

**SOOTHEZE SIX PLUS PARACETAMOL 250MG/5ML ORAL
SUSPENSION**

PL 08977/0027

UKPAR

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**SOOTHEZE SIX PLUS PARACETAMOL 250MG/5ML ORAL
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LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Aspar Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension (PL 08977/0027) on 28th September 2007. This is a P licensed medicine available from pharmacies.

Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension contains the active ingredient paracetamol, which is an analgesic (relieves pain) and an antipyretic (lowers your temperature when you have a fever).

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension outweigh the risks, hence a Marketing Authorisation has been granted.

**SOOTHEZE SIX PLUS PARACETAMOL 250MG/5ML ORAL
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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Aspar Pharmaceuticals Limited a Marketing Authorisation for the medicinal product Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension (PL 08977/0027) on 28th September 2007. The product is a P licensed medicine available from pharmacies.

The application was submitted as a bibliographic application, for an active of well-established use, according to Article 10(a) of Directive 2001/83/EC (as amended).

Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension contains the active ingredient paracetamol. Paracetamol is a widely used general purpose mild analgesic and antipyretic. It is similar in efficacy to aspirin, but with no demonstrable anti-inflammatory activity.

PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

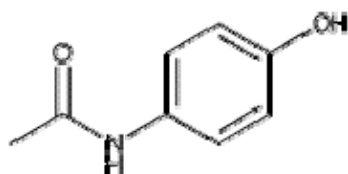
Paracetamol

Nomenclature:

INN: Paracetamol

Chemical name: N-(4-hydroxyphenyl)ethanamide

Structure:



Chemical Formula: $C_8H_9NO_2$

Molecular formula: $C_8H_9NO_2$

Molecular weight: 151.2

CAS No: 103-90-2

Physical form: White odourless crystalline powder

Solubility: Slightly soluble in water, freely soluble in ethanol and acetone, practically insoluble in ether

An appropriate active substance specification has been provided. The active substance paracetamol is the subject of BP and Ph Eur monographs.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Active paracetamol is stored in appropriate packaging. It is bulk packed in 25kg or 50kg lots and packed into fibre drums or 4-ply manila paper bags with 2-ply PE polythene bags as an inner liner. The specifications and typical analytical test reports are provided and are satisfactory.

Batch analysis data are provided and comply with the proposed specification.

A certificate of suitability has been provided for the active substance.

Appropriate stability data have been generated for drug substance stored in the same immediate packaging as the commercial packaging. This data demonstrates the stability of the drug substance and supports a retest period of 36 months, with no specific storage instructions.

DRUG PRODUCT**Other ingredients**

Other ingredients consist of pharmaceutical excipients, namely glycerol, xanthan gum, avicel, maltitol syrup, polysorbate 80, sodium saccharin, citric acid monohydrate, methyl hydroxybenzoate sodium (E219), propyl hydroxybenzoate sodium (E217), strawberry flavour, and purified water. Appropriate justification for the inclusion of each excipient has been provided.

The excipients used comply with their respective European Pharmacopoeial monographs, with the exception of three excipients: avicel and strawberry flavour which both comply with satisfactory in house specifications, and purified water which complies with British Pharmacopoeial specifications. Satisfactory certificates of analysis have been provided for all excipients.

There are no materials of human or animal origin contained in or used in the manufacturing process for the proposed product.

There were no novel excipients used and no overages.

Pharmaceutical development

Details of the pharmaceutical development of the drug product have been supplied and are satisfactory.

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls have been provided and are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on validation batches. The results are satisfactory.

Finished product specification

The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

Container Closure System

The container closure system consists of pharmaceutical grade alpha lightweight amber glass (medical) bottles, 100mL in size. The bottles are closed with a 28mm white screw cap with a three piece child resistant, tamper evident seal fitted with a polyethylene or polyvinylidene chloride (PVDC) laminated faced wad. A single ended polyethylene plastic 5mL measuring spoon is provided with all packs of the product.

