

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

-----  
**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

NDC 58980-415-12

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

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

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

STRATUS  
PHARMACEUTICALS, INC.

RETAIN CARTON FOR COMPLETE INFORMATION  
TAMPER EVIDENT: 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  
combination of bisacodyl and  
other inactive ingredients.

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  
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, flatulence, 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 or 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

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           |                    |
| 4 | NDC:58980-415-50 | 1 in 1 BOX  | 06/01/2020           |                    |
| 4 |                  | 50 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 5 | NDC:58980-415-16 | 1 in 1 BOX  | 05/01/2025           |                    |
| 5 |                  | 16 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug        | M007  | 05/30/2014                  |                           |

**Labeler** - Stratus Pharmaceuticals (789001641)

### **Establishment**

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

Revised: 4/2025

Stratus Pharmaceuticals