

**ALOPHEN- bisacodyl tablet, coated**  
**NUMARK BRANDS, INC**

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**Drug Facts**

| <b>Active ingredient (in each enteric coated tablet)</b> | <b>Purpose</b> |
|----------------------------------------------------------|----------------|
| 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<br>12 years of age and<br>over | 1-3 tablets in a<br>single daily<br>dose |
| children 6 to under<br>12 years of age             | 1 tablet in a<br>single daily<br>dose    |
| children under 6<br>years of age                   | consult a<br>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.*

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EDISON, NJ 08818 1-800-214-2379 Rev. 4/21

LOT #

EXP. DATE



NDC 69846-140-01

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**Alophen<sup>®</sup>**  
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**Gentle, Effective**

## Overnight Relief

100 Tablets, 5 mg. each

### REFER TO OUTER CARTON FOR FULL INFORMATION

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NDC 69846-140-01  
*Now Smaller, Easier to Swallow*

**Alophen<sup>®</sup>**  
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Comfort Coated  
Stimulant Laxative

*Gentle, Effective  
Overnight Relief*

100 Tablets, 5 mg. each

**REFER TO OUTER CARTON FOR FULL INFORMATION**

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


**DIRECTIONS:** do not chew tablets. Adults and children 12 years of age and over, take 1-3 tablets in a single dose. Children 6 to under 12 years of age, take 1 tablet in a single dose. Children under 6 years of age, consult a doctor. **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.

**ACTIVE INGREDIENT:** Bisacodyl

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LOT #  
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## ALOPHEN

bisacodyl tablet, coated

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69846-140 |
| <b>Route of Administration</b> | 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 |
|-----------------|----------|
|-----------------|----------|

|                                                            |  |
|------------------------------------------------------------|--|
| <b>Acacia</b> (UNII: 5C5403N26O)                           |  |
| <b>Ammonia</b> (UNII: 5138Q19F1X)                          |  |
| <b>Calcium Carbonate</b> (UNII: H0G9379FGK)                |  |
| <b>Carnauba Wax</b> (UNII: R12CBM0EIZ)                     |  |
| <b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)                  |  |
| <b>Starch, Corn</b> (UNII: O8232NY35J)                     |  |
| <b>D&amp;C Yellow No. 10</b> (UNII: 35SW5USQ3G)            |  |
| <b>Fd&amp;C Yellow No. 6</b> (UNII: H77VEI93A8)            |  |
| <b>Hypromellose, Unspecified</b> (UNII: 3NXW29V3WO)        |  |
| <b>Ferrosoferric Oxide</b> (UNII: XM0M87F357)              |  |
| <b>Anhydrous Lactose</b> (UNII: 3SY5LH9PMK)                |  |
| <b>Magnesium Stearate</b> (UNII: 70097M6I30)               |  |
| <b>Methylparaben</b> (UNII: A2I8C7HI9T)                    |  |
| <b>Polydextrose</b> (UNII: VH2XOU12IE)                     |  |
| <b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A) |  |
| <b>Polyvinyl Acetate Phthalate</b> (UNII: 58QVG85GW3)      |  |
| <b>Povidone, Unspecified</b> (UNII: FZ989GH94E)            |  |
| <b>Propylene Glycol</b> (UNII: 6DC9Q167V3)                 |  |
| <b>Propylparaben</b> (UNII: Z8IX2SC1OH)                    |  |
| <b>Shellac</b> (UNII: 46N107B71O)                          |  |
| <b>Dimethicone</b> (UNII: 92RU3N3Y1O)                      |  |
| <b>Sodium Alginate</b> (UNII: C269C4G2ZQ)                  |  |
| <b>Sodium Benzoate</b> (UNII: OJ245FE5EU)                  |  |
| <b>Sodium Bicarbonate</b> (UNII: 8MDF5V39QO)               |  |
| <b>Stearic Acid</b> (UNII: 4ELV7Z65AP)                     |  |
| <b>Sucrose</b> (UNII: C151H8M554)                          |  |
| <b>Talc</b> (UNII: 7SEV7J4R1U)                             |  |
| <b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)                 |  |
| <b>Triacetin</b> (UNII: XHX3C3X673)                        |  |
| <b>Triethyl Citrate</b> (UNII: 8Z96QXD6UM)                 |  |

### Product Characteristics

|                 |                |                     |          |
|-----------------|----------------|---------------------|----------|
| <b>Color</b>    | YELLOW, ORANGE | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND          | <b>Size</b>         | 6mm      |
| <b>Flavor</b>   |                | <b>Imprint Code</b> | TCL;003  |
| <b>Contains</b> |                |                     |          |

### 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 Drug | M007     | 04/15/1907 | 06/01/2024 |

**Labeler** - NUMARK BRANDS, INC (080184668)

Revised: 12/2023

NUMARK BRANDS, INC