

Phospho-soda

**Sodium dihydrogen phosphate dihydrate /
Disodium phosphate dodecahydrate**

Oral saline laxative

COMPOSITION

Each dose (45 mL) contains:

Sodium dihydrogen phosphate dihydrate 24.4 g;

Disodium phosphate dodecahydrate 10.8 g

Also includes: Ethanol, sodium benzoate. Sodium content 5.0 g per each 45 mL dose.

MODE OF ACTION

Phospho-soda produces bowel actions which cleanse the bowel. Phospho-soda acts by osmotic process to increase fluid retention in the lumen of the small intestine. Fluid accumulation in the ileum produces distension and, in turn, promotes peristalsis and bowel evacuation. It usually work within 30 minutes, although it may take as long as six hours.

INDICATIONS

Phospho-soda is used as part of a bowel cleansing procedure before X-ray of the bowel, colonoscopy (looking into the bowel with an instrument) or before a bowel operation.

CONTRAINDICATIONS

Phospho-soda is contraindicated:

- In children under 15 years (particularly at risk of dehydration).
- Patient with faecal impaction, paralytic ileus, bowel obstruction, hypomotility, Hirschsprung's disease (congenital megacolon), imperforate anus, congestive heart failure, ascites conditions, renal insufficiency and impaired renal function and pre-existing potential fluid/electrolyte disturbance.
- Patients at risk of dehydration due to altered senses and/or poor fluid intake.
- Patients with known or suspected gastrointestinal obstruction or lack of motility.
- Patients with known active inflammatory bowel disease.
- Patients when nausea, vomiting or abdominal pain are present.
- Patients with known hypersensitivity to active ingredients or any of the excipient.

WARNING

Serious electrolyte disturbances (hypernatremia, hypokalemia, hyperphosphatemia, hypocalcemia) dehydration, metabolic acidosis, renal failure, tetany and death have been attributed to physicians prescribing more than 45 ml dose (usually a minimum of 90 ml during a 24-hour period) as a bowel preparation for colonoscopy, surgery or barium enema and/or prescribing it for people at medical risk.

PRECAUTIONS

Phospho-soda should be used with extreme caution in the elderly, in frail or debilitated patients, and patients with a colostomy or patients on a low salt diet, as they are particularly at risk.

These patients should receive additional fluids by mouth both prior to and after administration of Phospho-soda to ensure that dehydration does not occur.

Close attention should be paid to their hydration status, and their electrolyte levels (particularly potassium, calcium and phosphorus) should be monitored.

Patients undergoing major bowel procedures, who are on nil by mouth for significant periods of time, should have their electrolyte monitored and receives intravena fluids containing potassium and calcium prior to surgery.

Use with cautions in patients taking diuretics.

Concurrent administration of polyethylene glycol bowel cleansing preparations and Phospho-soda may be dangerous and is not recommended.

Extra time should be taken to explain dosage instructions to elderly patients and those patients who may be at risk.

Patients should be advised not to use Phospho-soda when nausea, vomiting, abdominal pain are present unless directed by a doctor.

Diabetes.

As the liquid diet during the period of administration and prior to bowel surgery, X-ray of the colon or colonoscopy may affect the blood glucose levels of diabetic patients, adjustment of their insulin or oral antidiabetic medication may be necessary.

Use with caution in patients with impaired renal function (avoid if severe), heart disease, acute myocardial infarction, unstable angina, pre-existing electrolyte disturbances, or with patients who are taking medications known to prolong QT interval, ulcerative colitis, diabetes mellitus, reflux oesophagitis, impaired gag reflex, unconscious or semi conscious or possibility of regurgitation or aspiration.

INTERACTIONS

Use with caution in patients taking calcium channel blockers, diuretics, lithium treatment or other medications that might affect electrolyte levels as hyper-phosphataemia, hypocalcaemia, hypokalaemia, hypernatraemic dehydration and acidosis may occur.

During the intake of Phospho-soda the absorption of drugs from the gastrointestinal tract may be delayed or even completely prevented.

The efficacy of regularly taken oral drugs, such as oral contraceptives, anti-epileptic drugs, antidiabetics, or antibiotics may be reduced or completely absent. Concurrent administration of polyethylene glycol bowel cleansing preparations and Phospho-soda may be dangerous and is not recommended.

DOSAGE

On the day before, drink only clear liquids for breakfast, lunch and dinner and between times.

