

**STRATUSCARE BISACODYL- bisacodyl suppository**  
**Stratus Pharmaceuticals**

*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.*

-----  
**BISACODYL USP**

**Drug Facts**

**Active ingredient (in each suppository)**

Bisacodyl 10mg

**Purpose**

Stimulative laxative

**Uses**

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 15 minutes to 1 hour

**Warning**

**for rectal use only**

**Do not use**

- more than once per day
- for a period of longer than one week unless directed by a doctor
- laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor

**Ask a doctor before use if you have**

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

**When using this product** you may have abdominal discomfort, faintness, rectal burning and mild cramps

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement after use of a laxative because this may indicate a serious condition.

**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.

## Directions

Adults and children 12 years of age and older	Children 6 to under 12 years	Children under 6
One suppository once daily	1/2 suppository once daily	Ask a doctor

- Detach one suppository from the strip and remove from foil
- Carefully insert well into rectum
- Do not use more than once per day

## Other information

- Store at 15°C to 30°C (59°F to 86°F). Do not exceed 30°C (86°F).
- Individually sealed for your protection. Do not use if foil is torn or open.

## Inactive ingredients

Hydrogenated Vegetable Oil

## Questions or comments?

1-800-442-7881

### ***Distributed by:***

Stratus Pharmaceuticals Inc  
12379 SW 130th Street  
Miami, Florida 33186

## PRINCIPAL DISPLAY PANEL - 10 mg Blister Pack Box

STRATUSCARE

12

Suppositories  
Comfort Shaped

Distributed by:  
STRATUS  
PHARMACEUTICALS INC

NDC 58980-415-12

Gentle Laxative  
(BISACODYL USP 10 mg)

- Stimulant laxative
- Gentle yet effective

WORKS IN

15 MINUTES  
TO 1 HOUR

Compare to the active  
ingredient in Dulcolax®\*

# STRATUSCARE

(BISACODYL USP 10 mg)

## Gentle Laxative

- Stimulant laxative
- Gentle yet effective

**12**  
Suppositories  
Comfort Shaped

WORKS IN  
15 MINUTES  
TO 1 HOUR



NDC 58980-415-12

STRATUS  
PHARMACEUTICALS, INC.

STRATUS  
PHARMACEUTICALS, INC.

# STRATUSCARE

## Gentle Laxative

(BISACODYL USP 10 mg)

**12**  
Suppositories  
Comfort Shaped

- Stimulant laxative
- Gentle yet effective



WORKS IN  
15 MINUTES  
TO 1 HOUR

Compare to the active  
ingredient in Dulcolax\*

NDC 58980-415-12

Distributed by:  
**STRATUS**  
PHARMACEUTICALS, INC.

STRATUSCARE  
(BISACODYL USP 10 mg)

Gentle Laxative

- Stimulant Laxative
- Gentle yet effective

WORKS IN  
15 MINUTES  
TO 1 HOUR

**12**  
Suppositories  
Comfort Shaped

NDC 58980-415-12

Distributed by:  
**STRATUS**  
PHARMACEUTICALS, INC.

STRATUS  
PHARMACEUTICALS, INC.

RETAIN CARTON FOR COMPLETE INFORMATION  
DANGER EVIDENCE: DO NOT USE IF CARTON IS  
OPENED OR IF BUSTER UNIT IS TORN, BROKEN OR  
SHOWS ANY SIGNS OF TAMPERING



BS128X-2014-73

Distributed by:  
Stratus Pharmaceuticals Inc  
12379 SW 130th Street  
Miami, Florida 33186

\*This product is not manufactured  
as a sterile ointment. It is a  
sterile, single-dose, oral  
medication. Do not use if  
the package is damaged or  
expired.

STRATUS  
PHARMACEUTICALS, INC.

STRATUS  
PHARMACEUTICALS, INC.

**Active ingredient (in each suppository)** Bisacodyl 10mg. Stimulate the bowels

**Uses**  
■ for relief of occasional constipation and irregularity  
■ this product generally produces bowel movement in 15 minutes to 1 hour

**Warnings**  
Do not use ■ more than once per day ■ for a period of longer than one week unless directed by a doctor ■ laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor  
When using this product you may have abdominal discomfort, faintness, rectal burning and mild cramps  
Stop use and ask a doctor if ■ you have rectal bleeding or fall to have a bowel movement after use of a laxative because this may indicate a serious condition.  
If pregnant or breastfeeding, 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.

**Directions**  
Adults and children 12 years of age and older ■ Children under 6  
One suppository once daily ■ 1/2 suppository once daily ■ Ask a doctor  
■ Detach one suppository from the strip and remove from foil ■ Carefully insert well into rectum  
■ Do not use more than once per day  
■ Store at 15°C to 30°C (59°F to 86°F). Do not exceed 30°C (86°F).  
■ Individually sealed for your protection. Do not use if foil is torn or open.

**Other information**  
**Inactive ingredients** Hydrogenated Vegetable Oil  
Question for comment? 1-800-442-7881

STRATUSCARE  
(BISACODYL USP 10 mg)

Gentle Laxative

- Stimulant laxative
- Gentle yet effective

**12**  
Suppositories  
Comfort Shaped

WORKS IN  
15 MINUTES  
TO 1 HOUR

NDC 58980-415-12

Distributed by:  
**STRATUS**  
PHARMACEUTICALS, INC.

STRATUS  
PHARMACEUTICALS, INC.

**STRATUSCARE BISACODYL**

bisacodyl suppository

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-415
<b>Route of Administration</b>	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
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-415-04	4 in 1 BOX; Type 0: Not a Combination Product	05/30/2014	
2	NDC:58980-415-08	8 in 1 BOX; Type 0: Not a Combination Product	05/30/2014	
3	NDC:58980-415-12	12 in 1 BOX; Type 0: Not a Combination Product	05/30/2014	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/30/2014	

**Labeler** - Stratus Pharmaceuticals (789001641)

## Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products		059890491	MANUFACTURE(58980-415)

Revised: 11/2022

Stratus Pharmaceuticals