

# **TAGITOL V- barium sulfate suspension**

## **E-Z-EM Canada Inc**

-----

### **HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use TAGITOL V safely and effectively. See full prescribing information for TAGITOL V.**

**TAGITOL V (barium sulfate) oral suspension**

**Initial U.S. Approval: 2016**

### ----- **INDICATIONS AND USAGE** -----

TAGITOL V is a radiographic contrast agent indicated in adult patients for use in computed tomography (CT) colonography as a fecal tagging agent (1)

### ----- **DOSAGE AND ADMINISTRATION** -----

- The recommended dose is:
  - One 20 mL bottle (8g barium sulfate) with each meal (breakfast, lunch and dinner) the day *before* the CT colonography examination (2.1).
  - Total dose = 3 bottles (24 g barium sulfate)
- For oral use only (2.2).

### ----- **DOSAGE FORMS AND STRENGTHS** -----

- Oral suspension : barium sulfate (40% w/v) 20 mL single dose bottles as a ready to use suspension for oral administration (3)

### ----- **CONTRAINDICATIONS** -----

TAGITOL V is contraindicated in patients with:

- Known or suspected perforation of the gastrointestinal (GI) tract (4)
- Known obstruction of the GI tract (4)
- Conditions associated with high risk of GI perforation or aspiration (4)
- Known hypersensitivity to barium sulfate or any of the excipients of TAGITOL V (4)

### ----- **WARNINGS AND PRECAUTIONS** -----

- Hypersensitivity reactions: Emergency equipment and trained personnel should be immediately available (5.1)
- Intra-abdominal barium leakage: May occur in conditions which increase the risk of perforation such as - carcinoma, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, diverticulitis, or severe stenosis or obstructing lesions of the GI tract (5.2)
- Delayed GI transit and obstruction: Patients should maintain adequate hydration in days following a barium sulfate procedure to avoid obstruction or impaction by baroliths (5.3)
- Aspiration pneumonitis: Caution is recommended in patients with a history of food aspiration and in patients with known swallowing disorders (5.4)

### ----- **ADVERSE REACTIONS** -----

Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6)

**To report SUSPECTED ADVERSE REACTIONS, contact Bracco Diagnostics Inc at 1-800-257-5181 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 3/2022**

---

## **FULL PRESCRIBING INFORMATION: CONTENTS\***

### **1 INDICATIONS AND USAGE**

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 Recommended Dosing**

- 2.2 Important Administration Instructions
  - 3 DOSAGE FORMS AND STRENGTHS**
  - 4 CONTRAINDICATIONS**
  - 5 WARNINGS AND PRECAUTIONS**
    - 5.1 Hypersensitivity Reactions
    - 5.2 Intra-abdominal Barium Leakage
    - 5.3 Delayed Gastrointestinal Transit and Obstruction
    - 5.4 Aspiration Pneumonitis
    - 5.5 Systemic Embolization
  - 6 ADVERSE REACTIONS**
  - 8 USE IN SPECIFIC POPULATIONS**
    - 8.1 Pregnancy
    - 8.2 Lactation
    - 8.4 Pediatric Use
    - 8.5 Geriatric Use
  - 11 DESCRIPTION**
  - 12 CLINICAL PHARMACOLOGY**
    - 12.1 Mechanism of Action
    - 12.2 Pharmacodynamics
    - 12.3 Pharmacokinetics
  - 13 NONCLINICAL TOXICOLOGY**
    - 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
  - 16 HOW SUPPLIED/STORAGE AND HANDLING**
    - 16.1 How Supplied
    - 16.2 Storage and Handling
  - 17 PATIENT COUNSELING INFORMATION**
- \* Sections or subsections omitted from the full prescribing information are not listed.
- 

## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

TAGITOL V is indicated for use in adult patients for use in computed tomography (CT) colonography as a fecal tagging agent.

### **2 DOSAGE AND ADMINISTRATION**

#### **2.1 Recommended Dosing**

- The recommended oral dose of TAGITOL V is one 20 mL bottle (8 g barium sulfate) with each meal (breakfast, lunch and dinner) the day *before* the colonography examination. Total dose = 3 bottles (24 g barium sulfate).

#### **2.2 Important Administration Instructions**

- TAGITOL V is typically provided to the patient for self-administration. Advise patients to carefully read and follow the Patient Instructions for Use to be provided to the

patient.

- Shake bottle for 15 seconds prior to administration.
- For oral use only.
- Encourage patients to hydrate following the barium sulfate procedure.
- Discard any unused suspension.

