SEVPOS

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for Sevpos (Sevelamer Carbonate Tablets 400 mg and 800 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Sevelamer is a non-absorbed phosphate binding crosslinked polymer, free of metal and calcium. Sevelamer contains multiple amines separated by one carbon from the polymer backbone.

INDICATION: It is indicated for control of serum phosphorus in patient with chronic kidney disease on dialysis.

DOSAGE AND ADMINISTRATION: The recommended starting dose of sevelamer carbonate is 2.4 g or 4.8 g per day based on clinical needs and serum phosphorus level. Sevelamer carbonate must be taken three times per day with meals.

CONTRAINDICATION: It is contraindicated in patients having hypophosphataemia, bowel obstruction and hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Intestinal obstruction and ileus/subileus have been observed in patients during treatment with sevelamer hydrochloride. Serum vitamin A, D, E and K status should be assessed regularly in patients who are on sevelamer, folate deficiency may occur during long term sevelamer carbonate treatment. Metabolic acidosis, peritonitis, swallowing and choking difficulties and hypothyroidism have been reported in patients taking sevelamer.

DRUG INTERACTION: Sevelamer carbonate should not be taken simultaneously with ciprofloxacin. Also reduced levels of ciclosporin, mycophenolate mofetil and tacrolimus have been reported in transplant patients when co-administered with sevelamer hydrochloride. Hypothyroidism may occur with if taken with levothyroxine.

ADVERSE REACTIONS: Hypocalcaemia, hypercalcaemia, nausea, vomiting, constipation, diarrhoea, dyspepsia, flatulence, abdominal pain, Pruritus, rash, intestinal obstruction, ileus/subileus, and intestinal perforation.

MARKETED BY:

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IN/SEVPOS 400,800mg /Jun-15/01/AbPI (Additional information is available on request)