

## Package leaflet: Information for the patient

### **SODIO FOSFATO SELLA 16%/6% soluzione rettale**

Sodium phosphate monobasic dihydrate and sodium phosphate dibasic dodecahydrate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after a short period of treatment.

#### **What is in this leaflet**

1. What Sodio fosfato Sella is and what it is used for
2. What you need to know before you take Sodio fosfato Sella
3. How to take Sodio fosfato Sella
4. Possible side effects
5. How to store Sodio fosfato Sella
6. Contents of the pack and other information

#### **1. What SODIO FOSFATO SELLA is and what it is used for**

Sodio fosfato Sella contains the active substances sodium phosphate monobasic dihydrate and sodium phosphate dibasic dodecahydrate, that belong to the category of laxatives, used to softening and lubricate the faeces, easing the transit in the bowel and the evacuation. This medicine is used for treatment of constipation and to empty the bowel in preparation of surgery and some clinical exams, as radiological and endoscopic exams.

Talk to a doctor if you do not feel better or if you feel worse after a short period of treatment.

#### **2. What you need to know before you take SODIO FOSFATO SELLA**

##### **Do not take SODIO FOSFATO SELLA:**

- if you are allergic to sodium phosphate monobasic dihydrate, sodium phosphate dibasic dodecahydrate or any of the other ingredients of this medicine (listed in section 6);
- if you suffer acute pain in the abdomen or in some other part of the body (of unknown origin);
- if you suffer of nausea or vomit;
- if you suffer of obstruction or constriction (stenosis) of the intestine;
- if you suffer of partial obstruction of the intestine;
- if you suffer of some intestinal disease as mechanical ileus, paralytic ileus, intestinal inflammatory disorders and other conditions that may increase the absorption of the medicine;
- if you suffer of anal perforation, congenital or acquired megacolon, Hirschsprung's disease;
- if you have rectal bleeding, pain or haemorrhoids;
- if you are in a severe state of dehydration;
- if the patient is a child less than 12 years old;
- if you have some heart or kidney disease;
- if you have an increased level of phosphates in blood (hyperphosphatemia).
- if you are using other preparations containing sodium phosphates, among which oral solutions and tablets (see paragraph "Other medicines and SODIO FOSFATO SELLA")

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking SODIO FOSFATO SELLA.

During treatment with SODIO FOSFATO SELLA, it is advisable drinking much water, which helps to prevent the dehydration, particularly if there are conditions that could predispose the dehydration itself or if you are assuming medicinal products like diuretics, ACE inhibitors, sartans or nonsteroidal anti-inflammatory drugs.

If you use laxatives too much, too often or in a wrong way you could suffer of persistent diarrhoea with consequential loss of water, mineral salts (especially potassium) and other essential nutrient factors. In more serious cases an excessive loss of water (dehydration) or a lowering of potassium level in blood (hypokalemia)

may occur, which can cause cardiac or neuromuscular dysfunction, especially in the case of concurrent treatment with cardiac glycosides, diuretics or corticosteroids.

SODIO FOSFATO SELLA contains sodium phosphates, hence there is the risk of high levels of sodium and phosphates and low levels of calcium and potassium in blood (hypernatremia, hyperphosphatemia, hypocalcemia and hypokalemia), which can lead to tetany and renal insufficiency.

An excessive or wrong use of this medicine can cause dependency (the need of progressive increase the dosage), chronic constipation and loss of normal bowel functions (intestinal atony).

Avoid a prolonged use of this medicine. If you suffer of constipation for more than 2 weeks, if you notice a modification of your usual evacuation habits or to the characteristics of the faeces or if you do not feel better after the use of this medicine consult your doctor.

If you are aged and/or you are not in good health, especially if you suffer of uncontrolled arterial hypertension, ascites, cardiac diseases or change in rectal mucous membrane, like ulcer or fissures, use this medicine with caution and only after you have informed your doctor.

In case of constipation first of all correct your eating habits and integrate the daily diet with an adequate intake of fiber and water and make some physical activity. In many cases, an equilibrated diet rich in water and fiber (bran, fruit and vegetables) can resolve the problem of constipation. Many people think they suffer from constipation if they are unable to evacuate every day. This is wrong because this situation is perfectly normal for a large number of individuals. Consider, instead, that the constipation occurs when the evacuations are reduced when compared to the routine personal habits and are associated with the excretion of hard faeces. If you repeatedly suffer from episodes of constipation, please consult your doctor.

If during the administration of SODIO FOSFATO SELLA you notice resistance, stop the treatment immediately: a forced administration could lead to wounds.

### **Children**

This product has not to be used on children under the age of 12.

### **Elderly**

If you are aged consult your doctor before to use this medicine.

### **Other medicines and SODIO FOSFATO SELLA**

Inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This medicine is few absorbed in the bowel, so interacts poorly with other medicines.

Use this medicine with caution if you are assuming the following medicines:

- medicines that could modify the level of salts in the organism, as diuretics, calcium antagonists, lithium and corticosteroids, because the level of phosphates, calcium and sodium in the blood could be increased (hyperphosphatemia, hypercalcemia and hypernatremia);
- medicinal products that could modify some heart parameters (e.g. QT interval) as sodium phosphate could increase their toxicity;
- medicinal products based on lithium because the simultaneous use of SODIO FOSFATO SELLA and lithium can cause a reduction of lithium blood level, with a reduction of efficacy;
- medicines containing calcium, that could increase the risk of accumulation of calcium (ectopic calcification);
- preparations containing sodium phosphates, among which oral solutions and tablets (see paragraph 2. What you need to know before you take SODIO FOSFATO SELLA).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or breast-feeding, take this medicine only if necessary and under direct medical control.

