Product information

From Health Canada

Note - The product information found within this database originates from organizations not subject to the *Official Languages Act* and is available in the language in which it was written and submitted to Health Canada.

Note - The market status of a product is now available in the LNHPD and identifies if a product is "marketed" or "not marketed" in Canada. Product licence holders may voluntarily provide the Natural and Non-Prescription Health Products Directorate (NNHPD) with information about whether their product is currently available to Canadian consumers. Where no information has been provided, the default status is "not marketed". The "current status" field remains unaffected and will continue to indicate the status of the product licence (i.e., active, discontinued, stop sale, cancelled, or suspended). Note that where a licence has been suspended, cancelled or under stop sale, the product cannot be legally sold in Canada.

Product licence holders - if you wish to update a product's market status, you are invited to complete the Natural Health Products Market Notification Web Form. As with all other notifications, there is no current service standard. The NNHPD will process the market status

update as soon as feasible, based on its available resources. As a reminder, market notification is voluntary; therefore, a licence holder is not required to wait for the LNHPD to be updated before a licensed product is sold in Canada. As such, products that are identified in the LNHPD as "not marketed" may still be sold in Canada.

New search

Natural Product Number (NPN):
80027471

Market status:
Not Marketed

Licence Status:
Active

Brand name(s):
Polibar Plus ;
EZDose

Licence holder:
E-Z-EM Canada Inc.

Dosage Form:
Suspension

Recommended route of administration:
Oral

Rectal

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Recommended dose:

Sub population (Sub Pop.)				Quantity (Qty)					Freque	
Sub Pop.	Age	Min.	Max.	UoM [1] Age	Qty	Min.	Max.	UoM Qty	Freq.	M
Adults						60.0	300.0	mL		
Adults						500.0	1500.0	mL		
Adults						150.0	340.0	mL		
Adults						1000.0	2500.0	mL		
Adults						340.0	750.0	mL		

Footnotes

1 UoM: Unit of Measure

Recommended use or purpose:

S.O.

For radiological study of the gastrointestinal tract. For radiological study of the gastrointestinal tract. For use as radiological contrast media for upper and lower gastrointestinal procedures by conventional x-ray or computed tomography. For radiological study of the gastrointestinal tract. (as stated on TPD previous approved label) For use as radiological contrast media for upper and lower gastrointestinal procedures by conventional x-ray. (as stated on TPD previous approved product information insert)

Risk Information:

Cautions and Warnings

For professional use only. Do not store after diluting. Do not use if seal is damaged. Store at controlled room temperature. See product information insert for complete details. Diagnostic procedures which involve the use of radiopaque contrast agents should be carried out under the direction of personnel with the requisite training and with a thorough knowledge of the particular procedure to be performed. A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, or a previous reaction to a contrast agent, warrant special attention. Caution should be exercised with the use of radiopaque media in severely debilitated patients and in those with marked hypertension or advanced cardiac disease. Ingestion of barium is not recommended in patients with a history of food aspiration. If barium swallow studies are required in these patients or in patients in whom integrity of the swallowing mechanism is unknown, proceed with caution. Administer initially small amounts such as a half-teaspoon of low-density barium and carefully observe swallowing under fluoroscopic control. If barium is aspirated into the larynx, further administration of barium should be immediately discontinued. If no aspiration is noted, additional barium may be given with continued fluoroscopic monitoring for aspiration. After any barium study of the G.I. tract, it is important to rehydrate the patient as quickly as possible to prevent impaction of the barium. To prevent barium impaction in the colon may also require the use of cathartics following completion of the examination. Saline cathartics are recommended on a routine basis and especially in patients with a history of constipation unless clinically contraindicated. Where enema tips are used, care must be taken during insertion into the patient, since forceful or too deep insertion may cause tearing or perforation of the rectum. When balloon retention tips are used, care should be taken to avoid over-inflation of the balloon, since overfilling or asymmetrical filling with displacement of the tip may occur. Such a displacement can lead to rectal perforation or barium granulomas. Inflation of the balloon should be done under fluoroscopic control by qualified profession personnel.

