

THE MAGIC BULLET- bisacodyl suppository

Concepts in Confidence

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

The Magic Bullet

DRUG FACTS

Active Ingredient

Bisacodyl
10 mg per suppository.

Purpose

Stimulant
Laxative

Use

rectally for relief of occasional constipation. This product generally produces a bowel movement within 15 minutes to one hour.

Warnings

Do not use

if presence nausea, vomiting, rectal bleeding, or in children under 5 years of age or for more than one week unless directed by a doctor.

Use of this product

may cause abdominal discomfort, faintness, rectal burning and mild cramps.

Stop use and ask a doctor if

rectal bleeding occurs or if you fail to have a bowel movement after using a laxative. This may indicate a serious condition.

Ask a doctor before use

If pregnant or breast feeding, or if a sudden change in bowel habits persists for more than two weeks.

Frequent or continued use of this product may result in dependence on laxatives.

DRUG FACTS (continued)

Keep this and all medication out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Remove plastic wrap and insert rounded end first into the rectum.

Adults and children over the age of 12 – dosage – 10 mg, one suppository, in a single daily dose. Children 6-12 – dosage – 5 mg, one-half suppository, in a single daily dose. Children under 6 – consult a doctor.

Other information

Store below 86°F (30°C)

Inactive ingredients

Polyethylene glycol, propylene glycol diacetate.

Mfg. for Concepts in Confidence

Boynton Beach, FL 33426

(800) 822-4050

Rev 09/16

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Rev 05/14

PRINCIPAL DISPLAY PANEL - 100 Suppositories

NDC 57648-002-01

100 SUPPOSITORIES

THE MAGIC BULLET™

LAXATIVE SUPPOSITORIES

EACH CONTAINING 10 mg BISACODYL USP
Contains No Hydrogenated Vegetable Oil

TAMPER RESISTANT: Individually Sealed For Your Protection

NDC 57648-002-01

100 SUPPOSITORIES

THE MAGIC BULLET™

LAXATIVE SUPPOSITORIES

EACH CONTAINING 10 mg BISACODYL USP
Contains No Hydrogenated Vegetable Oil



TAMPER RESISTANT: Individually Sealed For Your Protection

Drug Facts	Drug Facts (Continued)
Active ingredient Bisacodyl 10mg per suppository	Purpose Stimulant Laxative
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Warnings Do not use in the presence of nausea, vomiting, rectal bleeding, or in children under 6 years of age, or for more than one week unless directed by a doctor. Use of this product may cause abdominal discomfort, faintness, rectal burning and mild cramps. Stop use and ask a doctor if rectal bleeding occurs or if you fail to have a bowel movement after using a laxative. This may indicate a serious condition. Ask a doctor before use if pregnant or breast feeding, or if a sudden change in bowel habits persists for more than two weeks. Frequent or continued use of this product may result in dependence on laxatives.	Directions Remove plastic wrap and insert rounded end first into rectum. Adults and children over the age of 12 – dosage is 10 mg, one suppository, in a single daily dose. Children 6-12 – dosage is 5 mg, one-half suppository, in a single daily dose. Children under 6 – consult a doctor.
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	Mfg. for Concepts in Confidence Boynton Beach, FL 33426 (800) 822-4050
	Rev. 09/16

PRINCIPAL DISPLAY PANEL - 10 Suppositories

NDC 57648-002-10

THE MAGIC BULLET™

LAXATIVE SUPPOSITORIES

EACH CONTAINING 10 mg BISACODYL USP

TAMPER RESISTANT:
INDIVIDUALLY SEALED FOR YOUR PROTECTION

Contains No Hydrogenated Vegetable Oil

10 SUPPOSITORIES

Concepts in Confidence

NDC 57648-002-10

THE MAGIC BULLET™

Laxative Suppositories
Each Containing 10mg Bisacodyl USP

TAMPER RESISTANT:
INDIVIDUALLY SEALED FOR YOUR PROTECTION

Contains No Hydrogenated Vegetable Oil



10 SUPPOSITORIES

<p>Drug Facts</p> <p>Active ingredient Bisacodyl 10mg per suppository</p> <p>Purpose Stimulant Laxative</p> <p>Use rectally for relief of occasional constipation. This product generally produces bowel movement in 15 minutes to 1 hour.</p> <p>Warnings Do not use in the presence of nausea, vomiting, rectal bleeding, or in children under 6 years of age, or for more than one week unless directed by a doctor. Use of this product may cause abdominal discomfort, faintness, rectal burning and mild cramps. Stop and ask a doctor if rectal bleeding occurs or if you fail to have a bowel movement after using a laxative. This may indicate a serious condition. Ask a doctor before use if pregnant or breast feeding, or if a sudden change in bowel habits persists for more than two weeks. Frequent or continued use of this product may result in dependence on laxatives.</p> <p>Keep this and all medications out of the reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p> <p>Directions Remove plastic wrap and insert rounded end first into rectum. Adults and children over the age of 12 – dosage is 10 mg, one suppository, in a single daily dose. Children 6-12 – dosage is 5 mg, one-half suppository, in a single daily dose. Children under 6 – consult a doctor.</p> <p>Other information store below 86° F (30° C)</p> <p>Inactive ingredients polyethylene glycol, propylene glycol diacetate</p>	<p>Mfg. for Concepts in Confidence Boynton Beach, FL 33426</p> <p>(800) 822-4050 Rev. 05/14</p>
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THE MAGIC BULLET

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57648-002
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	10 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
PROPYLENE GLYCOL DIACETATE (UNII: 5Z492UNF9O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57648-002-10	10 in 1 CARTON; Type 0: Not a Combination Product	01/01/2004	

2	NDC:57648-002-01	100 in 1 CARTON; Type 0: Not a Combination Product	01/01/2004	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334		01/01/2004	

Labeler - Concepts in Confidence (793444902)

Establishment			
Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549198	manufacture(57648-002)

Revised: 4/2023

Concepts in Confidence