# HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet TARGET Corporation

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.

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#### **Drug Facts**

Active ingredients (in each geltab)
Acetaminophen 250 mg
Aspirin 250 mg (NSAID)\*

Caffeine 65 mg

#### **Purposes**

Pain reliever

Pain reliever

Pain reliever aid

#### Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - premenstrual and menstrual cramps

#### Warnings

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness

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

- skin reddening
- blisters
- rash

<sup>\*</sup>nonsteroidal anti-inflammatory drug

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

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**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

**Stomach bleeding warning**: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**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 heartbeat.

#### Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- 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 a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

#### Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

#### Stop use and ask doctor if

• an allergic reaction occurs. Seek medical help right away.

- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- painful area is red and swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

These could be signs of a serious condition.

#### If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

#### 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. 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 use more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 geltabs every 6 hours; do not take more than 8 geltabs in 24 hours
- children under 12 years: do not use unless directed by a doctor

#### Other information

• store between 20°-25°C (68°-77°F)

#### **Inactive ingredients**

black printing ink,corn starch, D&C yellow #10 aluminum lake, edetate disodium, FD&C blue #1 aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hydroxypropyl cellulose, hydroxypropyl cellulose-low substituted, hypromellose, iron oxide black, maltitol, povidone, purified water, stearic acid, talc, titanium dioxide

#### **Questions?**

Call 1-800-910-6874

#### **Principal Display Panel**

Compare to active ingredients in Excedrin® Extra Strength† extra strength

#### headache relief

acetaminophen, 250 mg pain reliever aspirin (NSAID), 250 mg pain reliever caffeine, 65 mg pain reliever aid

**GELTABS** 

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Excedrin® Extra Strength.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by Target Corporation Minneapolis, MN 55403

#### Package Label

Exp. Date:

Lot No.:

PLD-D514C FC008571



01 0434 R03 C-000703-01-04

# **Drug Facts** (continued

product because too much caffeine may cause nervousness about as much caffeine as a cup of coffee. Limit the use of

Pain reliever aid

Purposes Pain relieve

Active ingredients (in each geltab)

- if you have ever had an allergic reaction to acetaminophen, aspirin
  - with any other drug containing acetaminophen (prescription or If you are not sure whether a drug contains nonprescription).

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or

recovering from chicken pox or flu-like symptoms should not use this

Reye's syndrome: Children and teenagers who have or are

product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could

# Ask a doctor or pharmacist before use if you are

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Liver warning: This product contains acetaminophen. Severe liver

■ more than 4,000 mg of acetaminophen in 24 hours

damage may occur if you take:

with other drugs containing acetaminophen

Shock

may include: hives a facial swelling

asthma (wheezing)

 ringing in the ears or loss of hearing occurs painful area is red or swollen

3 or more alcoholic drinks every day while using this product
 Stomach bleeding warning: This product contains an NSAID, which

may cause severe stomach bleeding. The chance is higher if you:

are age 60 or older

- fever gets worse or lasts for more than 3 days

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**Drug Facts** (continued

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caffeine-confaining medications, foods, or beverages while taking this mitability, sleeplessness, and, occasionally, rapid heartbeat

- or any other pain reliever/fever reducer
- acetaminophen, ask a doctor or pharmacist

children under 12 years: do not use unless directed by a doctor

adults and children 12 years and over take 2 geltabs every 6 hours; do not take more than 8 geltabs in 24 hours

do not use more than directed drink a full glass of water with each dose

# Ask a doctor before use if you have liver disease

- you have a history of stomach problems, such as heartburn kidney disease

Inactive ingredients black printing ink, com starch, D&C

store between 20°-25°C (68°-77°F)

Other information

yellow #10 aluminum lake, edetate disodium, FD&C blue #1

aluminum lake, FD&C red #40 aluminum lake, gelatin, glycerin, hydroxypropyl cellulose, hydroxypropyl cellulose, hydroxypropyl cellulose, low substituted hypromellose, iron oxide black, matitiol, povidone, purified water,

■ you have asthma
■ you are taking a diuretic

# Stop use and ask a doctor if

have bloody or black stools

have stomach pain that does not get better

This product is not manufactured or distributed by

Questions? Call 1-800-910-6874

stearic acid, talc, titanium dioxide

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Excedrin® Extra Strength

- pain gets worse or lasts for more than 10 days

These could be signs of a serious condition.

MANPER EVIDENT: DO 40T USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSIRG

WARRAIDS AND PRODUCT INFORMATION. KEEP OUTER CARTON FOR COMPLETE

 take other drugs containing prescription or nonprescription NSAIDs take a blood thinning (anticoagulant) or steroid drug have had stornach ulcers or bleeding problems

have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed aspirin, ibuprofen, naproxen, or others

Caffeine warning: The recommended dose of this product contains

NDC 11673-686-80



80 **GELTABS** 

Compare to active ingredients in Excedrin® Extra Strength<sup>†</sup>

temporarily relieves minor aches and pains due to

monsteroidal anti-inflammatory drug

Caffeine 65 mg.

premenstrual and menstrual cramps

toothache

muscular aches

a cold

headache

## extra strength eadache reli

acetaminophen, 250 mg pain reliever aspirin (NSAID), 250 mg pain reliever caffeine, 65 mg pain reliever aid



80 GELTABS

#### **TARGET Extra Strength Headache Relief**

#### **HEADACHE RELIEF EXTRA STRENGTH**

acetaminophen, aspirin, caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-686
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	250 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
MALTITOL (UNII: D65DG142WK)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM OXIDE (UNII: LMI2606933)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	

Product Characteristics			
Color	white (green)	Score	no score
Shape	CAPSULE (Round shaped)	Size	13mm
Flavor		Imprint Code	Р
Contains			

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:11673- 686-20	1 in 1 BOX	01/31/2018	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
	NDC:11673- 686-80	1 in 1 BOX	01/31/2018	
2		80 in 1 BOTTLE, PLASTIC; 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	01/31/2018	

## Labeler - TARGET Corporation (006961700)

Revised: 7/2023 TARGET Corporation