### **3 DOSAGE FORMS AND STRENGTHS**

Oral suspension: barium sulfate (40% w/v) supplied as a ready-to-use suspension in a 20 mL, single-dose, bottle for oral administration. Each 20 mL bottle contains 8 g of barium sulfate.

### **4 CONTRAINDICATIONS**

TAGITOL V is contraindicated in patients with:

- known or suspected perforation of the gastrointestinal (GI) tract;
- known obstruction of the GI tract;
- high risk of GI perforation such as those with a recent GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to the pelvis;
- high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation;
- known hypersensitivity to barium sulfate or any of the excipients of TAGITOL V.

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1 Hypersensitivity Reactions**

Barium sulfate preparations contain a number of excipients, including natural and artificial flavors and may induce serious hypersensitivity reactions. The manifestations include hypotension, bronchospasm and other respiratory impairments, dermal reactions including rashes, urticaria and itching. A history of bronchial asthma, atopy, or a previous reaction to a contrast agent may increase the risk for hypersensitivity reactions. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.

#### **5.2 Intra-abdominal Barium Leakage**

The use of TAGITOL V is contraindicated in patients at high risk of perforation of the GI tract [see *Contraindications (4)*]. Administration of TAGITOL V may result in leakage of barium from the GI tract in the presence of conditions that increase the risk of perforation such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with a severe stenosis at any level of the gastrointestinal tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation.

### **5.3 Delayed Gastrointestinal Transit and Obstruction**

Orally administered barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with the following conditions are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired gastrointestinal motility, electrolyte imbalance, dehydration, on a low residue diet, on medications that delay GI motility, constipation, cystic fibrosis, Hirschsprung disease, and the elderly. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration following a barium sulfate procedure.

### **5.4 Aspiration Pneumonitis**

The use of TAGITOL V is contraindicated in patients at high risk of aspiration [see *Contraindications (4)*]. Oral administration of barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanism. Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis.

### **5.5 Systemic Embolization**

Barium sulfate products may occasionally intravasate into the venous drainage of the large bowel and enter the circulation as a "barium embolus" leading to potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, septicemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of barium sulfate products, monitor patients for potential intravasation when administering barium sulfate.

## **6 ADVERSE REACTIONS**

The following adverse reactions have been identified from spontaneous reporting or clinical studies of barium sulfate administered orally. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure:

- Nausea, vomiting, diarrhea and abdominal cramping
- Serious adverse reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### *Risk Summary*

TAGITOLV is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug [see *Clinical Pharmacology (12.3)*].

### **8.2 Lactation**

## Risk Summary

TAGITOL V is not absorbed systemically by the mother following oral administration and breastfeeding is not expected to result in exposure of the infant to the drug [see *Clinical Pharmacology* (12.3)]

### 8.4 Pediatric Use

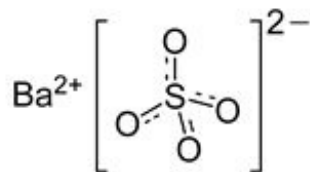
TAGITOL V is not indicated for pediatric use.

### 8.5 Geriatric Use

Clinical studies of TAGITOL V do not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

## 11 DESCRIPTION

TAGITOL V (barium sulfate) is a radiographic contrast agent that is supplied as a 40% w/v, off-white to lightly colored, free-flowing, ready-to-use suspension with an apple aroma for oral administration. The active ingredient barium sulfate is designated chemically as BaSO<sub>4</sub> with a molecular weight of 233.4 g/mol and the following chemical structure:



TAGITOL V contains the following excipients: carboxymethylcellulose sodium, citric acid, glycerin, maltodextrin, natural and artificial apple flavor, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, xanthan gum, and xylitol.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in TAGITOL V) is opaque to x-rays and therefore acts as a positive contrast agent for radiographic studies.

### 12.2 Pharmacodynamics

Barium sulfate is biologically inert and has no known pharmacological effects.

### **12.3 Pharmacokinetics**

Under physiological conditions, barium sulfate passes through the gastrointestinal tract in an unchanged form and is absorbed only in pharmacologically insignificant amounts.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

No animal studies have been performed to evaluate the carcinogenic potential of barium sulfate or potential effects on fertility.

## **16 HOW SUPPLIED/STORAGE AND HANDLING**

### **16.1 How Supplied**

TAGITOL V (barium sulfate) is an oral suspension (40% w/v) supplied as a box of three 20 mL bottles. Each bottle contains 8 grams barium sulfate.

Provided as: 24 boxes, each containing 3 (20 mL) bottles (NDC 32909-814)

### **16.2 Storage and Handling**

Store at room temperature 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Do Not Freeze.