Specifications and Certificates of Analysis for all packaging components used have been provided. These are satisfactory.

All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for contact with food.

Stability

Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 2 years has been set, which is satisfactory. Storage conditions are “Do not store above 25 degrees”, “Store in the original packaging”, “Protect from light”

Bioequivalence Studies

There was no bioequivalence study carried out to support this application. The legal basis of the application is that it is a bibliographic application, therefore a bioequivalence study is not required.

Conclusion

The grounds for this application are considered adequate. It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

The application was submitted as a bibliographic application, for an active of well-established use.

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

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 feverish cold, and as an antipyretic.

CLINICAL PHARMACOLOGY

No new data are submitted and none are required for this type of application.

EFFICACY

No new data are submitted and none are required for this type of application. However, the applicant has provided an expert review of clinical trials published in the literature confirming the efficacy and safety of Paracetamol Suspension.

SAFETY

No new data are submitted and none are required for this type of application. The applicant has provided an expert safety review of Paracetamol Suspension. No new safety issues have been identified. The clinical safety of Paracetamol Suspension is well established following many years of use.

EXPERT REPORT

A satisfactory clinical expert report has been submitted with appropriate CV.

PRODUCT INFORMATION:

Summary of Product Characteristics

The approved SPC is satisfactory.

Patient Information Leaflet

The PIL is in line with the approved SPC and is satisfactory.

Labelling

Colour mock-ups of the label and carton have been provided. The labelling is satisfactory.

DISCUSSION

Analgesics containing paracetamol have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

The application was submitted under the legal basis of a bibliographic application. In this regard, the applicant has submitted an adequate literature review and analysis of over 54 publications including a spontaneous adverse events report from MHRA. The literature review confirms the therapeutic effectiveness of a paracetamol oral suspension preparation and no new safety issues have been detected.

CONCLUSION

Sufficient clinical information has been submitted to support this application. Paracetamol has wide safety margin at this therapeutic dose range. Its pharmacokinetics are linear particularly at this relatively low dosage. When used as indicated, paracetamol oral suspension has a favourable benefit-to-risk ratio. Therefore, a Marketing Authorisation may be granted on medical grounds.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

Analgesics containing paracetamol have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

The applicant has submitted an adequate literature review for this bibliographic application. The literature review confirms the therapeutic effectiveness of a paracetamol oral suspension preparation and no new safety issues have arisen.

PRODUCT LITERATURE

The approved SPC, PIL and labelling are satisfactory.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with paracetamol is considered to have demonstrated the therapeutic value of the active substance. The risk benefit is, therefore, considered to be positive.

SOOTHEZE SIX PLUS PARACETAMOL 250MG/5ML ORAL SUSPENSION

PL 08977/0027

STEPS TAKEN FOR ASSESMENT

- 1 The MHRA received the marketing authorisation application on 13th February 2004
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 1st March 2004
- 3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 6th August 2004, and further information relating to the clinical dossier on 17th September 2004
- 4 The applicant responded to the MHRA's requests, providing further information for the clinical sections and the quality sections on 4th January 2006
- 5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 4th January 2006
- 6 The applicant responded to the MHRA's request, providing further information for the quality sections on 8th July 2006, 2nd October 2006, and 25th August 2007
- 7 The application was determined on 28th September 2007

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension is as follows:

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: 250mg

Excipients with known effects

Each 5ml of Suspension contains:-

Maltitol: 1.0ml

Sodium Methylparahydroxybenzoate (E219): 9.0mg

Sodium Propylparahydroxybenzoate (E217): 1.0mg

For a 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 feverish cold, and as an antipyretic.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Route of Administration: Oral

Shake well before use:

Dose:

Adults and children 12 years and over:

The optimal dosage range is 500mg to 1g Paracetamol, i.e. 10 to 20 ml Sootheze Six Plus Paracetamol Suspension (maximum 1 g), which may be repeated every 4 hours to a maximum of 4g Paracetamol /day (80ml Sootheze Six Plus Paracetamol Suspension).

