PAIN RELIEF- acetaminophen tablet, film coated, extended release H E B

HEB Pain Relief 8 HR Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- headache
- minor pain of arthritis
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have

liver disease

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• do not take more than directed (see overdose warning)

adults and children 12 years and over	 take 2 caplets every 8 hours with water swallow whole; do not crush, chew, split or dissolve do not take more than 6 caplets in 24 hours do not use for more than 10 days unless directed by a doctor
children under 12 years	• do not use

Other information

• store at $20-25^{\circ}$ C (68-77°F). Avoid excessive heat 40° C (104° F).

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Tylenol® 8HR active ingredient

PAIN RELIEF 8 HR

Acetaminophen Extended-Release Tablets, 650 mg

Pain Reliever – Fever Reducer

ACTUAL SIZE

For up to 8 Hour Relief of Minor Muscle Aches & Pain

Headache/Backache/Minor Pain of Arthritis

See New Warning

GLUTEN FREE

50 Caplets* - 650 mg EACH

*Capsule-Shaped Tablets





EXP

LOT NO.



U.S. Patent 7,897,172

Contains No Aspirin

DO NOT USE IF PRINTED FOIL UNDER CAP IS

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Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Drug Facts (continued)

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Directions

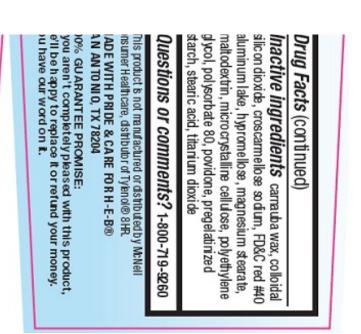
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-	
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12 years



PAIN RELIEF

acetaminophen tablet, film coated, extended release

Product I	nformation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-455

Route of Administration ORAL

Active Ingredient/Active Moiety

-	Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 IT	L9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics				
	Color	RED	Score	no score

Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	L217
Contains			

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:37808-455-71	1 in 1 CARTON	10/01/2005		
	1	50 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	10/01/2005	

Labeler - HEB (007924756)

Revised: 12/2019 HE B