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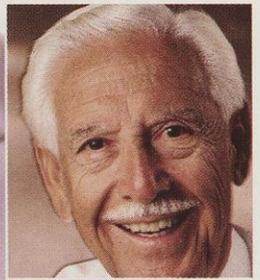
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INTRODUCING  
COLONOSCOPY  
THAT BENEFITS YOUR

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TABLET



# AN EVOLUTION IN PREPARATION PATIENTS AND YOU

## New VISICOL™

(sodium phosphate monobasic monohydrate, USP,  
sodium phosphate dibasic anhydrous, USP)

### TABLETS

## The tablet evolution

- ~ **Highly effective colon cleansing.** 84% of VISICOL™ patients were rated good to excellent for colon cleansing vs. 76% for the leading liquid purgative. ( $p=ns$ )
- ~ **Well tolerated.** Less than 1% of patients reported a problem tolerating VISICOL™ Tablets due to taste.<sup>1</sup>
- ~ **High patient acceptance.** Greater than 92% of patients completed the VISICOL™ dosing regimen based on tablet count.<sup>1</sup>

**Patients with electrolyte abnormalities such as hypernatremia, hyperphosphatemia, hypokalemia, or hypocalcemia should have them corrected before receiving Visicol™ Tablets. Visicol™ Tablets should be used with caution in patients with impaired renal function, pre-existing electrolyte disturbances, or in people taking drugs that may affect electrolyte levels. Overdose or use of over-the-counter sodium phosphate products by persons in whom they are contraindicated has resulted in some deaths caused by electrolyte abnormalities, cardiac arrhythmias, or significant fluid shifts.**

Visicol™ Tablets should not be used in patients with congestive heart failure, ascites, unstable angina pectoris, gastric retention, ileus or acute obstruction or pseudo-obstruction, severe chronic constipation, bowel perforation, acute colitis, toxic megacolon, or hypomotility syndrome. Side effects occurring in >3% of patients were nausea, vomiting, bloating and abdominal pain.

1. Data on file.

Please see next page for summary of prescribing information



1787 Sentry Park West • Building 18 • Suite 440  
Blue Bell, PA 19422 • Tel: 1-877-330-0351  
WWW.VISICOL.COM

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IP-0002 Rev. 12/11/00

## Visico™ Tablets

(sodium phosphate monobasic monohydrate, USP, sodium phosphate dibasic anhydrous, USP)

### BRIEF SUMMARY OF PRESCRIBING INFORMATION

#### CLINICAL STUDIES

A total of 957 adult patients were enrolled and treated in the controlled clinical trials of Visico™ Tablets. Males and females were about equally represented. Approximately 87% of the study population was Caucasian. Visico™ Tablets were found to be comparable in cleansing efficacy to the comparison drug, a commercially available polyethylene glycol-salt (PEG-salt solution) solution (Cherry Flavor NuLYTELY®). Two identical, single (investigator) blind, randomized, multicenter trials were conducted comparing the efficacy and safety of Visico™ Tablets and the PEG-salt solution comparator as a colon cleansing agent in patients undergoing routine diagnostic colonoscopy. In each study, over 200 patients were randomized to self-administer the Visico™ Tablets and over 200 were randomized to self-administer the PEG-salt solution comparator. Colonoscopy was generally performed within 5 hours of the second dose. Physicians used a four-point, validated Physician Questionnaire to assess efficacy. The distribution of "excellent", "good", "fair" and "inadequate", as evaluated by the physician performing the colonoscopy, was comparable in both groups. Cleansing efficacy observed in these studies is described in the following table.

#### Observed overall colon cleansing efficacy of Visico™ Tablets versus PEG-salt solution comparator in the all assessed patient population

Efficacy Rating	Study A		Study B	
	Visico Tablets n (%)	PEG-salt solution Comparator n (%)	Visico Tablets n (%)	PEG-salt solution Comparator n (%)
Excellent or Good	171 (82.2)	156 (75.4)	183 (86.3)	170 (78.0)
Fair	34 (16.3)	49 (23.7)	26 (12.3)	45 (20.6)
Inadequate	3 (1.4)	2 (1.0)	3 (1.4)	3 (1.4)
Total patients	208	207	212	218
p value†	n.s.		n.s.	