Children aged 6 to 12 years:

Route of administration: Oral

5 to 10ml (250mg to 500mg Paracetamol). Repeat every 4 hours, if necessary, up to a maximum of 4 doses per 24 hours.

Children under 6 years:

Not recommended

The Elderly:

In the elderly, the rate and extent of Paracetamol absorption is normal but plasma half-life is longer and Paracetamol clearance is lower than in your adults.

4.3 CONTRAINDICATIONS

Sootheze Six Plus Paracetamol Suspension is contra-indicated in patients with known hypersensitivity to Paracetamol, or any of the other components.

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.

Important information about some of the ingredients

- Maltitol liquid (E965): If you have been told by your doctor that you or your child have intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217): May cause allergic reactions (possibly delayed).

The Label contains the following statements:

Keep out of reach of children.

Do not exceed the recommended dose.

Do not take more than 4 doses in 24 hours.

Leave at least 4 hours between doses.

Do not give for more than 3 days without consulting a doctor

As with all medicines, if you are currently taking any other medicine consult your doctor or pharmacist before taking this product.

If symptoms persist consult your doctor.

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

Contains Paracetamol.

Immediate advice should be sought in the event of an overdose, even if the child seems well. (label)

Immediate advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage. (leaflet)

Do not give with any other Paracetamol-containing products.

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 risk of bleeding; occasional does have no significant effect.

Patients who have taken barbiturates, tricyclic, antidepressants and alcohol may show diminished ability to metabolise large doses of Paracetamol, the plasma half-life of which can be prolonged.

Alcohol can increase the hepatotoxicity of Paracetamol overdosage and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of Paracetamol.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induce liver enzymes and may prevent attainment of therapeutic Paracetamol levels by increasing first pass metabolism or clearance.

4.6 PREGNANCY AND LACTATION

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.

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None known.

4.8 UNDESIRABLE EFFECTS

Paracetamol has been widely used and, when taken at the usual recommended dosage, side effects are mild and infrequent and reports of adverse reactions are rare. Skin rash and other allergic reactions occur rarely.

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.

4.9 OVERDOSE

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 and any patient who had ingested around 7.5g or more of Paracetamol in the preceding 4 hours should undergo gastric lavage.

Administration of oral methionine or intravenous N-acetylcysteine, which may have beneficial effect up to at least 48 hours after overdose, may be required. General supportive measures must be available.

Symptoms of Paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Live 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, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Liver damage if possible in adults who have taken 10g or more of Paracetamol.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

ATC Code: NO2 BE01

Pharmacotherapeutic group: Analgesic

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 30-90 minutes post dose and the plasma half-life is in the range of 1 to 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 overdosage 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

No data of relevant to the prescriber, which is additional to that already included in other section of the SPC.

6 PHARMACEUTICAL PARTICULARS**6.1 LIST OF EXCIPIENTS**

Glycerol
Xanthan Gum
Avicel RC591 (microcrystalline cellulose and carboxycellulose sodium)
Maltitol liquid (E965)
Polysorbate 80
Saccharin Sodium (E954)
Citric Acid Monohydrate
Sodium Methyl parahydroxybenzoate (E219)
Sodium Propyl parahydroxybenzoate (E217)
Strawberry flavour (containing propylene glycol)
Purified Water

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

2 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

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 from high density polyethylene, with a 2.5ml and 5ml measure is supplied with all packs of this product.

Pack sizes available: 100ml

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MARKETING AUTHORISATION HOLDER

Aspar Pharmaceuticals Limited
29-30 Capitol Way
Capitol Way Industrial Park
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
28/09/2007

PATIENT INFORMATION LEAFLET

Patient Information Leaflet PL 08977 / 0027

Please read all of this leaflet carefully before you start taking this medicine.

Keep the leaflet as you may need to read it again.

This medicine has been prescribed for you or your child and you should not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

If you have any further questions or are not sure about anything, please ask your doctor or pharmacist.

