SUMMARY OF PRODUCT CHARACTERISTICS

1) NAME OF THE MEDICINAL PRODUCT

COLOKIT, tablet

2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium phosphate monobasic monohydrate ..... 1102 mg
Disodium phosphate anhydrous ..... 398 mg
for one tablet.

For a full list of excipients, see section 6.1.

3) PHARMACEUTICAL FORM

Tablet.
White to off-white oval compressed tablet, marked “SLX” and “102”.

4) CLINICAL PARTICULARS

4.1 Therapeutic indications

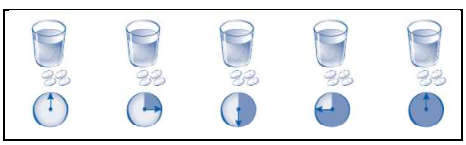
This medicine is indicated for colonic cleansing to ensure the preparation of patients prior to colonic surgery or colon endoscopic or radiological diagnostic procedures.

4.2 Posology and method of administration

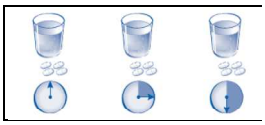
FOR ADULTS ONLY.
Do not administer to children under 18 years of age.
In the elderly, the dosage is identical to that of adults.
The usual adult dosage of COLOKIT is 32 tablets. The total dose of phosphate is 32.79 g.
The intake of COLOKIT tablets should begin the day before the colonoscopy. The day before the colonoscopy, patients may have a light, low-fibre breakfast (coffee or tea with or without sugar, toast, butter or equivalent, fruit jelly or honey). After noon, taking only "clear liquids" is permitted. "Clear liquid" may be water, light soup, diluted fruit juice without pulp, weak tea or black coffee, light soda with or without bicarbonate.

COLOKIT tablets should be administered in the following manner:

Recommended administration regimen:
The evening before the colonoscopy:
• Take 4 tablets with 250 ml of water (or another clear liquid),
• Then repeat 4 times in the same conditions, every 15 minutes, for a total of 20 tablets to swallow.



The day of the colonoscopy (starting 4-5 hours before the procedure):
• Take 4 tablets with 250 ml of water (or another clear liquid),
• Then repeat 2 times in the same conditions, every 15 minutes, for a total of 12 tablets to swallow.

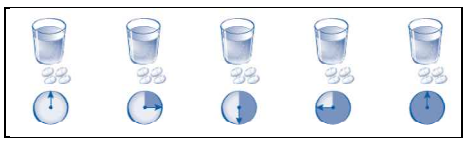


Alternative administration regimen in case of morning colonoscopy:
For early morning colonoscopy, it is possible to adapt the dosing schedule by taking all the tablets in the evening before the procedure, and with an interval of at least 4 hours between the beginning of the intake of the first 20 tablets (to be absorbed at the rate of 4 tablets with 250 ml of water or another clear liquid every 15 minutes) and the intake of the last 12 tablets (to be absorbed at the rate of 4 tablets with 250 ml of water or another clear liquid every 15 minutes).

Example of regimen:

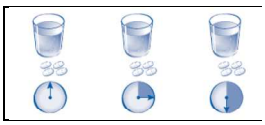
At 18.00:

• Take 4 tablets with 250 ml of water (or another clear liquid),
• Then repeat 4 times in the same conditions, every 15 minutes, for a total of 20 tablets to swallow.



At 22.00:

• Take 4 tablets with 250 ml of water (or another clear liquid),
• Then repeat 2 times in the same conditions, every 15 minutes, for a total of 12 tablets to swallow.



Patients should be advised of the importance of following rigorously the recommended fluid regimen and of drinking as much liquid as possible to replace lost fluids by increased intestinal peristalsis.
Drinking large amounts of clear liquid also helps ensure the cleanliness of the colon during colonoscopy.
Using COLOKIT tablets should not be repeated until at least 7 days.
No additional laxative treatment (especially those containing sodium phosphate) must be taken simultaneously.

4.3 Contraindications

Do not use:

- In children under 18 years,
- in patients over 75 years of age,
- in case of nausea, vomiting or abdominal pain,
- in case of hypersensitivity to the active substances or to any of the excipients, in particular macrogol.

Do not use in patients suffering from:

- clinically significant renal insufficiency,
- primary hyperparathyroidism associated with hypercalcemia,
- congestive heart failure,
- ascite,
- known or suspected occlusion,
- megacolon (congenital or acquired),
- perforation,
- ileus,
- active inflammatory disease of the bowel.

