SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol Seltzer
Superdrug Paracetamol Stomach Seltzer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 500 mg of paracetamol and 1222.2 mg of sodium hydrogen carbonate (Sodium bicarbonate).

Excipients with known effect
Each tablet contains 388 mg of sodium and 50mg of sorbitol.
For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.
Flat, white tablets with bevelled edges, which are scored on one side and plain on reverse.

4 CLINICAL PARTICULARS

4.1. Therapeutic indications

Paracetamol Seltzer is recommended for the relief of headache with upset stomach, dyspepsia or acid indigestion and will also help relieve the pain and discomforts of period pains, migraine, rheumatic pain, toothache, colds, flu and a sore throat. It is also effective in the symptomatic relief of fever.

4.2 Posology and method of administration

Posology
Do not take continuously for more than 3 days without consulting your doctor.

Adults, the elderly and children over 16 years:

Two tablets, to be dissolved in a glass of water, every 4 hours when necessary up to a maximum of 8 tablets in 24 hours.

Children aged 10 to 15 years:
One tablet every 4 to 6 hours when necessary to a maximum of four doses in 24 hours.

Paediatric population
Not recommended for children under 10 years of age.

Method of administration
For oral administration only, dissolved in water.

4.3. Contraindications

Hypersensitivity to the active substances or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is 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.

Do not exceed the recommended dose as excessive or prolonged use may lead to alkalosis.

Do not take with any other paracetamol-containing products.
If your symptoms persist for more than three days or worsen at any time, you should see your doctor.

Keep all medicines out of the reach and sight of children.

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.

This medicinal product contains sodium and sorbitol.
Sodium: This medicine contains 388 mg sodium per effervescent tablet, equivalent to 19.4 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Sorbitol: This medicine contains 50mg sorbitol in each effervescent tablet. Patients with rare hereditary fructose intolerance (HFI)_ should not take/be given this medicinal product.

4.5 Interactions with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by drugs such as metoclopramide or domperidone. Cholestyramine reduces the absorption of paracetamol. The anticoagulant effect of warfarin and other coumarins may be prolonged by regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. The risk of paracetamol toxicity may be increased in patients receiving other potential hepatotoxic drugs or drugs that induce liver enzymes, for example alcohol, barbiturates, or anticonvulsants (e.g. carbamazepine).

Prolonged concurrent use of aspirin or NSAIDs may increase the risk of adverse renal effects.

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)

Sodium bicarbonate may impair the oral absorption of antibacterials (e.g. tetracyclines, rifampicin), antifungals (e.g. ketoconazole), chloroquine, phenothiazines, phenytoin, penicillamine, and bisphosphonates. It is therefore appropriate to take paracetamol seltzer at least two hours before or after such drugs. Sodium bicarbonate also increases the excretion of lithium. It may accelerate the excretion of acidic drugs like salicylates and methotrexate by raising the urinary pH. The urinary excretion of basic drugs such as amphetamines or quinidine may be inhibited, occasionally leading to increased plasma concentrations.

4.6. Fertility, pregnancy and lactation

Pregnancy

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. 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.

Breastfeeding

Paracetamol is excreted in breast milk but not in a clinical significant amount. Available published data do not contraindicate paracetamol whilst breast-feeding.

The safety of sodium bicarbonate during pregnancy and lactation has not been established.

4.7. Effects on ability to drive and use machines

Paracetamol Seltzer has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The information below lists reported adverse reactions, ranked using the following frequency classification:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Blood and lymphatic system disorders
Not known: blood dyscrasias including thrombocytopenia and agranulocytosis

Immune system disorders
Hypersensitivity including skin rash may occur.
Not known: anaphylactic shock, angioedema

Skin and subcutaneous disorders
Very rare cases of serious skin reactions such as Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis, fixed drug eruption have been reported.

Absorption of neutralised sodium bicarbonate can cause alkalosis - this is usually transient and clinically insignificant in people with normal renal function. The release of carbon dioxide from bicarbonate containing antacids can cause belching, occasional nausea, abdominal distension and flatulence.

Metabolism and nutrition disorders
Not known: high anion gap metabolic acidosis.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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
- regularly consumes ethanol in excess of recommended amounts, or
- 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, gastrointestinal bleeding, disseminated intravascular coagulation 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.

Overdose of sodium bicarbonate may cause metabolic alkalosis. Patients with this acid-base disturbance may experience dyspnoea. While muscle weakness may occur as a result of potassium depletion, hypercalcaemic patients can develop twitching tetany. Severe overdoses may lead to convulsions and coma. Sodium overload can

take two forms: hypernatraemia and iso-osmotic fluid retention. Treatment consists of appropriate correction of fluid and electrolyte balance and is otherwise supportive

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC code: N02 B E 51
Paracetamol has analgesic and antipyretic effects and also weak anti-inflammatory effects.

5.2. Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring within 30 to 90 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations.

Paracetamol is metabolised predominantly in the liver and excreted mainly in the urine mainly as glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life of paracetamol is between 2 to 3 hours in adults but is shorter for adolescents and children because of the extent of sulphate conjugation.

Administration of sodium bicarbonate by mouth causes neutralisation of gastric acid with the production of carbon dioxide. Any bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine that is rendered alkaline and there is an accompanying diuresis.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

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

Citric acid (anhydrous)
Sodium carbonate (anhydrous)

Sorbitol
Saccharin sodium
Povidone
Dimeticone
Sodium lauryl sulphate

6.2. Incompatibilities

Not applicable

6.3. Shelf Life

36 months.

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and contents of container

Paracetamol Seltzer Tablets are packed into Paper / polyethylene / aluminium foil/ polyethylene (PPFP) or Surlyn laminate strips and enclosed in cardboard cartons.

Pack sizes of 12, 16, 24 and 30 tablets.

Not all pack sizes may be marketed.

6.6. Instruction for Use/Handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Zentiva Pharma UK Limited
12 New Fetter Lane
London

EC4A 1JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 17780/0060

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/02/2009

10 DATE OF REVISION OF THE TEXT

28/03/2025