FIRSTCARE CHILDRENS ALLERGY RELIEF- diphenhydramine hcl bar, chewable
USpharma Ltd

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.

FIRSTCARE CHILDREN'S ALLERGY RELIEF

Active ingredient (in each soft chew)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- Runny nose
- Itchy, watery eyes
- Sneezing
- Itching of the nose or throat

Warnings

Do not use

- To make child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

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

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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 Control Center (1-800-222-1222) right away.

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

- Instruct child to chew each soft chew thoroughly before swallowing
- find right dose on chart below

Age (yr)	Dose (soft chew)
Children under 2 years	Do not use
Children 2 to 5 years	Do not use unless directed by a doctor
Children 6 to 11 years	1 to 2 soft chews (12.5 mg to 25 mg)
Adults and children 12 years and over	2 to 4 soft chews (25 mg to 50 mg)

Other information

- each soft chew contains **sodium 7 mg**.

  very low sodium
- store in a cool dry place between 20-25°C (68-77°F).
- **Child Resistant Container;do not use if printed seal under cap is broken or missing.**

Inactive ingredients:

citric acid, flavor, glucose syrup, hydroxypropyl betadex, magnesium stearate, maltitol solution, maltodextrin, mineral oil, neotame, purified water, seaweed extract (carrageenan), sodium chloride, starch, sucralose, sucrose, trisodium citrate dihydrate.

Questions or comments?

Call **1-800-227-6151**

Package/Label Principal Display Panel

FIRSTCARE TM

*****MADE IN USA*****

Bubble Gum Flavored

CHILDEREN'S ALLERGY RELIEF

Diphenhydramine HCl Anthihistamine 12.5 mg

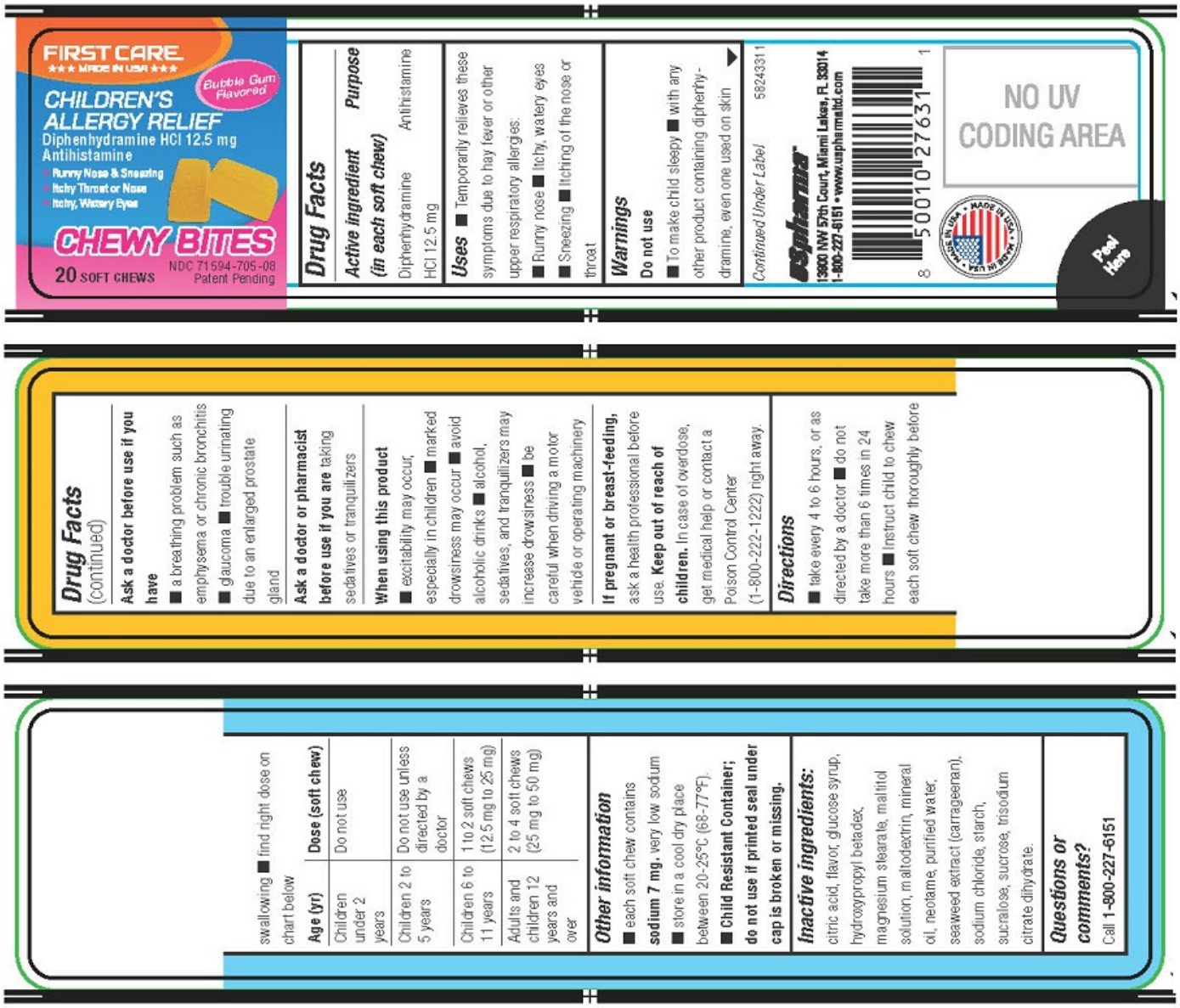
- **Runny Nose & Sneezing**
- **Itchy throat or Nose**
- **Itchy, Water Eyes**

CHEWY BITES

20 SOFT CHEWS

NDC 71594-705-08

Patent Pending



FIRSTCARE CHILDRENS ALLERGY RELIEF

diphenhydramine hcl bar, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71594-705
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**

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
NEOTAME (UNII: VJ597D52EX)	
CORN SYRUP (UNII: 9G5L16BK6N)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
MALTITOL (UNII: D65DG142WK)	
HYDROXYPROPYL BETADEX (UNII: 1I96OHX6EK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCROSE (UNII: C151H8M554)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	yellow (Light yellow to golden brown)	**Score**	no score
Shape	RECTANGLE	**Size**	18mm
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71594-705-08	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/21/2020	

Labeler - USpharma Ltd (080664601)

Registrant - USpharma Ltd (080664601)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	manufacture(71594-705) , pack(71594-705)

Revised: 12/2020 USpharma Ltd