SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots 6 Years Plus Paracetamol 250mg/5ml Oral Suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Per 5 ml
Paracetamol	250 mg
Excipients with known effect:	
Sorbitol solution (E420)	1.5 ml
Methyl hydroxybenzoate (E218)	7.5 mg
Benzyl alcohol	0.06 mg
Propylene glycol	17.8 mg

See section 4.4 for further information.

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Oral Suspension

An off-white, strawberry-flavoured, syrupy suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the treatment of mild to moderate pain and as an antipyretic. It can be used in many conditions including headache, toothache, earache, sore throat, colds and influenza, aches and pains and post-immunisation fever.

4.2 Posology and method of administration

For oral use only.

It is important to **shake the bottl**e for at least 10 seconds before use.

Children aged 6 to 12 years:

Child's Age	**How Much**	**How Often (in 24 hours)**

6-8 years	5 ml	4 times
8-10 years	7.5 ml (5ml + 2.5ml)	4 times
10-12 years	10 ml (5ml + 5ml)	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: 10-15 ml (Two to three 5 ml doses) up to 4 times a day.

Adults and children over 16 years: 10-20 ml (Two to four 5 ml doses) up to 4 times a day.

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 young adults.

4.3 Contraindications

Hypersensitivity to paracetamol, or any of the other ingredients.

4.4 Special warnings and precautions for use

Do not exceed the recommended dose. Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help straight away. Quick medical attention is critical for adults as well as children even if signs or symptoms are not noticed.

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Chronic alcohol users should consult a doctor before use.

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 the underlying cause of HAGMA in patients with multiple risk factors.

Glutathione deficiency can also increase the risk of hepatotoxicity with paracetamol use, even at therapeutic doses. Caution is advised for patients at risk of glutathione depletion (See section 4.9).

Hepatotoxicity at therapeutic dose
Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range. These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (adults <50 kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs and in acute and chronic malnutrition (low reserves of hepatic glutathione). Paracetamol should be administered with caution to patients with these risk factors. Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see section 4.9).

Dosage adjustment of paracetamol should be considered where there are risk factors for glutathione deficiency or hepatotoxicity and for those of low weight (for adults those weighing less than 50kg).

This medicine should not be diluted. Where a dilution of this medicine is required, Paracetamol 120mg/5ml Oral Suspension should be recommended.
Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Taking this product with other paracetamol-containing medicines could lead to overdose and should therefore be avoided.

The label will state:
Do not give anything else containing paracetamol while giving this medicine.
Do not give more medicine than the label tells you to.
If your child does not get better, talk to their doctor.
Talk to a doctor at once if your child takes too much of this medicine, even if they seem well

Keep out of the reach and sight of children.

The label should convey the following information:

For oral use only.
Never give more medicine than shown in the table.
Always use the syringe supplied with the pack.
Do not give to children under 6 years of age.
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.
As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before giving this product.
Do not store above 25°C. Store in the original package.
Shake the bottle for at least 10 seconds before use.

The leaflet will state:

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 than the doses 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.

Important information about some of the ingredients of this medicine
This medicine contains 1.1g of sorbitol in each 5ml dose, which is equivalent to 220mg/ml. Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine.

Methyl hydroxybenzoate (E218) may cause allergic reactions (possible delayed).

This medicine contains 0.06 mg of benzyl alcohol in each 5ml dose, which is equivalent to 0.012mg/ml. Benzyl alcohol may cause allergic reactions. High volumes should be used with caution and only if necessary, especially in patients who are pregnant or breast-feeding or subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

This medicine contains 17.8mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 3.56mg/ml.

This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

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.

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.

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 of paracetamol, 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 Fertility, pregnancy and lactation

Pregnancy
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.

When given to the mother in therapeutic doses (1 g single dose), paracetamol crosses the placenta into foetal circulation as early as 30 minutes after ingestion and is metabolised in the foetus by conjugation with sulfate and increasingly with glutathione.

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 this medicine on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during clinical trials and postmarketing experience with paracetamol are listed below by System Organ Class (SOC). The frequencies are defined according to the following convention:

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

Not known (cannot be estimated from the available data)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence is unavailable, frequency category is listed as 'Not known'.

System Organ Class (SOC)	**Frequency**	**Adverse Drug Reaction (Preferred Term)**
Blood and lymphatic system disorders	Not known	Blood disorder (including thrombocytopenia and agranulocytosis)[1]
Immune system disorders	Very rare	Anaphylactic reaction
	Very rare	Hypersensitivity
Hepatobiliary disorders	Not known	Liver injury[2]
Skin and subcutaneous tissue disorders	Very rare	Rash
	Not known	Fixed eruption
	Not known	Rash pruritic
	Not known	Urticaria
Renal and urinary disorders	Uncommon	Nephropathy toxic
	Not known	Renal papillary necrosis[3]
Investigations	Not known	Transaminases increased[4]
Metabolism and nutrition disorders	Not known	High anion gap metabolic acidosis[5]

[1] Reported following paracetamol use, but not necessarily causally related to the drug
[2] Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year

[3] Reported after prolonged administration

[4] Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these elevations are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.
[5]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

Very rare cases of serious skin reactions have been reported.

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.

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 patients who have taken more than recommended doses of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

Ingestion of paracetamol at therapeutic doses may lead to liver damage if the patient has risk factors. These include if:

- They are undergoing long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes

Or

- They regularly consume ethanol in excess of recommended amounts

Or

- They are likely to be glutathione deplete e.g. diet (malnutrition, fasting, dietary restrictions, eating disorders and starvation), catabolic states (sepsis), cachexia and chronic illness (cystic fibrosis, liver disease, HIV and muscular dystrophy).

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, coma 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.

Haemolytic anaemia (in patients with glucose-6-phosphate dehydrogenase [G6PD] deficiency): Haemolysis has been reported in patients with G6PD deficiency, with use of paracetamol in overdose.

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: N02BE01

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

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

Sorbitol solution (E420)
Glycerol
Dispersible cellulose (containing microcrystalline cellulose and sodium carboxymethylcellulose)
Hydroxyethylcellulose
Acesulfame potassium
Methyl hydroxybenzoate (E218)
Strawberry flavour ABJH9 (containing benzyl alcohol, ethyl benzoate, propylene glycol)
Cream flavour ACP3P (containing propylene glycol)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package.

6.5 Nature and contents of container

70ml or 80ml amber PET bottle with polypropylene child resistant closure with expanded polyethylene liner or polyethylene plug.

Syringe composed of a natural polypropylene barrel and a polyethylene pigmented white plunger.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

Trading as BCM

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0860

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/12/2024

10 DATE OF REVISION OF THE TEXT

07/10/2025