COLOKIT must not be used with other laxatives containing sodium phosphate.

4.4 Special warnings and precautions for use

In rare cases, COLOKIT was associated with severe and potentially fatal electrolyte disorders, in elderly patients. **So, the benefit/risk ratio of COLOKIT must be carefully assessed before use in this population at risk.**

Before initiating the treatment, it is necessary to ensure the absence of known contraindications and to stress on the importance of appropriate hydration. For at risk populations, it is important to check serum electrolyte concentrations before and after treatment (see below and section 4.2 and 4.3).

COLOKIT should be used with caution in patients with increased risk of underlying renal insufficiency, showing preexisting electrolyte disorders or with risk factor for electrolyte disorders (e.g., dehydration, gastric retention, colitis, inability to drink sufficient quantities of liquids, hypertension or other diseases treated by medicines that can induce dehydration, see below), hypotension with clinical consequences or associated with hypovolemia, heart disease, acute myocardial infarction, unstable angina or in the elderly or weakened patients. In these patients at risk serum electrolyte including sodium, potassium, calcium, chloride, bicarbonate, phosphate, urea and creatinine assessment should be performed before and after treatment.

Serum sodium and phosphate may increase and serum calcium and potassium may decrease, therefore, hypernatraemia, hyperphosphataemia, hypocalcaemia, hypokalaemia and acidosis may occur.

COLOKIT should be used with caution in patients with intestinal hypomotility, history of gastrointestinal surgery or who have other diseases predisposing to intestinal hypomotility. In patient with colostomy or ileostomy or being on a low salt diet, the medicine must be used with caution because dehydration, electrolytes or acid-base imbalance may occur.

Patients should be advised that they will have frequent and watery stools. They should be encouraged to drink as much liquid as possible to prevent dehydration. Dehydration and hypovolemia due to laxatives may be exacerbated by an insufficient intake of drinks, by vomiting, loss of appetite or the use of diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs) and nonsteroidal anti-inflammatory drugs (NSAIDs). In rare cases, dehydration and hypovolemia may be associated with acute renal failure with either sodium phosphate or PEG-3350.

Very rare cases of nephrocalcinosis associated with transient renal failure have been reported in patients using sodium phosphates for bowel preparation. The majority of cases occurred in elderly women taking anti-hypertensive agents and other drugs such as diuretics or NSAIDs which can cause dehydration. Patient hydration should first be assessed by identifying those who are predisposed to dehydration or those taking drugs that may decrease the glomerular filtration rate, such as angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), before using laxative preparations. Patients should be monitored appropriately. When prescribing COLOKIT, special attention must be paid to the contraindications and adequate hydration of the patient.

This medicine usually acts ½ hour to 6 hours after dosing. When there is no bowel movement increase within 6 hours after taking COLOKIT, the patient should be aware of the necessity to discontinue the drug and contact a doctor immediately because there is a risk of dehydration.
Single or multiple aphtous ulcerations, located in the sigmoid or rectum were observed by endoscopy. They consist in either lymphoid follicle or discrete inflammatory infiltrates or epithelial anomalies observed following the use of the bowel preparation. These anomalies have no clinical relevance and disappear upon discontinuation of treatment.

A slight prolongation of the QT interval may rarely occur because of electrolyte imbalance such as hypocalcaemia or hypokalaemia. These changes have no clinical relevance.

This medicine should not be used as a treatment for constipation.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be taken in patients taking calcium channel blockers, diuretics, lithium treatment or other medicines that might affect serum electrolyte concentrations and cause hyperphosphataemia, hypocalcaemia, hypokalemia, hypernatraemic dehydration or acidosis.

During COLOKIT ingestion, absorption of products in the gastro-intestinal tract may be delayed or even completely inhibited. The efficacy of usually orally administered medicines (e.g. oral contraceptives, antiepileptic drugs, antidiabetics, antibiotics) may be partially or completely reduced. Attention must also be given while taking drugs known to prolong the QT interval.

COLOKIT should be used with caution in patients taking drugs containing parathyroid hormone.

4.6 Pregnancy and lactation

No clinical data on exposed pregnancies are available or even data from animal studies on the embryonic/ fetal development, childbirth and postnatal development. The potential risk for humans is unknown. COLOKIT should not be used during pregnancy unless clearly necessary.

