CHILDRENS ALLERGY - diphenhydramine hydrochloride tablet
Capricorn Pharma Inc.

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.

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCl 12.5mg

Purpose

Antihistamine

Uses For the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies or allergic rhinitis.

Warnings

Do not use

- with any other product containing Diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of prostate gland

Ask a doctor before use if you are taking sedatives or tranquilizers

When using this product

- Avoid alcoholic beverages
- Marked drowsiness may occur
- Alcohol, sedatives and tranquilizers may increase the drowsiness effect
- Excitability may occur, especially in children
- Be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Center right away (1-800-222-1222).

Directions

- Take every 4 to 6 hours
- Do not take more than 6 times in 24 hours

Adults and Children 12 years of age and over	2 to 4 tablets
Children 6 to under 12 years of age	1 to 2 tablets
Children under 6 years of age	Consult a doctor
Children under 4 years of age	Do not use

Other Information

- Do not use if carton is opened or blister unit is broken
- Store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- See end panel for lot number and expiration date.

Inactive ingredients

aqueous ethyl cellulose dispersion, citric acid, crospovidone, D and C Red # 7 calcium lake, dibasic calcium phosphate, flavor, magnesium stearate, maltodextrin, mannitol, methacrylic acid copolymer, microcrystalline cellulose, modified food starch, silicon dioxide, sodium lauryl sulfate, sodium starch glycolate, sucralose, talc, triacetin

Principal Display Panel

Capricorn Pharma

ORIGINAL DEVELOPERS AND MANUFACTURERS

NDC 66007-212-02

COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S BENADRYL ALLERGY FASTMELT

Children's Allergy

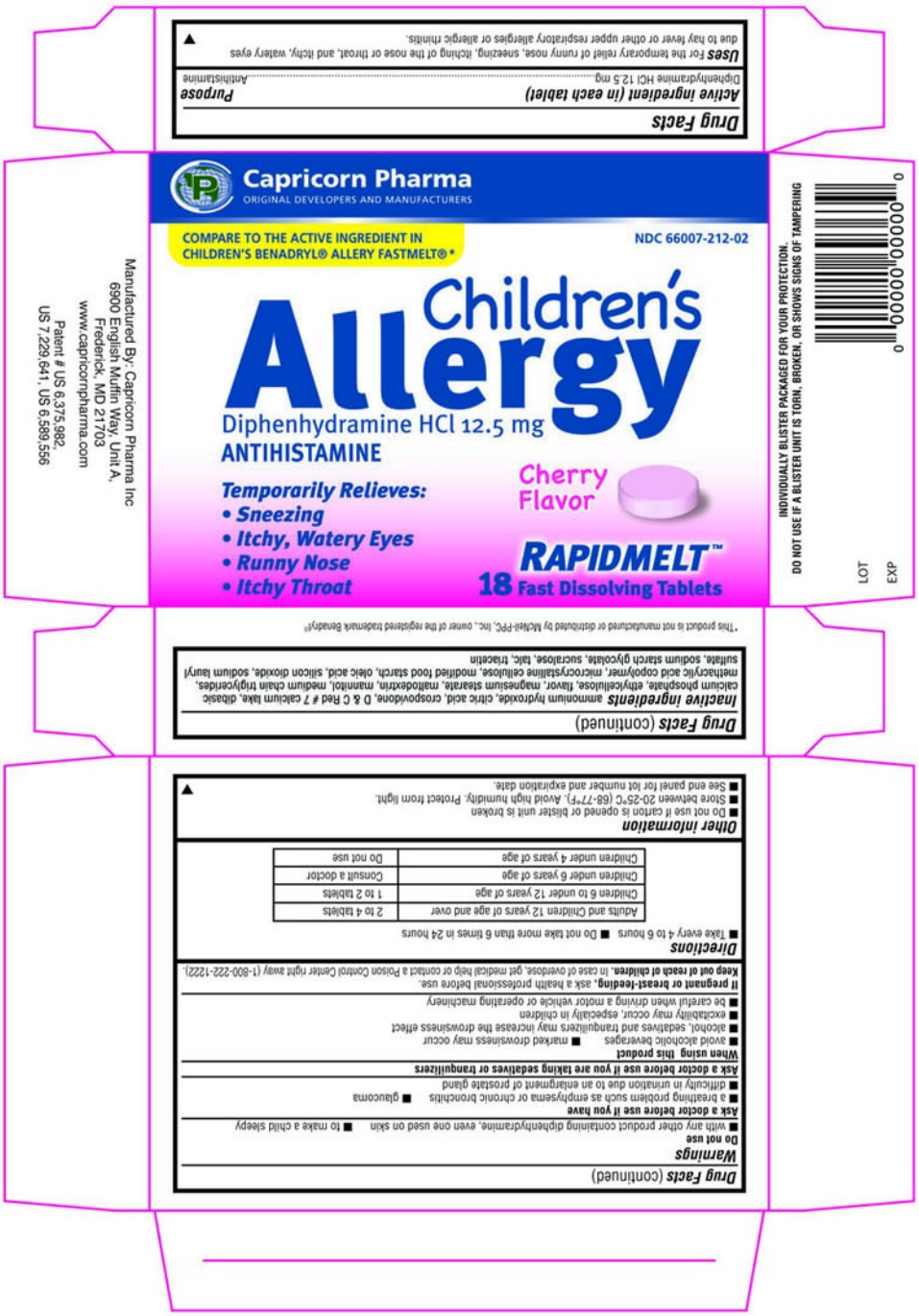
Diphenhydramine HCl 12.5mg

ANTIHISTAMINE

Temporarily Relieves:
- Sneezing
- Itchy, Watery Eyes
- Runny Nose
- Itchy Throat

Cherry Flavor

RAPIDMELT
18 Fast Dissolving Tablets



CHILDRENS ALLERGY

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66007-212
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ETHYLCELLULOSE (UNII: 7Z8S9VYZ4B)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CROSPOVIDONE (UNII: 68401960MK)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MANNITOL (UNII: 3OWL53L36A)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	
AMMONIA (UNII: 5138Q19F1X)	
CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85)	
OLEIC ACID (UNII: 2UMI9U37CP)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor	CHERRY	**Imprint Code**	None
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66007-212-02	3 in 1 CARTON		
1	NDC:66007-212-01	6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/29/2010	

Labeler - Capricorn Pharma Inc. (041704524)

Registrant - Capricorn Pharma Inc. (041704524)

Establishment

Name	Address	ID/FEI	Business Operations
Capricorn Pharma Inc.		041704524	manufacture

Revised: 10/2010 Capricorn Pharma Inc.