## **17 PATIENT COUNSELING INFORMATION**

After administration, advise patients to:

- Maintain adequate hydration [see *Dosage and Administration (2.2)* and *Warnings and Precautions (5.3)*].
- Seek medical attention for worsening of constipation or slow gastrointestinal passage [see *Warnings and Precautions (5.3)*].
- Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty [see *Warnings and Precautions (5.1)*].

### Administration Instructions

TAGITOL V is typically provided to the patient for self-administration. Advise patients to carefully read and follow the Patient Instructions for Use to be provided to the patient.

Provide the patient with any site specific instructions regarding their procedure and when to take meals.

### **Rx only**

Manufactured by  
EZEM Canada Inc  
Anjou (Quebec) Canada H1J 2Z4  
For

Bracco Diagnostics Inc.  
Monroe Township, NJ 08831

CLC8503  
rev. 05/22

## **INSTRUCTIONS FOR USE**

### **TAGITOL V (tag-i-täl vē)**

#### **(barium sulfate)**

#### **oral suspension**

Read this Instructions for Use before you drink TAGITOL V (barium sulfate) oral suspension. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **Important:**

**Take TAGITOL V exactly as your healthcare provider tells you.** Your healthcare provider will prescribe the dose that is right for you. You can ask your healthcare provider or pharmacist if you have any questions about how to take TAGITOL V.

#### **How should I store TAGITOL V?**

- Before using TAGITOL V store at room temperature between 68°F and 77°F (20°C and 25°C).
- **Do not** freeze.

Keep TAGITOL V and all medicines out of the reach of children.

#### **Supplies you will need:**

- 1 box containing **3 bottles** of TAGITOL V. Each bottle contains 20 mL of TAGITOL V

#### **How should I take TAGITOL V**

**The day before your procedure you will drink 1 bottle of TAGITOL V with each meal:**

- **Breakfast:** Shake 1 bottle of TAGITOL V for 15 seconds, open the bottle, and drink the liquid with breakfast.
- **Lunch:** Shake 1 bottle of TAGITOL V for 15 seconds, open the bottle, and drink the liquid with lunch.
- **Dinner:** Shake 1 bottle of TAGITOL V for 15 seconds, open the bottle, and drink the liquid with dinner.

Throw away any unused TAGITOL V with normal household trash. **Do not** throw away by flushing down the drain.

#### **What should I do if the TAGITOL V spills?**

If you spill the liquid while shaking or drinking it, you can clean it up. TAGITOL V is not harmful and can be thrown away with normal household trash.

If you spilled any of the liquid, check with your healthcare provider to find out if you need to change the date of the appointment for your procedure.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

Approved: August 2017

COE5502

Tagitol V Internal Label

NDC: 32909-814-53

**FECAL TAGGING**  
for CT Colonography

Bracco Diagnostics 20 mL  
NDC 32909-814-53

**TAGITOL™ V**  
(BARIUM SULFATE)  
ORAL SUSPENSION,  
40% w/v

For Oral Use Only  
Rx only

Single-dose bottle - for oral use only  
For use in CT colonography as a  
fecal tagging agent in adult patients.  
Store at USP controlled room  
temperature 20 to 25°C (68 to 77°F).  
Protect from freezing.

See prescribing information for  
complete dosage and  
administration information.  
Each mL contains 0.4 g barium  
sulfate and the following inactive  
ingredients: carboxymethylcellulose,  
cetyl alcohol, polyethylene glycol,  
citric acid, ethyl vanillin, glycerin,  
maltodextrin, polysorbate 80,  
potassium sorbate, purified water,  
saccharin sodium, simethicone  
emulsion, sodium benzoate, sodium  
citrate, xanthan gum, xylitol.

Manufactured by  
E-Z-EM Canada Inc.  
Anjou, Quebec H1J2Z4, Canada  
For Bracco Diagnostics Inc.  
Monroe Twp., NJ 08831  
rev. 05/22

10332909814530  
CIC8603

**Unvarnished Lot & Expiry  
Etching Area**

**TX1866**

Tagitol V Internal Label

NDC: 32909-814-55

**FECAL TAGGING**  
for CT Colonography

Bracco Diagnostics 20 mL  
NDC 32909-814-55

**TAGITOL™ V**  
(BARIUM SULFATE)  
ORAL SUSPENSION,  
40% w/v

For Oral Use Only  
Rx only

**DO NOT USE IF CAP RING IS  
BROKEN OR MISSING**

Single Dose Bottle - Discard Unused Portion  
For use in CT colonography as a  
fecal tagging agent in adult patients.  
Store at USP controlled room  
temperature 20 to 25°C (68 to 77°F).  
Do Not Freeze.

