Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Panadol Extra with Optizorb 500 mg/65 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol 500 mg
and Caffeine 65 mg. For full list of
excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

White to off-white, oval shaped tablets debossed with 'xPx', with the P enclosed within a circle on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of mild to moderate pain and relief of fever including:

Headache

Migraine

Muscle ache

Dysmennorhoea

Sore throat
Musculoskeletal pain

Fever and pain after vaccination

Pain after dental procedures/ tooth extraction

Toothache Earache/Otalgia

Pain of osteoaritis

Respiratory tract infections including cold and flu

4.2 Posology and Method of Administration

Oral use.

Adults (including the elderly), and children aged 12 years and over:

One or two tablets taken every 4 to 6 hours as required. The dose should not be repeated more frequently than every 4 hours. Do not exceed 8 tablets in 24 hours.

Not recommended for children under 12 years.

4.3 Contraindications

Hypersensitivity to paracetamol, caffeine or any of the other constituents.

4.4 Special Warnings and Precautions for Use

Patients should be advised not to take other paracetamol-containing products concurrently. The concomitant use with other products containing paracetamol may lead to an overdose.

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

Underlying liver disease increases the risk of paracetamol- related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

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 or 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.

Sodium methyl-, sodium ethyl- and sodium propyl-parahydroxybenzoates (E 219, E 215 and E 217) may cause allergic reactions (possibly delayed).

If symptoms persist consult your doctor. Keep out of the reach and sight of children.

Pack Label:

Immediate medical advice should be sought in the event of an overdose, even if you feel well. Do not take with any other paracetamol-containing products.

Patient Information Leaflet:

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 Interaction with Other Medicinal Products and Other Forms of Interaction

Paracetamol

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.

Caffeine

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

4.6 Pregnancy and Lactation

Pregnancy

Not recommended for use during pregnancy.

Paracetamol

As with the use of any medicine during pregnancy, pregnant women should seek medical advice before taking paracetamol. The lowest effective dose and shortest duration of treatment should be considered.

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

Lactation
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 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

None.

4.8 Undesirable Effects

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 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

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytope nia Agranulocytosis

Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

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

Caffeine	
Central Nervous system	Nervousness Dizziness
Cardiac disorders	Palpitations
Psychiatric disorders	Insomnia, restlessness, anxiety and irritability, nervousness
Gastrointestinal Disorders	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 such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.	

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions via Pharmacy and the Poisons Board, Pharmacovigilance Electronic Reporting System
(PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Formulation	Overdose
	Paracetamol Symptoms and Signs Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and have peaked usually 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. **Treatment** Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. If overdose is confirmed or suspected, seek immediate advice from nearest Emergency Medical Centre for management and

Formulation	**Overdose**
	expert treatment. This should happen even in patients without symptoms or signs of overdose due to the risk of delayed liver damage. Administration of N-acetylcysteine or methionine may be required. Caffeine Symptoms and Signs 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. Treatment No specific antidote is available, but

	supportive measures such as beta adrenoceptor antagonists to reverse the cardiotoxic effects may be used.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

ATC code: N02B E51

The combination of paracetamol and caffeine is a well-established analgesic combination.

5.2 Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Binding of paracetamol to plasma proteins is minimal at therapeutic concentrations. Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates. Less than 5% is excreted as unmodified paracetamol.

After oral administration caffeine is completely and rapidly absorbed from the gastrointestinal tract with peak concentrations occurring between 5 and 120 minutes depending on the dose, health status, and co-medications in fasted subjects. There is no evidence of pre-systemic metabolism. Caffeine is widely distributed throughout the body. The mean plasma protein binding of caffeine is approximately 35%. Caffeine

is metabolized almost completely (~99%) in the liver via oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. Hepatic cytochrome P450 isoenzyme CYP1A2 is involved in caffeine enzymatic metabolism. Elimination is almost entirely by hepatic metabolism in adults. Only a small percentage (1 to 2%) of the ingested dose of caffeine in humans is excreted unchanged in the urine. In adults, marked individual variability in the rate of elimination occurs. The mean plasma half-life after oral administration is about 4.9 hours with a range of 1.9 - 12.2 hours. In combination, no saturation of the elimination processes with the consequential risks of increased half-life and toxicity has been observed for paracetamol. The absorption of both active substances (i.e. paracetamol and caffeine) is quick as described in the individual pharmacokinetic properties. No interactions have been observed Panadol Extra (Optizorb) tablets contain alginic acid and calcium carbonate which improves early drug absorption compared to Panadol Extra Tablets. Human pharmacokinetic data demonstrate that paracetamol and caffeine from Panadol Extra (Optizorb) tablets showed faster and greater absorption in the first 60 minutes (Tmax, AUC0-30min and AUC0-60min) compared to Panadol Extra tablets. Total extent of absorption of paracetamol and caffeine from Panadol Extra (Optizorb) tablets is equivalent to that from Panadol Extra tablets (AUC0-∞ and AUC0-t).

5.3 Preclinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Starch pregelatinised,

Povidone k-25,

Calcium carbonate,

Crospovidone,

Alginic acid,

Magnesium stearate,

6.2 Sodium methyl (E 219), Sodium ethyl (E 215) and Sodium propyl (E 217) parahydroxybenzoates.

Incompatibilities (Major)

None.

6.3 Shelf-life

36 months.

6.4 Special Precautions for Storage

Store below 30C.

6.5 Nature and Contents of Container

Child resistant blisters of 250 um or 300 um opaque polyvinylchloride (PVC) heat sealed to a bilayer of 20um Aluminium foil/8 um PET. The PVC blisters are further packed into cardboard cartons.

6.6 Instructions for Use/Handling

None.

7. MARKETING AUTHORISATION HOLDER

HALEON KENYA LIMITED,
Likoni Road, Industrial Area,
PO Box 78392, 00507,
Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER

CTD1468

9. DATE OF FIRST AUTHORISATION

16TH April 2015

10 DATE OF REVISION OF THE TEXT

Jan 2026