PICOPREP®

Name of medicinal product: PICOPREP powder for oral solution

Qualitative and quantitative composition: Each sachet contains the following active ingredients:
Sodium picosulfate 10.0mg
Magnesium oxide, light 3.5g
Citric acid, anhydrous 12.0g

Pharmaceutical form: Powder for oral solution in sachet. White crystalline powder.

Clinical particulars
Therapeutic indications
To clean the bowel prior to X-ray examination or endoscopy.
To clean the bowel prior to surgery when judged clinically necessary.

Posology and method of administration
Route of administration: Oral
A low residue diet is recommended on the day prior to the hospital procedure. To avoid dehydration during treatment with PICOPREP it is recommended to drink approximately 250ml per hour, of water or other clear fluid while the washout effect persists.
Directions for reconstitution: Reconstitute the contents of one sachet in a cup of water (approximately 150ml). Stir for 2-3 minutes, the solution should now become an off-white, cloudy liquid with a faint odour of orange. Drink the solution. If it becomes hot, wait until it cools sufficiently to drink.
Adults (including the elderly): One sachet reconstituted in water as directed, taken before 8 am on the day before the procedure. Second sachet 6 to 8 hours later.
Children: 1 - 2 years: ¼ sachet morning, ¼ sachet afternoon
2 - 4 years: ½ sachet morning, ½ sachet afternoon
4 - 9 years: 1 sachet morning, ½ sachet afternoon
9 and above: adult dose

Contraindications
- Hypersensitivity to any of the ingredients of the product
- Congestive cardiac failure
- Gastric retention
- Gastro-intestinal ulceration
- Toxic colitis
- Toxic megacolon
- Ileus
- Nausea and vomiting
- Acute surgical abdominal conditions such as acute appendicitis
- Known or suspected gastro-intestinal obstruction or perforation.
- Severe dehydration
- Rhabdomyolysis
- Hypermagnesemia
- Active inflammatory bowel disease
- 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 special precautions for use
Because a clinically relevant benefit of bowel cleansing prior to elective, open colorectal surgery could not be proven, bowel cleansers should only be administered before bowel surgery if clearly needed. The risks of the treatment should be carefully weighed against possible benefits and needs depending on surgical procedures performed.
Recent gastro-intestinal surgery. Care should also be taken in patients with renal impairment, heart disease or inflammatory bowel disease.
Use with caution in patients on drugs that might affect water and/or electrolyte balance e.g. diuretics, corticosteroids, lithium.
PICOPREP may modify the absorption of regularly prescribed oral medication and should be used with caution e.g. there have been isolated reports of seizures in patients on antiepileptics, with previously controlled epilepsy.
An inadequate oral intake of water and electrolytes could create clinically significant deficiencies, particularly in less fit patients. In this regard children, 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. The period of bowel cleansing should not exceed 24 hours because longer preparation may increase the risk of water and electrolyte imbalance.
This medicine contains 5 mmol (or 195 mg) potassium per sachet. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.This medicine contains lactose as a component of the flavour. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
PICOPREP should not be used as a routine laxative.

Interaction with other medicinal products and other forms of interaction
As a purgative, PICOPREP increases the gastrointestinal transit rate. The absorption of other orally administered medicines (e.g. anti-epileptics, contraceptives, anti-diabetics, antibiotics) may therefore be modified during the treatment period.Tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, should be taken at least 2 hours before and not less than 6 hours after administration of PICOPREP to avoid chelation with magnesium.The efficacy of PICOPREP is lowered by bulk-forming laxatives. Care should be taken with patients already receiving drugs which may be associated with hypokalaemia (such as diuretics or corticosteroids, or drugs where hypokalaemia is a particular risk i.e. cardiac glycosides). Caution is also advised when PICOPREP is used in patients on NSAIDs or drugs known to induce SIADH e.g. tricyclic antidepressants, selective serotonin re-uptake inhibitors, antipsychotic drugs and carbamazepine as these drugs may increase the risk of water retention and/or electrolyte imbalance.

Pregnancy and lactation
For PICOPREP no clinical data on exposed pregnancy are available. Studies in animals have shown reproductive toxicity. As picosulfate is a stimulant laxative, for safety measure, it is preferable to avoid the use of PICOPREP during pregnancy.There is no experience with the use of PICOPREP in nursing mothers. However, due to the pharmacokinetic properties of the active ingredients, treatment with PICOPREP may be considered for females who are breastfeeding.

Effects on ability to drive and use machines: Not applicable.

Undesirable effects
Common ($\geq$1/100 to $\leq$1/10): Headache, Nausea and proctalgia.
Uncommon (($\geq$1/1000 to $\leq$1/100): Anaphylactic reaction, hypersensitivity, Hyponatraemia and hypokalaemia, Epilepsy, grand mal convulsion, confusional state, Vomiting, abdominal pain, aphthoid ileal ulcers ,Rash (including erythematous and maculo-papular rash, urticaria, purpura)
Not known (cannot be estimated from the available data): Diarrhoea (Isolated cases of severe diarrhoea have been reported post-marketing), faecal incontinence

Overdose: Overdosage would lead to profuse diarrhoea. Treatment is by general supportive measures and maintenance of fluid intake.

Pharmaceutical particulars
List of excipients
Potassium hydrogen carbonate
Sodium saccharin
Natural, spray dried orange flavour which contains acacia gum, lactose, ascorbic acid, butylated hydroxyanisole.

Incompatibilities: Not applicable

Shelf life: See outer carton

Special precautions for storage: Store below 30° C.

Manufacturer: Ferring Pharmaceutical (China) Co., Ltd., China
Marketing Authorization Holder: Ferring GmbH, Kiel; Germany

Revision date: July 2010

THIS IS A MEDICINE
- A MEDICINE IS A PRODUCT WHICH AFFECTS YOUR HEALTH. AND ITS CONSUMPTION CONTRARY TO INSTRUCTIONS IS DANGEROUS FOR YOU.
- STRICTLY FOLLOW THE DOCTOR'S PRESCRIPTION, THE METHOD OF USE AND THE INSTRUCTIONS OF THE PHARMACIST WHO SOLD THE MEDICINE.
- THE DOCTORS AND THE PHARMACISTS ARE EXPERTS IN MEDICINE, ITS BENEFITS AND RISKS.
- DO NOT BY YOURSELF INTERRUPT THE PERIOD OR TREATMENT PRESCRIBED FOR YOU.
- DO NOT REPEAT THE SAME PRESCRIPTION WITHOUT CONSULTING YOUR DOCTOR.
- KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

Council of Arab Health Ministers
Union of Arab Pharmacists

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