The name of this medicine is

Sootheze Six Plus

Paracetamol 250mg/5ml Oral Suspension

STRAWBERRY FLAVOUR, SUGAR FREE, COLOUR FREE

This medicine is suitable for children 6 years old and over. It also suits adults who find it easier to swallow than tablets.

Each 5ml of suspension contains 250mg of Paracetamol as the active substance. Other ingredients are glycerol, xanthan gum, avicel, maltitol liquid (E965), polysorbate 80, sodium saccharin (E954), citric acid monohydrate, methyl parahydroxybenzoate sodium (E219), propyl parahydroxybenzoate sodium (E217) and purified water. The flavouring is strawberry (contains propylene glycol).

The Product Licence Holder and distributor is:

Aspar Pharmaceutical Ltd, Colindale London NW9 0EQ

The manufacturer is Orbis Consumer products Ltd Northfield Industrial Estate, Middlesex, HA0 1NW

What the Sootheze Six Plus Suspension Sootheze Six Plus Suspension is and what it is used for

Sootheze Six Plus Suspension is a strawberry flavoured off-white suspension and is easy to swallow. It is a mild to moderate pain killer. Paracetamol is an analgesic, which is also an antipyretic, which means it relieves pain and lowers the temperature when you have a fever.

The product is available in amber glass bottle packed into boxboard carton containing 100ml, 140ml, 200ml, 250ml or 500ml bottles (**not all pack sizes may be marketed**).

Who can take Sootheze Six Plus Suspension

This medicine suits most children over 6 years of age and for adults who have difficulty in swallowing pain relieving tablets.

Before taking your medicine

- **Do not take** if you are allergic to paracetamol or any of the other ingredients.
- Talk to your doctor **BEFORE** taking this medicine, if you suffer from severe liver or kidney problems including non-cirrhotic alcoholic liver disease.
- Do not use any other medicines or remedies that contain paracetamol while you are using this medicine.

Talk to your doctor or pharmacist **BEFORE** taking this medicine if:

- Your child has any serious kidney or liver problems.
- Your child is taking any other medicine including :
 - antidepressants
 - sedatives
 - metoclopramide or domperidone (used to treat nausea or vomiting)
 - cholestyramine (used to treat high cholesterol)
 - anticoagulants (drugs that thin your blood such as warfarin)
 - anticonvulsants (drugs to treat epilepsy)

If you are unsure if another medicine you are taking is one of those mentioned above, then show the pack to your pharmacist.

The following additional warnings are included in case an adult is taking this product:

- You can use Sootheze Six Plus Suspension while you are taking oral contraceptives ('the pill') or tablets for epilepsy but it may not work so well on your pain or feverishness.
- If you drink large amounts of alcohol, you may be more susceptible to the side-effects of paracetamol.
- You should ask your doctor or pharmacist to advise before taking this medicine in pregnancy or while breast-feeding.

If you have any queries regarding this medicine you should talk to your doctor or pharmacist before taking this product.

Important information about some of the ingredients of Sootheze Six Plus

- Maltitol liquid: If you have been told by your doctor that you or your child have intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium methylhydroxybenzoate (E219) and sodium propylhydroxybenzoate (E217): May cause allergic reactions (possibly delayed).

Taking your medicine

This medicine is for oral administration only.

A double-ended spoon (2.5ml and 5ml) is provided in the pack to ensure accuracy, which holds either 2.5ml or 5ml of the suspension.

DOSE:

WARNING: Do not exceed the stated dose

Shake the bottle thoroughly before measuring the dose.

Unless otherwise directed by a doctor:

Children 6-12 years:	One to two 5ml spoonfuls every 4 hours
Adults and children over 12 years:	Two to four 5ml spoonfuls every 4 hours
Children under 6 years:	Ask a pharmacist to recommend a suitable product

Do not repeat doses more frequently than 4 hourly.

Do not use more than 4 doses each day.

If your child's symptoms persist for more than 3 days consult your doctor.

For short term use only

Prolonged use of suspension is not recommended.

