

**SIMPEX BISACODYL LAXATIVE- bisacodyl tablet, coated**  
**Simpex Pharma Pvt. Ltd**

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**SIMPEX Bisacodyl laxative**

**Drug Facts**

**Active ingredient (in each tablet)**

Bisacodyl 5 mg

**Purpose**

Stimulant Laxative

**Uses**

- relieves occasional constipation and irregularity
- this product generally produces bowel movement in 6 to 12 hours

**Warnings**

**Do not use**

- if you can not swallow without chewing. ask a doctor before use if you have
- stomach pain, nausea or vomiting
- a sudden change in bowel habits that lasts more than weeks

**When using this product**

- do not chew or crush tablet (s)
- do not use within 1 hour after taking an antacid or milk
- you may have stomach discomfort, faintness or cramps

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement after use a laxative. these could be signs of a serious condition.
- you need to use a laxative for more than 1 week if pregnant or breast-feeding, ask a health professional before use.

**keep out of reach of children.**

In case of overdose, get medical help or contact a poison control center right away.

**Directions**

- take with a glass of water.

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Adults and children 12 years and over

take 1 to 3 tablets in a single daily dose

Children 6 to under 12 years of age

take 1 tablet in a single daily dose

Children under 6 years

ask a doctor

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**Other information**

- preserve in well-closed containers at a temperature not exceeding 30°C
- avoid excessive humidity

**Inactive ingredients**

anhydrous lactose, colloidal anhydrous silica, hypermellose, iron oxide red, iron oxide yellow, macrogol, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, povidone, sodium bicarbonate, sodium lauryl sulfate, sodium starch glycolate type A, talc, titanium dioxide, triethyl citrate

**Package Labeling:**

**SIMPEX**  
**Bisacodyl laxative**  
 Coated Tablets 5mg  
 100 Tablets

Overnight relief from constipation

Gentle  
 Effective  
 Dependable

84901252093389


Distributed by:  
 Lot No.:  
 Mfg. Date:  
 Exp. Date:

Do not use if imprinted safety seal under cap is broken or missing.

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<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each tablet)</b> Bisacodyl 5 mg	<b>Purpose</b> Stimulant Laxative	<ul style="list-style-type: none"> <li>a sudden change in bowel habits that lasts more than weeks</li> </ul>	
<b>Uses</b> <ul style="list-style-type: none"> <li>relieves occasional constipation and irregularity</li> <li>this product generally produces bowel movement in 6 to 12 hours</li> </ul>		<b>When using this product</b> <ul style="list-style-type: none"> <li>do not chew or crush tablet (s)</li> <li>do not use within 1 hour after taking an antacid or milk</li> <li>you may have stomach discomfort, faintness or cramps</li> </ul>	
<b>Warnings</b> <b>Do not use</b> <ul style="list-style-type: none"> <li>if you can not swallow without chewing, ask a doctor before use</li> <li>if you have stomach pain, nausea or vomiting</li> </ul>		<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>you have rectal bleeding or fail to have a bowel movement after use a laxative, these could be signs of a serious condition.</li> </ul>	

<b>Drug Facts (continued)</b>		<b>Drug Facts (continued)</b>	
<ul style="list-style-type: none"> <li>you need to use a laxative for more than 1 week if pregnant or breast-feeding, ask a health professional before use.</li> </ul>		children 6 to under 12 years of age	1 tablet in a single daily dose
keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away.		children under 6 years	ask a doctor
<b>Directions</b> <ul style="list-style-type: none"> <li>take with a glass of water.</li> </ul>		<b>Other information</b>	
adults and children 12 years and over		<ul style="list-style-type: none"> <li>preserve in well-closed containers at a temperature not exceeding 30°C.</li> <li>avoid excessive humidity</li> </ul>	
1 to 3 tablets in a single daily dose		<b>Inactive ingredients</b> anhydrous lactose	

<b>Drug Facts (continued)</b>		 Manufactured by: <b>SIMPEX PHARMA PVT. LTD.</b> C-7 to C-13 & C-59 to C-64, Sigaddi Growth Center, SIDCUL, Sigaddi, Kotdwar - 246149, Distt. Pauri Garhwal, Uttarakhand, India.
colloidal anhydrous silica, hypermellose, iron oxide red, iron oxide yellow, macrogol, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, povidone, sodium bicarbonate, sodium lauryl sulfate, sodium starch glycolate type A, talc, titanium dioxide, triethyl citrate		

<b>SIMPEX BISACODYL LAXATIVE</b>			
bisacodyl tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76457-003
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
BISACODYL (UNII: 10X0709Y6I) (DEACETYLBISACODYL - UNII:R09078E41Y)	BISACODYL	5 mg	
<b>Inactive Ingredients</b>			
Ingredient Name	Strength		
ANHYDROUS LACTOSE (UNII: 3S5YLH9PMK)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
POVIDONE (UNII: FZ989GH94E)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)			

Product Characteristics				
<b>Color</b>	white (Clear)	<b>Score</b>	no score	
<b>Shape</b>	CAPSULE (BiConvex)	<b>Size</b>	16mm	
<b>Flavor</b>		<b>Imprint Code</b>	;	
<b>Contains</b>				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76457-003-00	100 in 1 CARTON; Type 0: Not a Combination Product	02/09/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M007	02/09/2018		

**Labeler** - Simpex Pharma Pvt. Ltd (916758275)

Establishment			
Name	Address	ID/FEI	Business Operations
Simpex Pharma Pvt. Ltd		916758275	manufacture(76457-003)

Revised: 11/2023

Simpex Pharma Pvt. Ltd