

FLEET- bisacodyl tablet
C.B. Fleet Company, 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 tablet)

Bisacodyl 5 mg.....Stimulant Laxative

Use

For relief of occasional constipation.

Warnings

May cause abdominal discomfort, faintness and cramps.

If pregnant or breast-feeding, ask a health professional before use.

Ask a doctor before using any laxative if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

Swallow tablets whole. It is important that you do not chew or crush. Do not give to children under 6 years of age, or to persons who cannot swallow without chewing, unless directed by a doctor.

Do not take within 1 hour after taking an antacid, milk or milk products.

Stop using this product and consult a doctor if you

- have rectal bleeding
- have no bowel movement after use

These symptoms may indicate a serious condition.

Keep out of reach of children

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

Directions

Single Daily Dosage

adults and children 12 years and over	1 - 3 tablets
children 6 to under 12 years	1 tablet
children under 6 years	ask a doctor

Other Information

- this product generally produces bowel movement in 6-12 hours
- each tablet is imprinted with "TCL 0003" for identification
- store at temperatures not above 86F (30C)
- do not use if foil imprinted with "Bisacodyl 5mg Laxative Tablet" is broken or missing
- consult Physicians' Desk Reference for complete professional labeling

Inactive Ingredients

acacia, anhydrous lactose, beeswax, calcium sulfate, carnauba wax, colloidal silicon dioxide, corn starch, DandC yellow 10 lake, FDandC yellow 6 lake, gelatin, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, polyvinyl acetate phthalate, povidone, sodium starch glycolate, stearic acid, sucrose, talc, titanium dioxide

Questions?

1-866-255-6960 or www.fleetlabs.com



The image shows the packaging for Fleet Bisacodyl Tablets. On the left is a green and pink box with the 'Fleet' logo in white. To the right, the text reads 'BISACODYL tablets' in pink and grey, followed by 'for fast, dependable relief of occasional constipation'. Below this is a small orange circle labeled 'actual size' and a larger orange circle. At the bottom, it says '#1 DOCTOR RECOMMENDED LAXATIVE BRAND' and '25 Comfort Coated 5 mg Tablets'.

FLEET

bisacodyl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0704
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Bisacodyl (UNII: 10X0709Y6I) (Bisacodyl - UNII:10X0709Y6I)		Bisacodyl	5 mg	
Inactive Ingredients				
Ingredient Name		Strength		
ACACIA (UNII: 5C5403N26O)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
CALCIUM SULFATE (UNII: WAT0DDB505)				
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)				
GELATIN (UNII: 2G86QN327L)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SHELLAC (UNII: 46N107B71O)				
POVIDONE (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SUCROSE (UNII: C151H8M554)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	24mm	
Flavor		Imprint Code	TCL003	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0704-02	25 in 1 CARTON		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	06/05/2002		

Labeler - C.B. Fleet Company, Inc. (003119054)