titanium dioxide (E171)
Quinoline Yellow (E104)

Printing Ink
Shellac
Titanium dioxide (E171)
Iron oxide, black (E172)
Propylene glycol
Ammonium hydroxide
Simeticone

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Cartons of 8, 10, 12 or 24 capsules in blister strips, composed of white, opaque, unplasticised polyvinyl chloride and printed aluminium foil, coated on the bright side with heat seal lacquer, compatible to PVC.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/152/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 02 December 2010

10 DATE OF REVISION OF THE TEXT

January 2024