ACTIDOSE AQUA- 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®-Aqua 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. 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	1 g/kg (5 mL/kg)	25 – 50 g (120 – 240 mL)	50 – 100 g (240 – 480 mL)
Multiple Dose	1 g/kg	25 – 50 g	50 – 100 g

	(5 mL/kg) every 4 – 6 hours	(120 – 240 mL) every 4 – 6 hours	(240 – 480 mL) every 4 – 6 hours

- 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, sucrose, and water.

Questions?

Please call 1-800-328-5113

Package/Label Principal Display Panel

NDC 0574-0521-04

ACTIDOSE®-Aqua

ACTIVATED CHARCOAL SUSPENSION

25 grams Activated Charcoal

POISON ADSORBENT

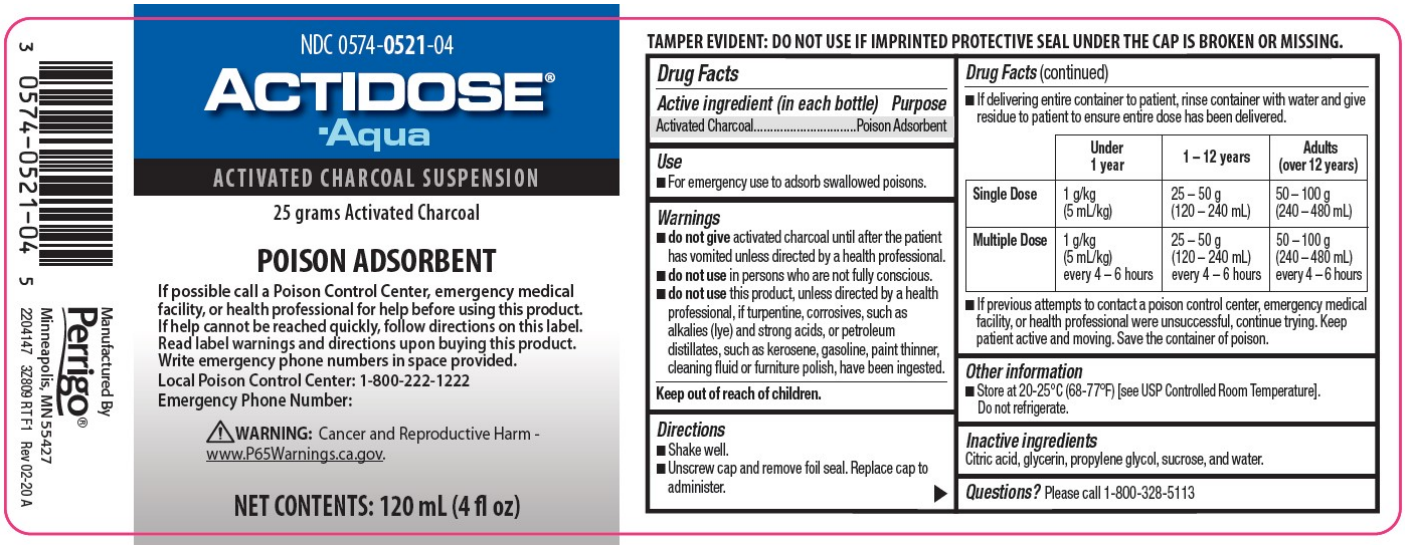
If possible call a Poison Control Center, emergency medical facility, or health professional for help before using this product. If help cannot be reached quickly, follow directions on this label. Read label warnings and directions upon buying this product. Write emergency phone numbers in space provided.

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

Emergency Phone Number:

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

NET CONTENTS: 120 mL (4 fl oz)



ACTIDOSE AQUA

activated charcoal suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0574-0521
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)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-0521-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
2	NDC:0574-0521-08	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
3	NDC:0574-0521-25	72 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2099	

4	NDC:0574-0521-74	120 mL in 1 TUBE; Type 0: Not a Combination Product	11/10/2020	
5	NDC:0574-0521-76	240 mL in 1 TUBE; Type 0: Not a Combination Product	12/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part357	11/10/2020	

Labeler - Padagis US LLC (967694121)

Revised: 12/2021 Padagis US LLC