### **Driving and using machines**

SODIO FOSFATO SELLA does not alter the capability of driving or using machinery. Nevertheless, it is possible that during the treatment some side effect arises. For this reason it is advisable to know the reaction to the product before driving or using machinery.

### **SODIO FOSFATO SELLA contains methyl parahydroxybenzoate and propyl parahydroxybenzoate**

Methyl parahydroxybenzoate and propyl parahydroxybenzoate could cause allergic reactions (also delayed).

## **3. How to take SODIO FOSFATO SELLA**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Consult your doctor or pharmacist if you are not sure.

The correct dose is the lowest one sufficient to produce an easy evacuation. It is recommended to initially use the minimum dose expected to produce an evacuation.

### **Use in adults and adolescents more than 12 years old**

Recommended dose is one 120 ml bottle per day. Do not use more than recommended dose. Each bottle is to be used for a single administration, any drug residue should be discarded. Use this product at room temperature, if you prefer it be lukewarm put the closed bottle in warm water. It is advisable to assume the product laying on the left side of the body.

To obtain a better effect follow this instructions for use:

1. Remove the cap from the tube.
2. Hold the bottle, lubricate the tube with a few drops of solution and, lay down on your side and gently insert the tube into the rectum, then squeeze the bottle thoroughly until all the solution has passed out the bottle. It is expected that some residual liquid is left in the bottle.
3. After administration has been completed, remove the cannula by holding the bottle.
4. Remain lying down for a few minutes, possibly on the stomach or with your knees near to the chest, before getting seated (genupectoral position). Go to the toilet as soon as you feel the urge to evacuate, which usually occurs within 5 minutes. In any case it is not necessary to hold the solution for more than 10-15 minutes.

### **If you take more SODIO FOSFATO SELLA than you should**

If you use an excessive dose of this medicine, could occur:

- stomach and bowel irritation, abdominal pain, nausea, vomit and diarrhoea with following loss of water, mineral salts (mainly potassium), nutritive substances. In this case drink much water to replace the losses;
- increase of thirst, weakness, accumulation of liquid in some areas (edema), bones pain (osteomalacia) and lowering of level of albumin in blood (hypoalbuminemia);
- serious dehydration and lowering of potassium level in the blood (hypokalemia) with following dysfunction of heart, nerves and muscles, mainly if you are assuming medicines for the stimulation of cardiac functionality (cardiac glycosides), to increase urine production (diuretics) or corticosteroids
- increase of phosphates (hyperphosphatemia) or lowering of calcium (hypocalcemia) in blood, with following uncontrolled contractions of muscles (tetany), convulsions and heart dysfunctions like bradycardia, QT prolongation, arrhythmias, coma and cardiac arrest;
- increase of sodium levels (hypernatremia) and lowering of magnesium level (hypomagnesemia) in blood;
- lowering of blood pressure (hypotension), acceleration of pulse (tachycardia) and increase of organism acidity (metabolic acidosis).

See also paragraph 2 "Warnings and precautions" for what laxatives abuse is concerned.

If you are aged, children or you suffer of renal insufficiency this symptoms are more likely.

In case of accidentally ingestion or overdose of Sodium phosphate Sella tell your doctor immediately or contact your nearest hospital.

If you have some doubts on the use of this medicine ask to your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

**Not known** (frequency could not be defined from available data)

- hypersensitivity reactions (for example hives);
- vesicles, hitch, burning;
- crampiform pain or abdominal colic;
- diarrhoea, with loss of fluids and electrolytes, more frequent in case of severe constipation;
- irritation of lower tract of bowel (rectal irritation);
- nausea, vomit;
- increase of phosphates or sodium level in blood (hyperphosphatemia, hypernatremia);
- decrease of calcium or potassium level in blood (hypocalcemia, hypokalemia);
- accumulation of calcium in some internal area of the body (calcification).

Respect of instructions provided with this leaflet decrease the risk of side effects.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system at the website: <http://agenziafarmaco.gov.it/responsabili>. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store SODIO FOSFATO SELLA**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after "Scade/Expiry".

Expiry date refers to the last days of the month.

Expiry date refers to the medicine in its integrity and correctly stored package.

Store this medicine in its original container to protect it from light.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What SODIO FOSFATO SELLA contains**

Active substances are sodium phosphate monobasic dihydrate and sodium phosphate dibasic dodecahydrate. 100 ml of product contain 18.08 g of sodium phosphate monobasic dihydrate (corresponding to 16 g of sodium phosphate monobasic monohydrate) and 8.03 g of sodium phosphate dibasic dodecahydrate (corresponding to 6 g of sodium phosphate dibasic heptahydrate)

The other ingredients are: methyl parahydroxybenzoate, propyl parahydroxybenzoate and purified water.

### **What SODIO FOSFATO SELLA looks like and contents of the pack**

Package with 1, 4 or 20 bottles.

### **Marketing Authorisation Holder and manufacturer**

Laboratorio Chimico Farmaceutico A.Sella srl

via Vicenza 67 – 36015 Schio (VI)

### **Last revision of the Package leaflet**

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