

TENSION HEADACHE RELIEF- acetaminophen, caffeine tablet

Walgreen Company

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.

Walgreens 44-572

Active ingredients (in each gelcap)

Acetaminophen 500 mg
(formulated with 65 mg caffeine)

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches

Warnings

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

- more than 4,000 mg of acetaminophen in 24 hours
- 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.

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

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

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

- new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

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.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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**
- adults and children 12 years and over: take 2 gelcaps every 6 hours. Do not take more than 6 gelcaps in 24 hours.
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, shellac glaze, silicon dioxide, simethicone, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel**Walgreens**

Compare to Excedrin[®] Tension
Headache active ingredients^{††}

NDC 0363-0572-31

Tension Headache Relief

**ACETAMINOPHEN /
CAFFEINE / PAIN RELIEVER**

ASPIRIN FREE GELCAPS

80 GELCAPS
QUICK GELS™

ACTUAL SIZE

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**

†Walgreens Pharmacist Survey

††This product is not manufactured or distributed by GSK Consumer Healthcare S.A., owner of the registered trademark Excedrin® Tension Headache.

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

Walgreens

100% SATISFACTION
GUARANTEED

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50844 REV1119C57231



Walgreens 44-572

TENSION HEADACHE RELIEF

acetaminophen, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0572
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0572-31	1 in 1 CARTON	02/09/2009	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0572-09	1 in 1 CARTON	02/09/2009	07/08/2018
2		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	02/09/2009	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
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LNK International, Inc.		038154464	PACK(0363-0572)
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Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0572)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0572)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0572)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0572)

Revised: 2/2020

Walgreen Company