

CHILDRENS PAIN RELIEF- acetaminophen 80 mg tablet

Allegiant Health

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

Acetaminophen 80 mg

Purpose

Analgesic/Antipyretic

Uses

temporary relief of minor aches and pains associated with common cold and flu headache toothache sore throat immunizations and reduction of fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes more than 5 doses in 24 hours taken with other drugs containing acetaminophen

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly

Do not use

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask doctor before use if your child has

liver disease

Ask doctor or pharmacist before use if

the user is taking the blood thinning drug warfarin

When using this product

do not exceed recommended dose; taking more than the recommended dose (overdose) may not provide more relief and could cause serious health problems

Stop use and ask a doctor if

symptoms do not improve pain gets worse or lasts more than 5 days fever gets worse or lasts for more than 3 days new symptoms occur redness or swelling is present You may report side effects to 888-952-0050

Keep Out of Reach of Children

In case of accidental overdose, contact a doctor or Poison Control Center immediately. Prompt medical attention is critical even if you do not notice any signs or symptoms

Directions

this product does not contain directions or complete warnings for adult use chew tablets before swallowing all dosages may be repeated every 4 hours, but not more than 5 doses in a 24 hour period follow the chart below for proper dosing or as directed by a doctor if possible, use weight for dosing, otherwise use age

Weight (lbs)	Under 24	24-35	36-47	48-59	60-71	72-95
Age (yrs)	Under 2	2-3	4-5	6-8	9-10	11
Tablets	Consult a doctor	2	3	4	5	6

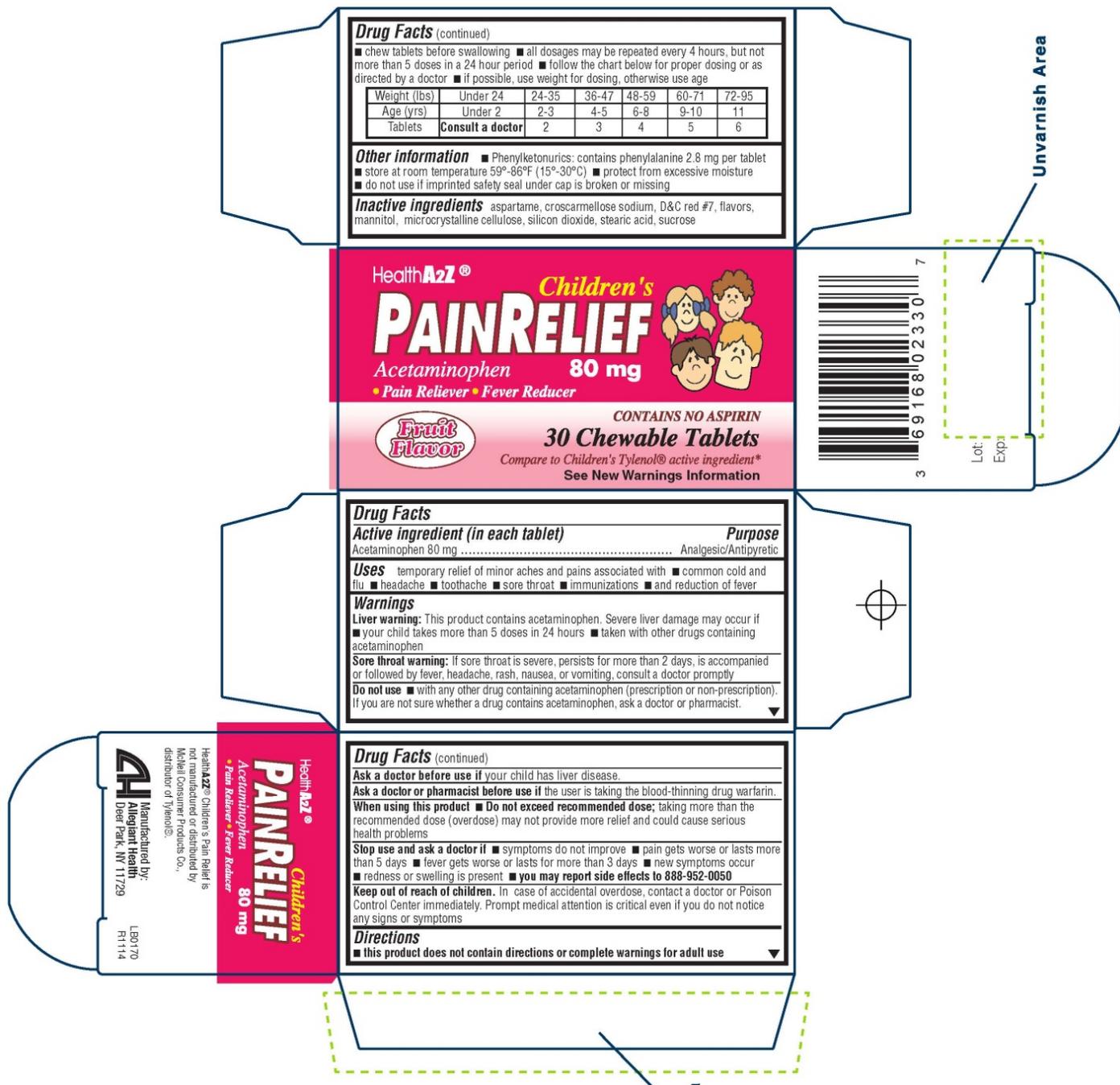
Other information

Phenylketonurics: contains phenylalanine 2.8 mg per tablet store at room temperature protect from excessive moisture do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

aspartame, croscarmellose sodium, D&C red #7, flavors, mannitol, microcrystalline cellulose, silicon dioxide, stearic acid, sucrose

Package/Label Principal Display Panel



CHILDRENS PAIN RELIEF

acetaminophen 80 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-023
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	10 mm
Flavor	FRUIT	Imprint Code	AZ023
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-023-30	30 in 1 BOX; Type 0: Not a Combination Product	03/03/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/03/2015	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	LABEL(69168-023) , MANUFACTURE(69168-023) , PACK(69168-023) , RELABEL(69168-023) , REPACK(69168-023)

Revised: 3/2015

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