If you take too much (overdose)

As with any medicine, immediate medical advice should be sought in the event of an overdose, even if you or your child feels well, because of the risk of delayed serious liver damage. If you cannot do this, go to the nearest hospital casualty department and take along any medicine that is left.

If you miss a dose

Just give the next dose when needed. Do **NOT** give a double dose to make-up for the missed dose.

Possible Side Effects

Like all medicines Paracetamol can have side effects. A few people may get skin rashes or other sorts of allergy. Very rarely, people taking paracetamol can feel unusually tired, get unexpected bruising or bleeding, or get more infections (such as colds) than usual. If you noticed any of these changes, talk to your doctor or pharmacist.

If you noticed any unpleasant effects from this medicine, even if they are not mentioned here, stop using Sootheze Six Plus Suspension. Tell your doctor or pharmacist

Storing your Medicine**KEEP MEDICINE OUT OF THE REACH & SIGHT OF CHILDREN**

Do not store above 25°C.

Keep container in its original outer carton to protect from light

Do not use after the expiry date printed on the carton.

Wipe the neck of the bottle clean and do not overtighten on replacing the cap.

OTHER INFORMATION

Remember:

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or Pharmacist who have access to additional information.

For further information please contact:

Aspar Pharmaceuticals Ltd, Colindale, London NW9 0EQ

Sootheze Six Plus Suspension is a registered trade mark

Barcode: To be inserted (Barcode & Pharmacode may be introduced)

Item Code: To be inserted

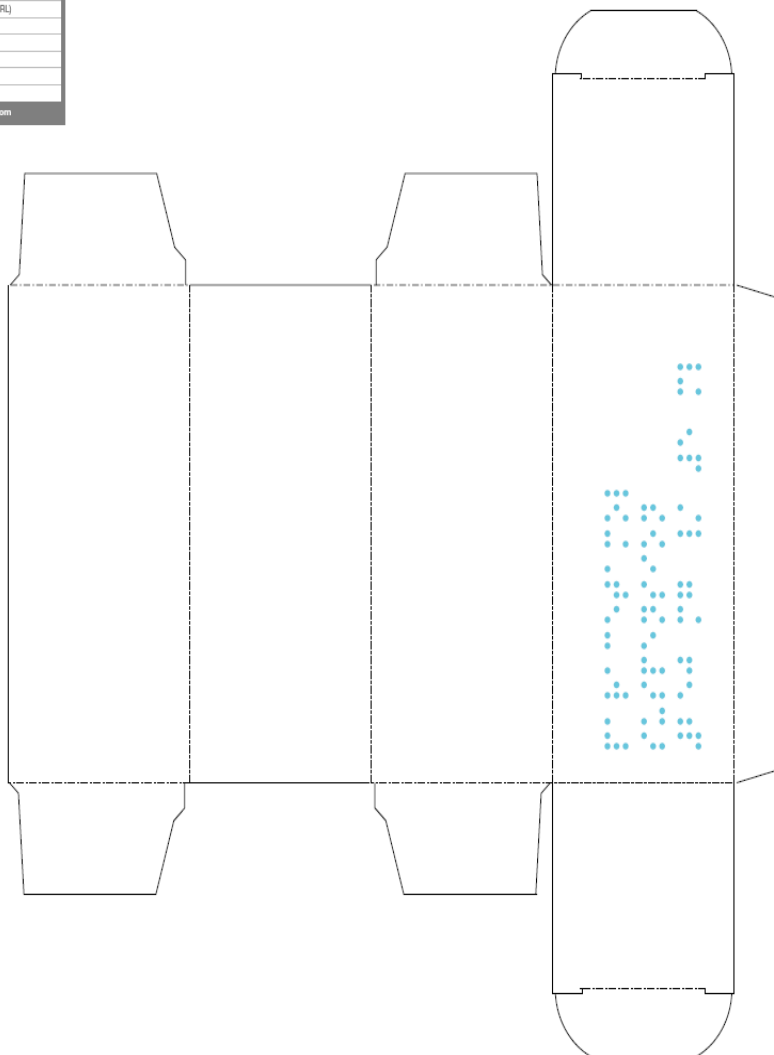
LABELLING

Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension

(GIRL)

 n.com





ASPAR
"SOOTHEZE" PLUS
250mg/5ml Carton

Braille reads vertical from base
left to right

**paracetamol
suspension
#250 mg / #5ml**

NOTE: (# denotes unique number sign)