†p values (Cochran-Mantel-Haenszel Test) were calculated for comparisons between Excellent and Good versus Fair versus Inadequate; Visico™ Tablets and PEG-salt solution comparator.

The efficacy of overall colonic cleansing with the Visico™ Tablets was comparable to the PEG-salt solution. In addition, the incidence of "inadequate" colon cleansing ratings due to poor purgative preparation was similar between Visico™ Tablets and the PEG-salt solution comparator. Also, cleansing efficacy in the ascending colon with Visico™ Tablets was comparable to the PEG salt solution.

#### INDICATIONS AND USAGE

Visico™ Tablets are indicated for cleansing of the bowel as a preparation for colonoscopy, in adults 18 years of age or older.

#### CONTRAINDICATIONS

Visico™ Tablets are not to be used in patients with congestive heart failure, ascites, unstable angina pectoris, gastric retention, ileus or acute obstruction or pseudo-obstruction, severe chronic constipation, bowel perforation, acute colitis, toxic megacolon, or hypomotility syndrome (such as hypothyroidism, scleroderma).

Visico™ Tablets are contraindicated in patients with a known allergy or hypersensitivity to sodium phosphate salts or any of its ingredients.

#### WARNINGS

Administration of other sodium phosphate-containing products, such as enemas or non-prescription liquid purgatives has resulted in fatalities due to significant fluid shifts, severe electrolyte abnormalities, and cardiac arrhythmias. These have been observed in patients with renal insufficiency or bowel perforation, and with misuse or overdose of these products.

Use with caution in patients with impaired renal function, pre-existing electrolyte disturbances (such as dehydration or those secondary to the use of diuretics), or people taking drugs that may affect electrolyte levels. Patients with electrolyte abnormalities such as hypernatremia, hyperphosphatemia, hypokalemia, or hypocalcemia should have them corrected before treatment with Visico™ Tablets.

#### PRECAUTIONS

##### General

Patients should be instructed to drink at least 8 ounces of clear liquids with administration of Visico™ Tablets. Inadequate fluid intake, as with any effective purgative, may lead to excessive fluid loss and hypovolemia.

Undigested or partially digested Visico™ Tablets may be seen in the watery diarrhea stool or during colonoscopy. In addition, undigested tablets from other medications may be seen.

Patients should be instructed not to administer additional agents, particularly additional sodium phosphate-based purgative or enema products.

Prolongation of the QT interval has been observed in some patients who were dosed with Visico™ Tablets. QT prolongation with Visico™ Tablets has been associated with electrolyte imbalances, such as hypokalemia and hypocalcemia. Visico™ Tablets should be used with caution in patients who are taking medications known to prolong the QT interval, since serious complications may occur. In these studies, prolongation of the QT interval was also observed in some patients treated with PEG-salt solution.

Administration of Visico™ Tablets may induce colonic mucosal aphthous ulcerations, an endoscopic finding observed with other sodium phosphate cathartic preparations. This colonoscopic finding should be considered in patients with known or suspect inflammatory bowel disease.

Because published data suggest that sodium phosphate absorption may be enhanced in patients experiencing an acute exacerbation of chronic inflammatory bowel disease, Visico™ Tablets should be used with caution in such patients.

Visico™ Tablets were not studied in patients within 3 months of an acute myocardial infarction or cardiac surgery, including coronary artery bypass graft surgery, and therefore should be used with caution in such patients.

#### Drug Interactions

Medications administered in close proximity to Visico™ Tablets may not be absorbed from the gastrointestinal tract due to the rapid intestinal peristalsis and watery diarrhea induced by the purgative agent.

#### Preparative Diet

Because of the mechanism of action of Visico™ Tablets, patients should be advised to take only clear liquids by mouth for at least 12 hours prior to starting the purgative regimen.

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Visico™. Studies to evaluate the effect of Visico on fertility or its mutagenic potential have not been performed.

#### Pregnancy

Category C. Reproduction studies have not been conducted with Visico™. It is also not known whether Visico™ can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Visico™ Tablets should be given to a pregnant woman only if clearly needed.

#### Pediatric Use

Safety and efficacy of Visico™ Tablets have not been demonstrated for patients less than 18 years of age.

