SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Valubabe (Paracetamol) 125mg/5ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains: Paracetamol BP…… 125mg Excipients: For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension
Pink coloured, viscous aqueous suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains. For the reduction of fever and to be used as an adjunctive treatment to relieve symptoms of cold and flu.

4.2 Posology and method of administration

For the relief of fever after vaccinations at 2, 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 4 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 (small end). If necessary, after 4-6 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 – 6 months	One 2.5 mL spoonful (small end)	4 times
6 – 24 months	One 5 mL spoonful (large end)	4 times
2 – 4 years	One 5.0 mL spoonful (large end) and one 2.5 mL spoonful (small end)	4 times
4 – 8 years	Two 5 mL spoonfuls (large end)	4 times
8 – 10 years	Three 5 mL spoonfuls (large end)	4 times
10 - 12 years	Four 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		

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
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 and symptoms are not noticed.

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

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 underlying cause of HAGMA in patients with multiple risk factors.

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.

The label contains the following statements:

• 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 spoon supplied with the pack. Do not overfill the spoon.
• 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 25ºC. 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.

The leaflet contains 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.
• Very rare cases of serious skin reactions have been reported. Symptoms may include:
    - Skin reddening
    - Blister
    - 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 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 indicates 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 known.

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.

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.

Consumers are advised to report adverse events related to the use of medicines and medical product to the nearest NAFDAC office, NAFDAC PRASCOR (20543 TOLL FREE from all networks),

pharmacovigilance@nafdac.gov.ng or via the eReporting platform available on the

NAFDAC Website:

https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=NG.

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 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 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 hospitals. Management of patients who are 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**

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 the 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**

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Distribution

Peak plasma concentrations occur about 30 minutes to 2 hours after oral doses. 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 but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol overdosage and cause liver damage.

Elimination It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 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**

Methyl paraben, Propyl paraben, Sugar, Citric Acid Anhydrous, Propylene Glycol, Sorbitol 70%, Allura red, Purified water.

6.2 **Incompatibilities**

None known

6.3 **Shelf life**

36 months.

6.4 **Special precautions for storage**

Store in a dry place below 30degrees

Keep out of sight and reach of children

6.5 **Nature and contents of container**

Bottles:	Amber Glass bottle
Closure:	Aluminum ROPP cap
Pack size:	100ml
Dosing device:	2.5/5ml polypropylene measuring cup

6.6 **Special precautions for disposal and other handling**

Shake well before use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. **APPLICANT**

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