Not knowing if COLOKIT is excreted in breast milk and also if the sodium phosphate may pass into breast milk, it is advisable to draw the milk and not to use as soon after the first intake of COLOKIT up to 24 hours after taking the second dose. Therefore, women should not breastfeed their babies within 24 hours after taking the second dose of COLOKIT.

4.7 Effects on ability to drive and use machines

COLOKIT may cause dizziness, probably due to dehydration, and this may have a minor or moderate influence on the ability to drive and use machines.

4.8 Undesirable effects

The side effects listed below have been reported at frequencies corresponding to: very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100), rare (≥ 1/10,000 to <1/1,000), very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Immune system disorders
Very rare:
Hypersensitivity: urticaria, angioedema, anaphylactic shock.

Metabolism and nutrition disorders
Uncommon:
Dehydration

Very rare:
Hyperphosphataemia,
Hypocalcaemia,
Hypokalaemia,
Hypernatraemia,
Metabolic acidosis,
Tetany.

Not known:
Hyponatremia possibly complicated with neurological disorders of confusion or convulsions type.

Nervous system disorders:
Very common:
Dizziness.

Common:
Headache.

Very rare:
Loss of consciousness,
Paresthesia.

Cardiac disorders:
Very rare:
Myocardial infarction,
Arrhythmias.

Vascular disorders:
Very rare:
Hypotension.

Gastrointestinal disorders:
Very common:
Diarrhea,
Abdominal pain,
Abdominal distension,
Nausea.

Common:
Vomiting
Abnormal colonoscopy (single or multiple aphthous like ulcerations located in the sigmoid and rectum without clinical relevance and disappearing spontaneously without treatment).

Not known:
Gastritis, gastric ulcerations.

Skin and subcutaneous tissue disorders:
Very rare:
Allergic dermatitis.

Musculoskeletal and connective tissue disorders:
Very rare:
Muscle cramps.

Renal and urinary disorders:
Very rare:
Acute renal failure
Chronic renal failure
Nephrocalcinosis.

General disorders and administration site conditions:
Very common:
Chills
Asthenia

Common:
Chest pain.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (Ansm) and réseau des Centres Régionaux de Pharmacovigilance. Website: www.ansm.sante.fr.

4.9 Overdose

When taking excessive doses of COLOKIT, fatal cases of hyperphosphataemia with concomitant hypocalcaemia, hypernatraemia and acidosis have been reported in children or patients with bowel obstruction.

In case of overdose, patients experience the following symptoms: dehydration, hypotension, tachycardia, bradycardia, tachypnea, cardiac arrest, shock, respiratory failure, dyspnea, convulsions, paralytic ileus, anxiety, pain. Overdoses can lead to high sodium and phosphate serum concentrations and to a decrease in calcium and potassium concentrations. In such cases, hypernatraemia, hyperphosphataemia, hypocalcaemia, hypokalaemia and acidosis may occur.

Cases of complete recovery after overdose have also been documented both in children after accidental ingestion of COLOKIT and in patients with bowel obstruction, one having taken six times the recommended dose.

Treatment of overdose usually consists in rehydration; the administration of intravenous 10% calcium gluconate may be needed.

5) PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OSMOTICALLY ACTING LAXATIVE

ATC code: A06AD

COLOKIT is a saline laxative that acts by an osmotic process by increasing fluid retention in the lumen of the small intestine. The fluid accumulation in ileum produces distention and thus facilitates peristalsis and bowel evacuation.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No animal studies on the reproductive toxicity have been performed with COLOKIT.

6) PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 8000, magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

High-density polyethylene (HDPE) bottles with child-resistant polypropylene cap, containing two silica gel desiccant bags.

Bottle contains 32 tablets.

6.6 Special precautions for disposal

No special requirements.

7) MARKETING AUTHORISATION HOLDER

LABORATOIRES MAYOLY SPINDLER
6 AVENUE DE L'EUROPE
78400 CHATOU
FRANCE

8) MARKETING AUTHORISATION NUMBER(S)

34009 347 188 1 6: 32 tablets in bottle (HDPE) with cap (polypropylene).

9) DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 March 2010
Date of renewal of the authorisation: in progress.

10) DATE OF REVISION OF THE TEXT

April 2014.

11) DOSIMETRY

Not applicable.

12) INSTRUCTIONS FOR RADIOPHARMACEUTICS PREPARATION

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

List I.