SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sootheze Six Plus Paracetamol 250mg / 5ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient: Each 5ml of Suspension contains Paracetamol 250 mg

Excipients: Also contains maltitol syrup, glycerol, sodium methyl para hydroxybenzoate (E219) and sodium propyl para hydroxybenzoate (E217), see section 4.4 for further information

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Uniform, off-white Suspension with strawberry flavour

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Sootheze Six Plus Paracetamol Suspension is indicated for the treatment of mild to moderate pain. It is also used for the relief of the pain associated with feverishness and feverish cold, and as an antipyretic.

4.2. Posology and method of administration

It is important to shake the bottle for at least 10 seconds before use

Child's Age	How Much	How often (in 24 hours)*
6 – 8 years	One 5 mL spoonful (large end)	4 times
8 – 10 years	One 5 mL spoonful (large end) and one 2.5 mL spoonful (small end)	4 times
10 – 12 years	Two 5 mL spoonfuls (large end)	4 times

- Do not give more than 4 doses in any 24 hour period
- Leave at least 4 hours between doses

- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist
- Do not give to children under the age of 6 years.

Children aged 12-16 years: Two - three 5mL spoonfuls (large end) up to 4 times a day.

Adults and children over 16 years: Two - four 5mL spoonfuls (large end) up to 4 times a day.

In the elderly: The rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is longer than in young adults.

4.3. Contraindications

Sootheze S i x Plus Paracetamol Suspension is contra-indicated in patients with known hypersensitivity to paracetamol, or any of the other excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Sootheze Six Plus Paracetamol Suspension should be used with caution in moderate to severe renal impairment or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Sodium methyl para hydroxybenzoate (E219) and Sodium propyl para hydroxybenzoate (E217) may cause allergic reactions (possibly delayed).

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 and 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.

The label should contain the following statements:

- Contains paracetamol.
- Do not give this medicine with any other paracetamol-containing product.
- Do not give more medicine than the label tells you to. If your child does not get better, talk to your doctor.
- For oral use only.
- Do not give more than 4 doses in any 24 hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.
- Do not overfill the spoon.

- Always use the spoon supplied with the pack.
- As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
- Store below 25°C. Store in the original package.
- Keep this medicine out of sight and reach of children.
- Shake the bottle for at least 10 seconds before use
- Talk to a doctor at once if your child takes too much of this medicine, even if they feel well

The leaflet should contain the following statements:

- Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.
- If the child needs more doses than shown in the table, or if fever doesn't go away, speak to your doctor as soon as possible.
- Very rare cases of serious skin reactions have been reported. Symptoms may include:
  - Skin reddening
  - Blisters
  - Rash

  If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

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.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged,

The use of drugs that induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptives, may increase the extent of metabolism, resulting in reduced plasma concentrations of the drug and a faster elimination rate.

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 risk factors (see section 4.4).

4.6. Ferility, 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 the doctor regarding its use.

Breast Feeding
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Fertility
There is no information relating to the effects of Sootheze Six Plus Paracetamol Suspension on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects of paracetamol are rare. Very rarely hypersensitivity and anaphylactic reactions 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.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

Nephrotoxicity following therapeutic doses of paracetamol is uncommon. Papillary necrosis has been reported after prolonged administration.

Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol: these are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.

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 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:

A. Is on long term treatment with carbamazepine, phenobarbital, 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, hyperhidrosis, malaise, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. This may include hepatomegaly, liver tenderness, jaundice, acute hepatic failure and hepatic necrosis. Abnormalities of glucose metabolism and metabolic acidosis may occur. Blood bilirubin, hepatic enzymes, INR, prothrombin time, blood phosphate and blood lactate may be increased. 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

ATC Code:	NO2 BE01
Pharmacotherapeutic group: (Anilides)	O t h e r Analgesics and Anti-pyretics

Paracetamol has analgesic and antipyretic effects similar to those of aspirin and is useful in the treatment of mild to moderate pain. It has weak anti-inflammatory effects.

5.2. Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are reached 30 to 90 minutes post-dose and plasma half-life is in the range 1-3 hours after therapeutic doses. Drug is widely distributed throughout most body fluids. Following therapeutic doses 90-100% of the drug is recovered in the urine within 24 hours almost entirely following hepatic conjugation with glucuronic acid (about 60%), sulphuric acid (about 35%) or cysteine (about 3%). Small amounts of hydroxylated and deacetylated metabolites have also been detected. Children have less capacity for glucuronidation of the drug than do adults. In over-dosage, there is increased N-hydroxylation followed by glutathione conjugation. When the latter is exhausted, reaction with hepatic proteins is increased leading to necrosis.

5.3. Preclinical safety data

There are no clinically relevant preclinical safety data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerol
Xanthan Gum
Avicel RC591
Maltitol syrup
Polysorbate 80
Saccharin Sodium
Citric Acid Monohydrate
Sodium methyl para hydroxybenzoate (E219)
Sodium propyl para hydroxybenzoate (E217)
Strawberry flavour
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C.
Keep medicines in their original packs to protect from light.

6.5 Nature and contents of container

Amber Glass Bottle & 28mm White Closure:

Amber glass bottle closed with a three piece plastic child resistant, tamper evident closure fitted with a polyethylene or polyvinylidene chloride (PVDC) laminate faced wad.

A double-ended spoon, made form high density polyethylene, with a 2.5ml and 5ml measure is supplied with all packs of this product.

Pack sizes available: 100ml

6.6 Instruction for use and handling, (and disposal)

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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Colindale, London

NW9 0EQ

8 MARKETING AUTHORISATION NUMBER(S)

PL 08977 / 0027

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/09/2007

10 DATE OF REVISION OF THE TEXT

26/03/2025