PICCAN PARACETAMOL SUSPENSION SmPC

1. Name of the medicinal product

PiccanParacetamol Suspension120mg/5ml

2. Qualitative and quantitative composition

Acetaminophen 120mg/5ml

Sr. No	Ingredients	Spec	Qty Per 5ml	Function
1.	Granulated Sugar	BP	3000mg	Sweetener, thickening agent, coating agent
2.	Paracetamol BP	BP	120mg	API
3.	Vivapur MCG 611P	BP	100mg	Suspending agent, dispersant
4.	Sodium Benzoate	BP	5mg	Antimicrobial preservative, tablet and capsule lubricant
5.	Methyl Hydroxybenzoate	BP	0.75mg	Preservative
6.	Xanthan gum	BP	2mg	Suspending agent, stabilizing agent, thickening agent and emulsifying agent
7.	Liquid Sorbitol	BP	700mg	Humectant, plasticizer, stabilizing agent, sweetening agent, tablet and capsule diluent.
8.	Allura Red	FDA	0.2mg	Colourant
9.	Glycerin	BP	500mg	Solvent, sweetening agent, antimicrobial preservative, viscosity-increasing agent, plasticizer
10.	Strawberry Powder flavor	BP	5.0mg	Flavoring agent
11.	Titanium Dioxide	BP	10mg	White pigment, opacifier, coating agent
12.	Citric Acid	BP	4.8mg	Buffering Agent
13.	Purified Water	BP	5ML	Diluent

3. Pharmaceutical form

Oral Suspension

An opaque pink coloured colloidal viscous liquid.

4. Clinical particulars

Therapeutic indications

Effective relief from general body aches, cold symptoms, feverish conditions, headache, teething pains, post immunization fever and ear ache.

Posology and method of administration

Posology

For the relief of fever after vaccinations at 3 and 4 months
One 2.5 mL spoonful (small end). This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 6 hours between doses. If your baby still needs this

medicine two days after receiving the vaccine talk to your doctor or pharmacist.	
Age: 2 – 3 months	**Dose**
Pain and other causes of fever - if your baby weighs over 4 kg and was born after 37 weeks	One 2.5 mL spoonful If necessary, after 6 hours, give a second 2.5 mL dose
• Do not give to babies less than 2 months of age • Leave at least 4 hours between doses • Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.	

Child's Age	How Much	How often (in 24 hours)
3 – 1 years	One 2.5 mL	4 times
1- 6 years	One 5 mL	4 times
Above 6 years -12 years	10ml	4 times

• Do not give more than 4 doses in any 24 hour period
• Leave at least 6 hours between doses
• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist

Method of administration

For oral administration only

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

4.3 Contraindications
Hypersensitivity to paracetamol or to any of the excipients listed in section 6.1.

Patients with severe hepatic dysfunction.

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 hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

• Contains paracetamol.

• Do not give with any other paracetamol-containing products.

• For oral use only.

• Never give more medicine than shown in the table.

• Always use the dispenser supplied with the pack. Do not overfill the calibration for the doses.

• Do not give to babies less than 2 months of age.

• For infants 2-3 months no more than 2 doses should be given.

• 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 taking this product.

• Do not store above 25°C. Protect from light. Store in the original package.

• 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.

• If symptoms persist consult your doctor.

• Keep out of the sight and reach of children.

Excipients in the formulation

This product contains:

• Methyl and propyl hydroxybenzoates. These may cause allergic reactions (possibly delayed).

• Sucrose (3g per 5ml dose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

• Sorbitol. This medicine contains 700mg per 5ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

4.5 Interaction with other medicinal products and other forms of interaction

The hepatotoxicity of Paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants, and alcohol.

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

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.

Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

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.

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.

Breast-feeding

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Very rare cases of serious skin reactions have been reported.

Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adverse reactions are rare, and are generally associated with overdosage.

Allergic reactions occur occasionally.

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.

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.

Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration.

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 wih 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 depleted 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, 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

Pharmacotherapeutic group: Other Analgesics and Antipyretics (Anilides)

ATC Code: N02 BE01.

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Oral absorption is rapid and almost complete, it may be decreased if Paracetamol is taken following a high carbohydrate meal.

There is no significant protein binding with doses producing plasma concentrations of below 60mcg (µg)/ml, but may reach moderate levels with high or toxic doses.

Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid, sulphuric acid and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half-life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children.

Time to peak concentration, 0.5 - 2 hours; peak plasma concentrations, 5 - 20mcg (µg)/ml (with doses up to 650mg); time to peak effect, 1- 3 hours; duration of action, 3- 4 hours.

Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged.

Peak concentration of 10 - 15mcg(µg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose. Half life in breast milk is 1.35 - 3.5 hours.

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

Granulated Sugar

Vivaput

Sodium Benzoate

Methyl hydroxybenzoate

Xanthan gum

Sorbitol solution 70%

Allura Red

Glycerin

Strawberry powderflavor

Titanium dioxide

Purified water

6.2 Incompatibilities
None stated

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C. Protect from light. Store in the original package.

6.5 Nature and contents of container

Bottles:	Amber (Type III) Pet bottle
Closure:	HDPE, child resistant, tamper evident
Pack sizes:	100ml
Dosing device:	2.5/5/10ml measuring device.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT / MANUFACTURER

Name and Address of Manufacturer

MAY & BAKER NIGERIA PLC

1, May & Baker Avenue

Off Idiroko Road Ota

Ogun State

Name and Address of Applicant

Kensington International Marketing Company Nig. Ltd.,

9/11 Olatunde Onasanya Street

Ajuwon, Ifakoljaiye,

Lagos State.

8. Marketing authorisation number(s)

9. Date of revision of the text

8th February 2024