Clear liquids consist of the following:

- Water
- Strained fruit juices without pulp or seeds (apple, white grapes, orange)
- Clear broth
- Coffee or tea (without milk or non-dairy whitener)
- All of the following that are not coloured red or purple
- Carbonated or non carbonated soft drinks
- Fruit flavoured cordials
- Clear ice blocks

Do not eat or drink solid foods, milk or milk products.

On the day before a bowel operation, X-ray of the bowel or colonoscopy, Phospho-soda will be taken in two doses.

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RECOMMENDED DOSAGE

Adults only: Not to be given to children under the age of 15 years.

Elderly patients: As for adults.

The taking of Phospho-soda should be started the day before hospital appointment.

If the hospital appointment is before 12 noon the dosage instruction for a MORNING APPOINTMENT should be followed and for appointment after 12 noon the dosage instructions for AFTERNOON APPOINTMENT should be followed.

MORNING APPOINTMENT 8.00 AM - 12 NOON	AFTERNOON APPOINTMENT 12 NOON - 5 PM
<p>DAY BEFORE APPOINTMENT</p> <p>7 am - In place of breakfast, drink at least one full glass of "clear liquid" or water, more if desired.</p> <p>1st dose-straight after breakfast.</p> <p>Dilute the contents of one bottle (45 ml) in half a glass (120 ml) cold water.</p> <p>Drink this solution followed by one full glass (240 ml) of cold water, more if desired.</p> <p>1 pm lunch - in place of lunch, drink at least three full glasses (720 ml) of "clear liquid" or water, more if desired.</p> <p>7 pm - In place of supper, drink at least one full glass of "clear liquid" or water, more if desired.</p> <p>2nd dose-straight after supper.</p> <p>Dilute the contents of the second bottle (45 ml) in half a glass (120 ml) cold water.</p> <p>Drink this solution followed by one full glass (240 ml) of cold water, more if desired.</p> <p>Additional water or "clear liquids" may be taken up until midnight if necessary.</p>	<p>THE DAY BEFORE APPOINTMENT</p> <p>1 pm lunch - A light snack may be taken. After lunch no more solid food must be taken until after the hospital appointment.</p> <p>7 pm supper - In place of supper, drink at least one full glass of "clear liquid" or water more if desired.</p> <p>1st dose-straight after supper.</p> <p>Dilute the contents of one bottle (45 ml) in half a glass (120 ml) cold water.</p> <p>Drink this solution followed by one full glass (240 ml) of cold water, more if desired.</p> <p>During the evening drink at least three full glasses of water or "clear liquid" before going to bed.</p> <p>DAY OF YOUR APPOINTMENT</p> <p>7 am breakfast, In place of breakfast, drink at least one full glass of "clear liquid" or water, more if desired.</p> <p>2nd dose-straight after breakfast.</p> <p>Dilute the contents of the second bottle (45 ml) in half a glass (120 ml) cold water.</p> <p>Drink this solution followed by one full glass (240 ml) of cold water. More water or "clear liquid" may be taken up until 8 am.</p>

The product normally produces a bowel movement in 1/2 to 6 hours.

OVERDOSAGE

If serious side effects occur, although these are rare, you must contact the physician for the treatment.

Overdosage or retention may lead to severe electrolyte disturbance, including hyperphosphatemia, hypernatremia, hypocalcemia and hypokalemia as well as dehydration and hypovolemia with attendant signs and symptoms of these disturbances (such as metabolic acidosis, renal failure and tetany). Certain severe electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement.

There have been fatal cases of hyperphosphatemia with concomitant hypocalcemia, hypernatremia, and acidosis when Phospho-soda has been used in excessive doses, given to children or to obstruct patients.

There are also documented cases of complete recovery from overdoses in both children accidentally given Phospho-soda, and also in patients with obstruction, one of whom received a six fold overdose.

Recovery from the toxic effect of excess ingestion can normally be achieved by rehydration, though the intravenous administration of 10 % calcium gluconate may be necessary.

PREGNANCY AND LACTATION

There is no reliable data on teratogenesis in animals.

Due to there being no relevant data available to evaluate a potential malformative or foetotoxic effect when administered during pregnancy, this product should not be used during pregnancy.

Because of potential harm to the infant from phosphate excreted in breast milk, the use of this product is not recommended in breastfeeding mothers unless the probable clinical benefit outweighs the possible risk.

EFFECT ON DRIVING

Phospho-soda will not affect the ability to drive or operate machinery. However better to stay close to toilet until the purgative effect is complete.

SIDE EFFECTS

Dehydration and/or electrolyte disturbance, including hyperphosphatemia, hypocalcemia, hypokalemia, hypernatremia and acidosis, may occur in some at risk patients.

