ACTIDOSE- activated charcoal suspension Padagis US LLC

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.

ACTIDOSE® Drug Facts

Active ingredient

Activated Charcoal

Purpose

Poison Adsorbent

Use

For emergency use to adsorb swallowed poisons.

Warnings

- **do not give** activated charcoal until after the patient has vomited unless directed by a health professional.
- do not use in persons who are not fully conscious.
- do not use this product, unless directed by a health professional, if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, cleaning fluid or furniture polish, have been ingested.

Keep Out of Reach of Children

Directions

- Shake well.
- Unscrew cap and remove foil seal. Replace cap to administer.
- If delivering entire container to patient, rinse container with water and give residue to patient to ensure entire dose has been delivered.

| | Under 1 year | 1 - 12 years | Adults (over 12 years) |
|-------------|--------------|---|------------------------|
| Single Dose | | 25 - 50 g (120 - 240 mL) do not use 25 g in child weighing less | 50 g (240 mL) |

| Multiple Dose | pounds) do not use 50 g in child weighing less than 32 kg (70 pounds) Not recommended for children or adults | |
|---------------|---|--|
| | than 16 kg (35 | |

 If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying. Keep patient active and moving. Save the container of poison.

Other information

 Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]. Do not refrigerate.

Inactive Ingredients

Citric acid, glycerin, propylene glycol, sorbitol, and water.

Questions?

Please call 1-800-328-5113

Package/Label Principal Display Panel

NDC 0574-0520-04

ACTIDOSE® with SORBITOL

ACTIVATED CHARCOAL SUSPENSION

25 grams Activated Charcoal

48 grams Sorbitol

POISON ADSORBENT

If possible call a Poison Control Center, emergency medical facility, or health professional for help before using this product. If help cannot be reached quickly, follow directions on this label. Write emergency phone numbers in space provided.

Local Poison Control Center: 1-800-222-1222

Emergency Phone Number:

WARNING: Cancer and Reproductive Harm – www.P65Warnings.ca.gov.

NET CONTENTS: 120 mL (4 fl oz)



Manufactured By
Perrigo
®
Mirneapolis, MN55427
22xt 145 8/509 RT F1 Rev02-20 A

NDC 0574-0520-04 ACTIDOSE

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25 grams Activated Charcoal 48 grams Sorbitol

POISON ADSORBENT

If possible call a Polson Control Center, emergency medical facility, or health professional for help before using this product. If help cannot be reached quickly, follow directions on this label. Read label warnings and directions upon buying this product. Write emergency phone numbers in space provided. Local Poison Control Center: 1-800-222-1222 **Emergency Phone Number:**

MARNING: Cancer and Reproductive Harm www.P65Warnings.ca.gov.

NET CONTENTS: 120 mL (4 fl oz)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED PROTECTIVE SEAL UNDER THE CAP IS BROKEN OR MISSING.

| Drug Facts | Drug Facts (c | ontinued) | | |
|--|---------------|--|--|---------------------------|
| Active ingredient (in each bottle) Purpose Activated Charcoal | | Under 1 year | 1 – 12 years | Adults (over 12 years) |
| Use ■ For emergency use to adsorb swallowed poisons. | Single Dose | Do not use | 25 – 50 g (120 – 240 mL) do not use 25 g in child weighing less than | 50 g (240 mL) |
| Warnings do not give activated charcoal until after the patient has vomited unless directed by a health professional. do not use in persons who are not fully conscious. | | | 16 kg (35 pounds) do not use 50 g in child weighing less than 32 kg (70 pounds) | |
| ■ do not use this product, unless directed by a health | Multiple Dose | Not recommended for children or adults | | |
| professional, if turpentine, corrosives, such as | - W | | at a resistant annulus as | |

■ If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying. Keep patient active and moving. Save the container of poison.

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Directions ■ Shake well.
■ Unscrew cap and remove foil seal. Replace cap to

container with water and give residue to patient to ensure entire dose has been delivered.

■ If delivering entire container to patient, rinse

Keep out of reach of children.

■ Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

Do not refrigerate.

Inactive ingredients
Citric acid, glycerin, propylene glycol, sorbitol, and water.

Questions? Please call 1-900-328-5113

ACTIDOSE

activated charcoal suspension

Product Information

HUMAN OTC DRUG **Product Type Item Code (Source)** NDC:0574-0520

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|-------------------|
| ACTIVATED CHARCOAL (UNII: 2P3VWU3H10) (ACTIVATED CHARCOAL - UNII:2P3VWU3H10) | ACTIVATED CHARCOAL | 208 mg in 1 mL |

Inactive Ingredients Ingredient Name Strength ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) SORBITOL (UNII: 506T60A25R) WATER (UNII: 059QF0KO0R)

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0574-0520- 04 | 120 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/05/2020 | |
| 2 | NDC:0574-0520- 08 | 240 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/10/2021 | |
| 3 | NDC:0574-0520- 74 | 120 mL in 1 TUBE; Type 0: Not a Combination Product | 02/19/2021 | |

| | 40 mL in 1 TUBE; Type 0: Not a Combination roduct | 12/05/2020 | |
|-----------------------|---|-------------------------|-----------------------|
| | | | |
| Marketing In | nformation | | |
| - | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| Marketing | Application Number or Monograph | _ | _ |

Labeler - Padagis US LLC (967694121)

Revised: 12/2021 Padagis US LLC