ALOPHEN - bisacodyl tablet, coated
NUMARK BRANDS, INC

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.

Drug Facts

Active ingredient (in each enteric coated tablet)	***Purpose***
Bisacodyl 5 mg	Laxative

Use

for the relief of occasional constipation and irregularity. This product generally produces a bowel movement in 6-12 hours.

Warnings

Do not use

- unless directed by a doctor, when abdominal pain, nausea, or vomiting are present
- this product for more than 1 week unless directed by a doctor
- this product within 1 hour after taking an antacid or milk
- for children under 6 years of age
- for persons who can not swallow without chewing

Ask a doctor before use if you have

a sudden change in bowel habits over a period of 2 weeks.

When using this product

- do not chew the tablets
- it may cause abdominal discomfort, faintness, and cramps

Stop use and ask a doctor if

- rectal bleeding occurs
- there is failure to have a bowel movement after use of a laxative. These may indicate a serious condition.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not chew tablets

adults and children 12 years of age and over	1-3 tablets in a single daily dose
children 6 to under 12 years of age	1 tablet in a single daily dose
children under 6 years of age	consult a doctor

Other information

store at temperature not above 86° F(30 C)

Inactive ingredients

acacia, ammonium hydroxide, calcium carbonate, carnauba wax, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, iron oxide black, lactose anhydrous, magnesium stearate, methylparaben, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, povidone, propylene glycol, propylparaben, shellac glaze, simethicone, sodium alginate, sodium benzoate, sodium bicarbonate, stearic acid, sucrose, talc, titanium dioxide, triacetin, triethyl citrate

Questions?

call **1-800-214-2379**

PRINCIPAL DISPLAY PANEL

NDC 69846-140-01

Now Smaller,
Easier to Swallow

Alophen®
(Bisacodyl USP)

Comfort Coated
Stimulant Laxative

Gentle, Effective
Overnight Relief

100 Tablets, 5 mg. each

Do not use if printed "SEALED FOR YOUR PROTECTION" inner seal is broken or missing.

Dist. by: Numark Brands, Inc. 57001
EDISON, NJ 08818 1-800-214-2379 Rev. 4/21

LOT #

EXP. DATE

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REFER TO OUTER CARTON FOR FULL INFORMATION

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ALOPHEN

bisacodyl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69846-140
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Bisacodyl (UNII: 10X0709Y6I) (Deacetylbisacodyl - UNII:R09078E41Y)	Bisacodyl	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**

Acacia (UNII: 5C5403N26O)	
Ammonia (UNII: 5138Q19F1X)	
Calcium Carbonate (UNII: H0G9379FGK)	
Carnauba Wax (UNII: R12CBM0EIZ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Starch, Corn (UNII: O8232NY3SJ)	
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	
Fd&C Yellow No. 6 (UNII: H77VEI93A8)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Ferrosoferric Oxide (UNII: XM0M87F357)	
Anhydrous Lactose (UNII: 3SY5LH9PMK)	
Magnesium Stearate (UNII: 70097M6I30)	
Methylparaben (UNII: A2I8C7HI9T)	
Polydextrose (UNII: VH2XOU12IE)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Shellac (UNII: 46N107B71O)	
Dimethicone (UNII: 92RU3N3Y1O)	
Sodium Alginate (UNII: C269C4G2ZQ)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Bicarbonate (UNII: 8MDF5V39QO)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Sucrose (UNII: C151H8M554)	
Talc (UNII: 7SEV7J4R1U)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Triacetin (UNII: XHX3C3X673)	
Triethyl Citrate (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	YELLOW, ORANGE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	TCL;003
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69846-140-01	1 in 1 CARTON	04/15/1907	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part334	04/15/1907	

Labeler - NUMARK BRANDS, INC (080184668)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	manufacture(69846-140)

Revised: 12/2021 NUMARK BRANDS, INC