**Recommended Dosage: See  
Prescribing Information**

Each mL contains 0.4 g barium  
sulfate and the following inactive  
ingredients: carboxymethylcellulose,  
sodium, citric acid, glycerin,  
maltodextrin, natural and artificial  
apple flavor, polysorbate 80,  
potassium sorbate, purified water,  
saccharin sodium, simethicone  
emulsion, sodium benzoate, sodium  
citrate, xanthan gum, xylitol.

Manufactured by  
E-Z-EM Canada Inc.  
Anjou, Quebec H1J2Z4, Canada  
For Bracco Diagnostics Inc.  
Monroe Twp., NJ 08831  
rev. 05/22

10332909814554  
CIC8603

LOT

EXP

**CIC8603**

Tagitol V External Label



NDC 32909-814-55 24 Boxes (Each Box Containing 3 x 20 mL Bottles)



Bracco Diagnostics

# TAGITOL™ V

**(BARIUM SULFATE) ORAL SUSPENSION, 40% w/v**

**Single Dose Bottles – Discard Unused Portion**

For use in CT colonography as a fecal tagging agent in adult patients.

**Recommended Dosage: See Prescribing Information**

Each mL contains 0.4 g barium sulfate and the following inactive ingredients: carboxymethylcellulose sodium, citric acid, glycerin, maltodextrin, natural and artificial apple flavor, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, xanthan gum, xylitol.

Store at room temperature 20° to 25°C (68° to 77°F)

[See USP Controlled Room Temperature].

Do Not Freeze.

**Rx only**

Manufactured by  
E-Z-EM Canada Inc, Anjou, Quebec H1J2Z4, Canada  
for Bracco Diagnostics Inc., Monroe Twp., NJ 08831



(01)30332909814558

rev. 05/22

LOT

EXP

Lot and expiry encoding area  
1" x 2"

CEC8804



## Tagitol V Carton

The carton features the following information:

- Top Panel:** Bracco Diagnostics logo, NDC 32909-814-55, TAGITOL™ V (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v.
- Front Panel (Left):** TAGITOL™ V (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v. Includes three 20 mL bottles labeled 1. BREAKFAST, 2. LUNCH, and 3. DINNER. Below the bottles, it states: "Each mL contains 0.4 g barium sulfate and the following inactive ingredients: carboxymethylcellulose sodium, citric acid, glycerin, maltodextrin, natural and artificial apple flavor, polysorbate 80, potassium sorbate, purified water, saccharin sodium, simethicone emulsion, sodium benzoate, sodium citrate, xanthan gum, xylitol."
- Front Panel (Right):** Bracco Diagnostics logo, NDC 32909-814-55, TAGITOL™ V (BARIUM SULFATE) ORAL SUSPENSION, 40% w/v. "3 Bottles x 20 mL each". "For Oral Use Only Rx only". "Manufactured by E-Z-EM Canada Inc, Anjou, Quebec H1J2Z4, Canada for Bracco Diagnostics Inc. Monroe Twp., NJ 08831".
- Side Panel:** "FECAL TAGGING for CT Colonography" with a diagram of the colon. Includes storage instructions: "Store at room temperature 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Do Not Freeze." and "Single Dose Bottles – Discard Unused Portion 24 hours prior to procedure: patient should drink one 20 mL bottle of TAGITOL™ V at each meal- breakfast, lunch and dinner. Recommended Dosage: See Prescribing Information".
- Bottom Panel:** Lot and expiry encoding area (1" x 2"), barcode, and (01)30332909814551.

## TAGITOL V

barium sulfate suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:32909-814
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Barium Sulfate</b> (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	400 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>dimethicone 350</b> (UNII: 2Y53S6ATLU)	
<b>dimethicone 1000</b> (UNII: MCU2324216)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>potassium sorbate</b> (UNII: 1VPU26JZZ4)	
<b>saccharin sodium</b> (UNII: SB8ZUX40TY)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>trisodium citrate dihydrate</b> (UNII: B22547B95K)	
<b>water</b> (UNII: 059QF0K0OR)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>xylitol</b> (UNII: VCQ006KQ1E)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	APPLE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:32909-814-53	24 in 1 CASE	08/04/2017	03/31/2024
1		3 in 1 BOX		
1		20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:32909-814-55	24 in 1 CASE	10/01/2022	
2		3 in 1 BOX		
2		20 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
NDA	NDA208143	08/04/2017	

**Labeler** - E-Z-EM Canada Inc (204211163)

**Registrant** - E-Z-EM, INC. (002041226)

Revised: 10/2022

E-Z-EM Canada Inc