Prescribing Information: PICOLAX®

Please consult the full Summary of Product Characteristics before prescribing. Name of Product: PICOLAX. **Composition:** Active ingredients: sodium picosulphate and magnesium citrate. Each sachet contains 10 mg sodium picosulphate, 3.5 g light magnesium oxide and 12 g citric acid. **Indication:** To clean the bowel prior to X-ray examination, endoscopy or surgery. **Dosage:** To be reconstituted in water. Please consult the full Summary of Product Characteristics for information about reconstitution and fluid intake. **Adults (including the elderly):** The two PICOLAX sachets are taken dependent on the planned time of the procedure: The first reconstituted sachet is taken 10 to 18 hours before the procedure, followed by at least five 250 ml drinks of clear liquids (not only water), spread over several hours. The second reconstituted sachet is taken 4 to 6 hours before the procedure, followed by at least three 250 ml drinks of clear liquids (not only water), spread over several hours. Clear liquids (not only water) may be consumed until 2 hours before the time of the procedure. **Children** (a measuring spoon for paediatric dosing is included in the pack): **1 - 2 years:** first dose is 1 spoonful, second dose is 1 spoonful. **2 - 4 years:** first dose is 2 spoonfuls, second dose is 2 spoonfuls. **4 - 9 years:** first dose is 1 sachet, second dose is 2 spoonfuls. **9 years and above:** adult dose. Maintaining hydration in children is very important. Guidelines for treating dehydration in children should be followed to ensure adequate hydration during treatment with PICOLAX. **Contraindications:** Hypersensitivity to any of the ingredients, congestive cardiac failure, gastric retention, gastro-intestinal ulceration, toxic colitis, toxic megacolon, ileus, nausea and vomiting, acute surgical abdominal conditions such as acute appendicitis and gastro-intestinal obstruction or perforation. In patients with severely reduced renal function, accumulation of magnesium in plasma may occur; another preparation should be used in such cases. **Special Warnings and Precautions:** Take care in patients with recent gastro-intestinal surgery, renal impairment, heart disease and inflammatory bowel disease. Use with caution in patients on drugs that might affect water and/or electrolyte balance. PICOLAX may modify the absorption of regularly prescribed oral medication. An inadequate oral intake of water and electrolytes could create clinically significant abnormalities, particularly in less fit patients; the elderly, debilitated individuals and patients at risk of hypokalaemia may need particular attention. Prompt corrective action should be taken to restore fluid/electrolyte balance in patients with signs or symptoms of hyponatraemia or hypokalaemia. The period of bowel cleansing should not exceed 24 hours because longer preparation may increase the risk of water and electrolyte imbalance. For an early time of the day procedure it may be required to take the second dose during the night and possible sleep disturbance may occur. **Side effects:** Please consult the full Summary of Product Characteristics for further information about side effects. *Common:* vomiting, nausea, abdominal pain and headache. *Uncommon:* anaphylactoid reaction, hypersensitivity, hypokalaemia, epilepsy, generalised tonic-clonic seizure, loss of or depressed level of consciousness, syncope, dizziness, confused state including disorientation, diarrhoea, rash (incl. erythematous and maculo-papular rash, urticaria, purpura). *Rare:* hyponatraemia, presyncope, ileal ulcers, anal incontinence, proctalgia. **Nature and Contents of Container:** Carton containing two sachets. A measuring spoon for paediatric dosing is included in the pack. **Marketing Authorisation Number:** 03194/0014. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, United Kingdom. **Legal Category:** POM. **Basic NHS Price:** £33.90 for 10 x 2 sachets. **Date of Preparation of Prescribing Information:** January 2025. PICOLAX is a registered trademark.

Adverse events should be reported.
Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.** Adverse events should also be reported to Ferring Pharmaceuticals Ltd.
Tel: 0844 931 0050. Email: **medical.uk@ferring.com**

January 2025
UK-PIC-2500001