SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Moxie Paracetamol Suspension BP 120 mg/5 ml Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral suspension contains:

- **Paracetamol 120 mg** (for the infant strength)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A pink strawberry flavoured Viscous Oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of mild to moderate pain and as an antipyretic in infants and children, including:

- Teething pain
- Headache
- Toothache
- Sore throat
- Symptoms of cold and influenza
- Feverishness
- Minor aches and pains

4.2 Posology and method of administration

Posology
Doses should be based on the child's weight, using age only as a guide.

Recommended single dose: **15 mg/kg** every 4–6 hours as required, up to **60 mg/kg per 24 hours** (maximum 4 doses in 24 hours).

Children:

- **3–6 months (approx. 4–6 kg):** 2.5 ml (60 mg) every 4–6 h as required (max 4 doses/24 h).
- **6–24 months (approx. 6–12 kg):** 5 ml (120 mg) every 4–6 h (max 4 doses/24 h).
- **2–4 years:** 7.5 ml (180 mg) every 4–6 h (max 4 doses/24 h).
- **4–6 years:** 10 ml (240 mg) every 4–6 h (max 4 doses/24 h).
- **6–8 years (for 250 mg/5 ml strength):** 5 ml (250 mg) every 4–6 h (max 4 doses/24 h).
- **8–10 years:** 7.5 ml (375 mg) every 4–6 h.
- **10–12 years:** 10 ml (500 mg) every 4–6 h.

Adolescents and adults:
500–1000 mg every 4–6 hours as required. Do not exceed **4 g per 24 hours**.

Special populations

- **Hepatic impairment:** Use with caution; reduce dose or extend dosing interval.
- **Renal impairment:** Dose interval should be increased in patients with severe renal impairment.

Method of administration
Oral use. Shake the bottle well before each use. Administer using the supplied measuring device.

4.3 Contraindications

- Hypersensitivity to paracetamol or to any of the excipients listed in section 6.1.
- Severe hepatic impairment.

4.4 Special warnings and precautions for use

- Do not exceed the stated dose.

- Care is advised in the administration to patients with impaired hepatic or renal function.
- Cases of hepatotoxicity and acute liver failure have been reported in overdose, sometimes with fatal outcome.
- Prolonged or frequent use is discouraged.
- Avoid concurrent use of other paracetamol-containing medicinal products.
- Caregivers must ensure the correct strength is administered to avoid accidental overdose.
- Contains [sorbitol/maltitol/sucrose] – patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

- Hepatotoxicity risk may be increased in patients receiving enzyme-inducing drugs (e.g., rifampicin, carbamazepine, phenytoin, phenobarbital).
- Metoclopramide and domperidone may increase the absorption rate of paracetamol.
- Cholestyramine reduces absorption of paracetamol.
- Warfarin and other coumarins: prolonged regular use of paracetamol may enhance anticoagulant effect, increasing bleeding risk.

4.6 Fertility, pregnancy and lactation

Pregnancy: Epidemiological studies indicate no adverse effects when used at recommended doses. Use only if clearly needed.
Breast-feeding: Paracetamol is excreted in breast milk but not in clinically significant quantities. Compatible with breast-feeding.
Fertility: No adverse effects reported.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse effects are rare.

- **Immune system disorders:** Hypersensitivity reactions including skin rash, urticaria, anaphylaxis (rare).
- **Blood disorders:** Thrombocytopenia, leucopenia (very rare).
- **Hepatobiliary disorders:** Liver dysfunction with chronic use or overdose.
- **Skin disorders:** Serious cutaneous reactions (very rare).

4.9 Overdose

Toxicity: Hepatocellular necrosis may occur. High risk with doses >150 mg/kg.

Symptoms: Nausea, vomiting, pallor, anorexia, abdominal pain within first 24 h; liver damage apparent 12–48 h after ingestion.

Management: Immediate hospital referral. Gastric lavage/activated charcoal if within 1 h. Plasma paracetamol concentration should be measured. Antidote: **N-acetylcysteine (NAC)** should be administered as soon as possible.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics; anilide derivatives.
ATC code: N02BE01.

Paracetamol is an analgesic and antipyretic. Its mechanism involves inhibition of central prostaglandin synthesis.

5.2 Pharmacokinetic properties

- **Absorption:** Rapidly and almost completely absorbed from GI tract.
- **Distribution:** Peak plasma concentrations within 30–60 minutes.

- **Metabolism:** Primarily hepatic conjugation with glucuronic acid and sulphate; minor hydroxylation pathway producing NAPQI (detoxified by glutathione).
- **Elimination:** Half-life 1–4 hours in healthy subjects. Excreted in urine, mainly as conjugates.

5.3 Preclinical safety data

Conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential reveal no special hazard.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar

Glycerol

Strawberry Flavour

Xanthum Gum

Sorbitol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months unopened. Once opened: use within 3 months.

6.4 Special precautions for storage

Do not store above 25 °C. Keep bottle tightly closed.

6.5 Nature and contents of container

PET bottle with child-resistant closure and dosing syringe

6.6 Special precautions for disposal

No special requirements. Any unused medicinal product or waste should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Pharmalliance Consulting

3a, Olaide Benson Street, Maryland Ikeja

MANUFACTURER
Oak-Faith Pharm Resources Ltd., 21 Olufunmilayo Street Ketu, Lagos

8. MARKETING AUTHORISATION NUMBER(S)

A11-0803

9. DATE OF FIRST AUTHORISATION

November 2018

10. DATE OF REVISION OF THE TEXT

September 2025