NeutraSal®
Powder for Supersaturated Calcium and Phosphate Rinse

Ingredients: (Active) Dibasic Sodium Phosphate, Monobasic Sodium Phosphate, Calcium Glycerophosphate, Sodium Chloride, Sodium Bicarbonate
(Inactive) Silicon dioxide

Pharmaceutical Form:
NeutraSal is a powder in a packet intended to be dissolved or dispersed in water (tap water, distilled or purified water) before administration to form a solution supersaturated with respect to both calcium and phosphate ions.

Actions:
NeutraSal, when dissolved or dispersed in water before use, forms an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity.

Indications for Use:
NeutraSal is indicated for dryness of the mouth (hyposalivation, xerostomia); NeutraSal is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion; NeutraSal may be used as part of an oral hygiene program for patients with dry mouth. NeutraSal also provides intensive hygiene of the oral cavity.

NeutraSal is also indicated as an adjunct to standard oral care in relieving the discomfort associated with oral mucositis that may be caused by radiation or high dose chemotherapy.

Relief of dryness of the oral mucosa in these conditions is associated with amelioration of pain.

NeutraSal may be used for relief of dryness of the oral mucosa when hyposalivation results from any of the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjögren's syndrome.

Special precautions for use: Avoid eating or drinking for at least 15 minutes after use.
NeutraSal should not be swallowed and the solution should be spit out. NeutraSal is not intended for systemic use to treat any diseases of the throat or upper gastrointestinal tract.

NeutraSal is not intended for use as an antacid. If NeutraSal is swallowed accidentally, no adverse effects are anticipated.

NeutraSal must be dissolved in water before being used. Do not use if the packet is opened or shows sign of leakage or damage.

Contains sodium. Patients restricted to a low sodium diet should consult their physician before use.

Store at room temperature, avoid excessive heat or moisture.

Directions for Use:
Dissolve or disperse one packet of NeutraSal in a clean glass of approximately 30 mL (1 ounce) of tap water. Distilled or purified water can also be used. Use immediately after the solution appears clear or nearly clear in the glass, or in about 15 seconds. Product can be stirred in water.

(1) Swish the solution in the mouth thoroughly for 1 minute with 1/2 of the solution and spit out.

(2) Repeat with the remaining 1/2 of the solution and spit out.

- **For use during high dose chemotherapy or radiation treatment:** 4 doses per day from the onset of the cancer treatment or as needed. Up to 10 doses per day may be used if pain from mucositis is experienced. Use for the duration of the treatment or as instructed by physician.
- **Relief of dry mouth:** 2-10 times per day or as instructed by physician or as needed.

KEEP OUT OF REACH OF CHILDREN.

Caution: Federal law restricts this device to sale by or on the order of a physician or dentist.

Interaction with Other Medicinal Products and Other Forms of Interaction
There are no known interactions with medicinal or other products.

Stop Use and Consult Your Doctor or Dentist if:
- An allergic reaction occurs. Seek medical help right away.
- Pregnant or breast feeding, ask a health professional before use.
- In case of overdose, get medical help immediately or contact a Poison Control Center right away.

How Supplied:
NeutraSal is supplied in individual packets.
UPC-A: 3-65976-10130-5 (30 per box)
1 dose = 1 packet

Manufactured for:
OraPharma, Inc.,
a subsidiary of Valeant Pharmaceuticals International,
Rochester, NY 14609 USA

US Patent Pending
Rev. 01/16 9519800