#### Geriatric use

Of the total number of subjects in clinical studies of Visico™ Tablets, 27.7 percent were over 65, while 8.3% percent were over 75. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, greater sensitivity of some older individuals cannot be ruled out. Visico™ Tablets should be used with caution in elderly patients.

Sodium phosphate is known to be substantially excreted by the kidney, and the risk of adverse reactions with sodium phosphate may be greater in patients with impaired renal function. Elderly patients are more likely to have impaired renal function, and it may be useful to assess renal function.

#### ADVERSE REACTIONS

The most commonly observed adverse reactions (incidence  $\geq 1\%$ , all treated patients) occurring with the use of Visico™ Tablets are related to the desired purgative effect. Nausea, vomiting, abdominal bloating, abdominal pain, dizziness, and headache occur, and are generally transient and self-limited, requiring no specific treatment. All of these adverse events also occurred in patients who took the PEG-salt solution comparator. Small superficial mucosal ulcerations, typical of those previously reported from the use of liquid preparations of sodium phosphate, and instances of mucosal bleeding have been observed on colonoscopy.

One patient, with no history of heart disease, developed an initial episode of atrial fibrillation after severe vomiting immediately after taking Visico™ Tablets. Another patient, with known arteriosclerotic heart disease, who took the PEG-salt solution comparator developed atrial fibrillation and also vomited. No patient in the clinical studies developed predefined postural changes in vital signs with concomitant symptoms of lightheadedness or syncope.

#### Electrolyte Changes

Serum electrolyte changes have been observed in patients taking Visico™ Tablets, primarily affecting calcium, phosphate, and potassium. These changes essentially corrected within 48 to 72 hours after dosing, were not associated with any clinical adverse events and did not require treatment. No patient developed clinically significant hypocalcemia; among patients receiving Visico™ Tablets 60 grams (n=481) the mean decrease from baseline in calcium level was 0.5 mg/dL. No patient developed a calcium level below 7.1 mg/dL. No clinical adverse events suggestive of hypocalcemia were observed. Mean serum phosphorus levels increased by approximately 3.6 mg/dL transiently after taking Visico™ Tablets with no apparent clinical significance. A reactive decrease in serum phosphorus 2-3 days after dosing was observed; the mean decrease from baseline at that time was 0.7 mg/dL. The mean decrease in serum potassium after taking Visico™ Tablets was 0.5 mEq/L.

#### DRUG ABUSE AND DEPENDENCE

Under the direction of a physician, Visico™ Tablets are indicated for cleansing of the bowel when required as a preparation for colonoscopy, in adults 18 years of age or older. Laxatives and purgatives as a group have the potential for abuse by persons with eating disorders who "binge" and "purge".

#### OVERDOSAGE

There have been no reported cases of overdosage with Visico™ Tablets. Purposeful or accidental ingestion of more than the recommended dosage of Visico™ Tablets might be expected to lead to severe electrolyte disturbances, including hyperphosphatemia, hypocalcemia, hypernatremia, or hypokalemia, as well as dehydration and hypovolemia, with attendant signs and symptoms of these disturbances. Certain severe electrolyte disturbances may lead to cardiac arrhythmias and death. The patient who has taken an overdosage should be monitored carefully, and treated symptomatically for complications until stable.

#### DOSAGE AND ADMINISTRATION

The usual adult dosage of Visico™ Tablets for colon cleansing is 40 tablets taken in the following manner: The evening before the colonoscopy procedure, 3 Visico™ Tablets should be taken with at least 8 ounces of clear liquids every 15 minutes (the last dose will be 2 tablets) for a total of 20 tablets. The day of the colonoscopy procedure, (starting 3-5 hours before the procedure) 3 Visico™ Tablets should be taken with at least 8 ounces of clear liquids every 15 minutes (the last dose will be 2 tablets) for a total of 20 tablets.