Contra-Indications

Oral administration: Known or suspected fistula, perforation or obstruction in any part of the gastrointestinal tract or recent rectal biopsy. Rectal administration: Known or suspected fistula, perforation or obstruction of the lower gastrointestinal tract or recent rectal biopsy. Known hypersensitivity to barium sulfate or any components (see non-medicinal ingredients).

Known Adverse Reactions

Adverse reactions accompanying the use of barium sulfate formulations are infrequent and usually mild, though severe reactions (approximately 1 in 500,000) and fatalities (approximately 1 in 2,000,000) have occurred. Procedural complications are rare, but may include aspiration pneumonitis, barium impaction, granuloma formation, intravasation, embolization and peritonitis following intestinal perforation, vasovagal and syncopal episodes, and fatalities. EKG changes have been shown to occur following or during barium enemas. It is of the utmost importance to be completely prepared to treat any such occurrence. Due to the increased likelihood of allergic reactions in atopic patients, it is important that a complete history of known and suspected allergies as well as allergic-like symptoms, e.g. rhinitis, bronchial asthma, eczema and urticaria, be obtained prior to any medical procedure utilizing the products. A mild allergic reaction would most likely include generalized pruritus, erythema or urticaria (approximately 1 in 100,000 reactions). Such reactions will generally respond to an antihistamine such as 50 mg of diphenhydramine or its equivalent. In the rarer, more serious reactions (approximately 1 in 500,000) laryngeal edema, bronchospasm or hypotension could develop. Severe reactions which may require emergency measures are often characterized by peripheral vasodilation, hypotension, reflex tachycardia, dyspnea, agitation, confusion and cyanosis, progressing to unconsciousness. Treatment should be initiated immediately with 0.3 - 0.5 cc of 1:1000 epinephrine subcutaneously. If bronchospasm predominates, 0.25 - 0.50 gram of intravenous aminophylline should be given slowly. Appropriate vasopressors might be required. Adrenocorticosteroids, even if given intravenously, exert no significant effect on the acute allergic reaction for a

few hours. The administration of these steroid agents should not be regarded as emergency measures for the treatment of allergic reactions. Apprehensive patients may develop weakness, pallor, tinnitus, diaphoresis and bradycardia following the administration of any diagnostic agent. Such reactions are usually non-allergic in nature and are best treated by having the patient lie flat for an additional 10 to 30 minutes under observation. All E-Z-EM CANADA INC. products are latex free. However, allergic reactions to the enema accessories, in particular to retention catheters (tips) with latex cuffs, can occur. Such reactions could occur immediately and result in the previously mentioned acute allergic-like responses or might be delayed in appearance and result in a contact dermatitis. Known atopic patients particularly those with a history of asthma or eczema should be evaluated for alternative methods of administration in order to avoid these adverse reactions. All plastic/rubber accessories are disposable, single use devices that must not be reused or left in the body cavity for an extended period of time. In rare occasions following repeated administration, severe stomach cramps and diarrhea may occur. These are transitory in nature and are not considered serious.

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List of medicinal ingredients:

Medicinal ingredients	Quantity (Qty)	Extract	Potency
Barium Sulfate	105.0 % (w/v)		

List of non-medicinal ingredients:

- Citric acid
- Gum Arabic
- Hydrochloric Acid
- Polysorbate 80
- Potassium Chloride
- Potassium Sorbate

- Purified water
- Simethicone emulsion 30 %
- Sodium Saccharin
- Sodium benzoate
- Sodium carrageenan
- Sodium citrate
- Vanilla flavor
- Xanthan Gum
- sorbitol solution 70%

Date of licensing:

2011-09-27

Revised date of licence:

2018-06-25

Application information

User guide

Terminology guide

Related information

Compendium of monographs

Contact us

For technical support or if you have general questions concerning the content of this database, please contact the Natural Health Products Directorate (NHPD).

Date modified: 2023-10-17