The most common adverse event reported post marketing have been nausea, vomiting, abdominal pain, bloating and diarrhoea, asthenia, chills, headache, dizziness, allergic reaction with / without rash, fatigue, and gastrointestinal cramping.

Very rarely, single or multiple aphthoid-like punctiform lesions located in the rectosigmoid region have been observed by endoscopy.

The abnormalities are not clinically significant and disappear spontaneously without any treatment.

STORAGE

Do not store above 30°C

Keep it out of sight and reach of children.

Do not use Phospho-soda after the expiry date (Exp) printed on the label.

PACKAGE

Box, Bottle @ 45 mL Reg. No. DKI1848700135A1

**ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER**

Manufactured by:

CASEN RECORDATI, S.L.

Zaragoza, Spain

Imported by:

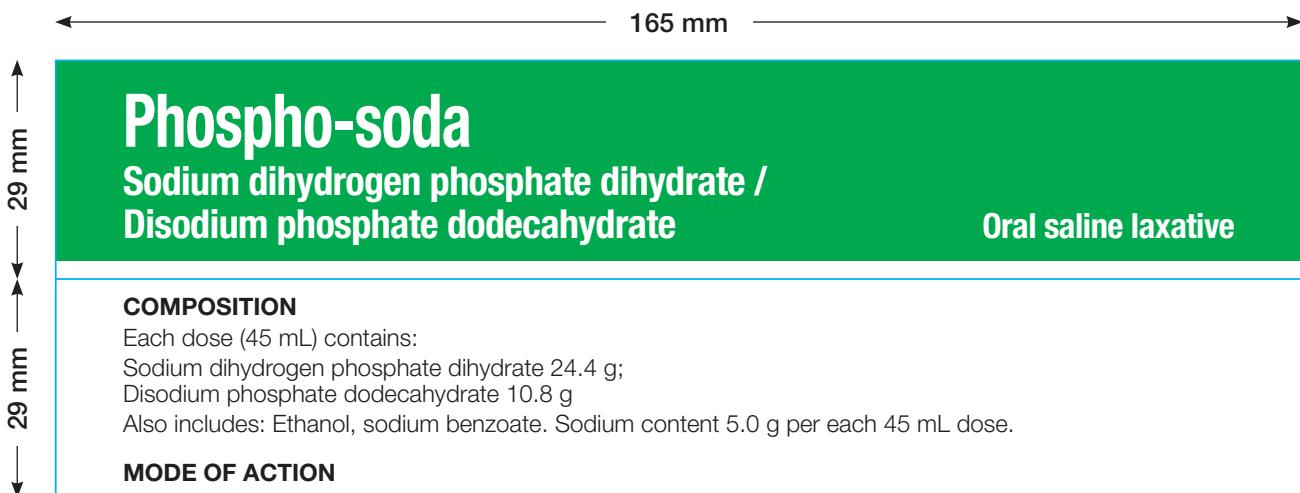
PT. COMBIPHAR

Bandung Barat, Indonesia

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 RECORDATI MATERIAL / MATERIAL Prospecto / Leaflet	Phospho-soda Oral saline laxative	NOMBRE DEL PROYECTO / PROJECT NAME RA_PS_ID_001	PAÍS / COUNTRY Indonesia / Indonesia
		NÚMERO DE PRUEBA / PROOF NUMBER 1	FECHA / DATE 26 / 07 / 2021
COLORES / COLOURS	 Negro  Pantone 355 C	CÓDIGO / CODE 90933997	SUSTITUYEA / REPLACE TO 90932601
TIPOGRAFÍAS / FONTS	Helvetica Neue	CÓDIGO LAETUS / LAETUS CODE	ESCALA / SCALE 1.1
TAMAÑO MÍNIMO / FONT MINIMUM SIZE 9 pt	INTERLINEADO / LEADING (LINE SPACING) 9,75 pt	PLANO PLEGADO / FOLDED PLANE CAS-4	ACABADO / FINISHED 1 tríptico con falsoe + 2 pliegues centrales paralelos al texto
TIPO DE PAPEL / PAPER TYPE Offset blanco	GRAMAJE / GRAMMAGE 40 (±4 %)	DIMENSIONES / SIZE 165 x 345 mm (±1 mm)	DIMENSIONES PLEGADO / FOLDED SIZE 165 x 29 mm (±1 mm)

ÁREA VISIBLE DEL PLEGADO



PLANO PLEGADO RECORDATI

PLANO: CAS-4

Tamaño: **165 x 345 mm** / Tamaño final de plegado: **165 x 29 mm**