ASPAR "SOOTHEZE" PLUS 250mg/5ml label

Proof 6 02.06.06

Each 5ml of Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension contains 250mg of Paracetamol. It also contains glycerol, sodium glycerophosphate, microcrystalline cellulose, methylcellulose, polyethylene glycol, saccharin sodium, citric acid monohydrate, methylhydroxybenzoate sodium (E211), propyl hydroxybenzoate sodium (E212) and purified water. The flavour is strawberry (contains Propylene Glycol).

USBS: Sootheze Six Plus Paracetamol 250mg/5ml Oral Suspension is a strawberry flavoured oral suspension and is easy to swallow. It is used for the relief of the pain associated with fever, headache and feverish cold. It can also relieve mild to moderate pain.

It is suitable for children 6 years and over and adults who have difficulty swallowing tablets. For oral administration only.

KEEP MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN

Do not store above 25°C. Store in the original container to protect from light. Do not use after the expiry date printed on the label.

ASPAR Sootheze SIX PLUS
Paracetamol 250mg/5ml Oral Suspension
100ml
Strawberry Flavour
SUGAR FREE
COLOUR FREE

Product Licence Holder
 Aspen Pharmaceuticals Limited
 29-30 Capital Way, Capital Way Industrial Park, Colindale
 London NW9 0EQ PL 08977/0027
 Sootheze Six Plus is a trademark

Read the enclosed leaflet before taking this medicine.
 A double-ended measuring spoon (5ml and 2.5ml) is provided to ensure accuracy of dose measured. APS+ 001

DOSE:
 Shake the bottle thoroughly before measuring the dose.
 Unless otherwise directed by a doctor:

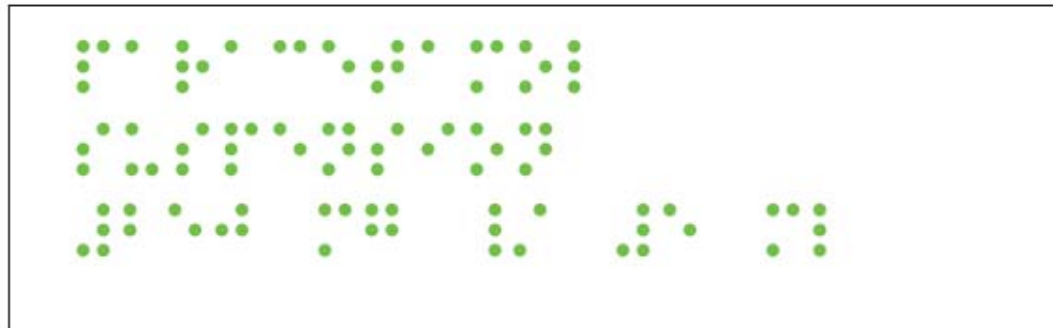
Children:	6-12 years:	One to two 5ml spoonfuls every 4 hours
Adults and children over 12 years:		Two to four 5ml spoonfuls every 4 hours
Children:	Under 6 years:	Ask a pharmacist to recommend a suitable product.

The dose should not be repeated more frequently than every 4 hours and not more than 4 doses should be taken in any 24 hour period.
 If symptoms persist for more than 3 days consult your doctor.

WARNING: Do not exceed the stated dose.
CONTAINS PARACETAMOL
 Do not give with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage.

Wipe the neck of the bottle clean and do not overtighten on replacing the cap. **P** Test prepared May 2005

BATCH: EXP:



Braille reads conventional left to right

paracetamol
 suspension
 # 250 mg / # 5 ml

NOTE: (# denotes unique number sign)