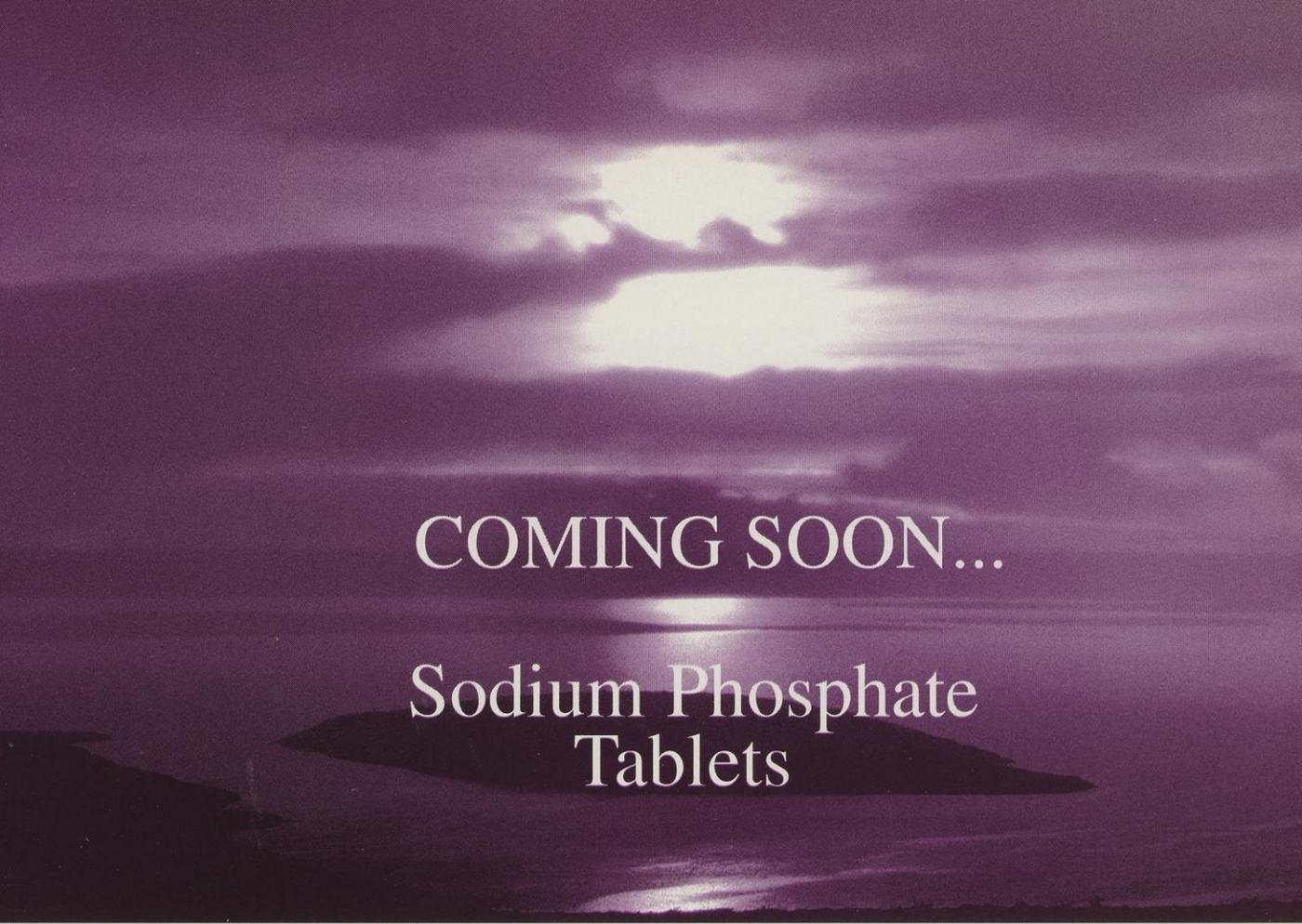
Patients are not to repeat this purgative agent within seven days of a previous administration. No additional enema or laxative is required, and patients should be advised NOT to take additional agents, particularly those containing sodium phosphate.

#### Rx only

#### FOR FULL PRESCRIBING INFORMATION CONSULT PACKAGE INSERT

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COMING SOON...

Sodium Phosphate  
Tablets



**VISICOL™**  
(sodium phosphate monobasic monohydrate, USP,  
sodium phosphate dibasic anhydrous, USP)  
**TABLETS**



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Sentry Park East • 1720 Walton Road

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