

ONELAX- bisacodyl suppository
AKRON PHARMA 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.

OneLAX
BISACODYL 10 mg Suppositories
Fast Acting Stimulant Laxative

Active Ingredients (per suppository)

Bisacodyl USP, 10 mg

Purpose

Laxative

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

- for relief of occasional constipation
- this product usually produces bowel movement in 1/4 to 1 hour

Warnings

For rectal use only.

Do not use laxative products

- when abdominal pain, nausea or vomiting are present
- for a period longer than one week

Ask a doctor before use if you have

noticed a sudden change in bowel habits that persist over a period of 2 weeks

When using this product

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

Stop use and ask a doctor if

rectal bleeding occurs, or you fail to have a bowel movement after using a laxative. This

may indicate a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

Directions

- adults and children 12 years of age and older
- detach one suppository from the strip
- remove from wrapper before inserting into the rectum
- the rectal suppository dose is one suppository per day or as directed by a doctor
- children under 12 years of age consult a doctor

Other information

store below 30° C (86° F)

Inactive ingredient

hydrogenated vegetable oil

Manufactured for:

Akron Pharma Inc.,
Fairfield, NJ-07004
www.akronpharma.com

Inactive ingredient hydrogenated vegetable oil

Other information ■ store at temperatures below 30°C (86°F)

Children under 12 years
 Adults and children 12 years and over ■ 1 suppository once daily
 Ask a doctor

Directions
 ■ tear off one suppository from the strip
 ■ continue tearing downward to almost the full length of the suppository (see illustration at the right)
 ■ gently remove the suppository from the wrapper
 ■ lie on your side and push suppository, with pointed end first, high into the rectum so it will not slip out
 ■ retain it for 15 to 20 minutes
 ■ Do not exceed recommended dose ■ If suppository seems soft, place in refrigerator for a short time before use

Warnings For rectal use only
 Do not use when abdominal pain, nausea, or vomiting are present.
 Ask a doctor before use if you have a sudden change in bowel habits that lasts over a period of 2 weeks.
 When using this product you may experience ■ rectal burning ■ mild cramps ■ abdominal discomfort ■ flatness
 Stop use and ask a doctor if ■ you have rectal bleeding ■ you fail to have a bowel movement after using a laxative. These may be signs of a serious condition.
 ■ you need to use a laxative for more than one week
 If pregnant or breast-feeding, ask a health professional before use.
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Active ingredient (in each suppository) Bisacodyl USP 10 mg
 Stimulant laxative

Purpose ■ relieves occasional constipation ■ this product generally produces a bowel movement in 15 minutes to 1 hour

NDC 71399-8460-2
 Compare to the active ingredient in Dulcolax® Suppositories*

OneLAX™

Bisacodyl 10mg Suppositories

Fast Acting Stimulant Laxative

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SUPPOSITORIES

TAMPER EVIDENT: SUPPOSITORIES ARE WRAPPED IN TAMPER EVIDENT SEALED WRAPPERS. DO NOT USE IF WRAPPER IS TORN OR OPEN WHEN PURCHASED.

Bisacodyl 10mg Suppositories

Akron Pharma
 Manufactured for: Akron Pharma Inc., Fairfield, NJ-07004
 www.akronpharma.com
 Questions or comments? toll-free (877)225-6999

*This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, owner of the registered trademark Dulcolax®





ONELAX

bisacodyl suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-8460
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
FAT, HARD (UNII: 8334LX7S21)	

Product Characteristics

Color	white (WHITE TO OFF WHITE)	Score	
Shape	OVAL (TORPEDO SHAPE)	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-8460-2	12 in 1 BOX	11/05/2021	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:71399-8460-5	50 in 1 BOX	11/05/2021	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	11/05/2021	

Labeler - AKRON PHARMA INC (067878881)

Revised: 3/2023

AKRON PHARMA INC