

TOPCARE EXTRA STRENGTH HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet, film coated
Topco Associates LLC

EXTRA STRENGTH Headache Relief

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID*)
Caffeine 65 mg
*nonsteroidal anti-inflammatory drug

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
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 • asthma (wheezing) • shock

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

- more than 8 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

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 heart beat.

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 are taking a diuretic • you have asthma

Ask a doctor or pharmacist before use if you are taking

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

Stop use and ask a 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 or 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 during the last 3 months of 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 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 of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- each caplet contains: **sodium 5mg** (low sodium)
- store at 20-25°C(68-77°F)
- close cap tightly after use

Inactive ingredients

croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol, polyvinyl alcohol, povidone K-30, purified talc, sodium lauryl sulfate, sodium starch glycolate, starch, titanium dioxide

Questions or comments:

Call **1-888-423-0139**

COMPARE TO EXCEDRIN® EXTRA STRENGTH ACTIVE INGREDIENTS⁺

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

⁺This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

Product of India

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION.

REV.00-112023 CT7616214201

Packaging



EXTRA STRENGTH
Headache Relief
 ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE
 PAIN RELIEVER / PAIN RELIEVER AID



100 CAPLETS

actual size

This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Extra Strength.
 DISTRIBUTED BY TOPCO ASSOCIATES LLC
 BLK GROVE VILLAGE, IL 60007

Product of India

READ AND KEEP OUTER CARTON FOR COMPLETE PRODUCT WARNINGS AND INFORMATION

UPC FPO

NO VARNISH
 LOT
 EXP
 C77616214201 REV/06-11/2023

SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Questions or comments: Call 1-888-423-0139
 Inactive ingredients: croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polydioxane, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, potassium hydroxide, sodium lauryl sulfate, sodium phosphate dibasic, stearic acid, titanium dioxide, xanthan gum
 Other information: Each caplet contains 2.5 mg of caffeine. Do not use more than 2 caplets every 6 hours; not more than 8 caplets in 24 hours. Do not use more than 2 caplets every 6 hours; not more than 8 caplets in 24 hours. Do not use more than 2 caplets every 6 hours; not more than 8 caplets in 24 hours. Do not use more than 2 caplets every 6 hours; not more than 8 caplets in 24 hours.
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 Drug Facts (Continued)

Drug Facts
Active ingredients (in each caplet)
 Acetaminophen 250 mg Pain reliever
 Aspirin 250 mg (NSAID) Pain reliever and nonsteroidal anti-inflammatory drug
 Caffeine 65 mg Pain reliever
Purposes
 Pain reliever and nonsteroidal anti-inflammatory drug
Warnings
 There's a serious risk of stomach bleeding and ulcers with this product. 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 redness, blisters, rash. 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, asthma (wheezing), shock.
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 • more than 8 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
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
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Drug Facts (Continued)
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 • do not use more than directed
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Questions or comments: Call 1-888-423-0139

Drug Facts (Continued)
Warnings (Continued)
 • you have a history of stomach problems, such as heartburn
 • you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
 • you are taking a diuretic
 • you have asthma
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
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 • you have asthma
Ask a doctor or pharmacist before use if you are taking
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 • any other drug, or are under a doctor's care for any serious condition
Stop use and ask a 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 or swollen
 • pain gets worse or lasts for more than 10 days
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 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 during the last 3 months of 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 right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

DRUG FACTS TABLE

Drug Facts	
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Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID)	Pain reliever
Caffeine 65 mg	Pain reliever aid
* nonsteroidal anti-inflammatory drug	
Uses	
<ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache a cold arthritis muscular aches toothache premenstrual and menstrual cramps 	
Warnings	
<p>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.</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness, blisters, rash. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock.</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> more than 8 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 <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> 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 	

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<p>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.</p> <p>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.</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> 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 are taking a diuretic you have asthma <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> a prescription drug for diabetes, gout, or arthritis any other drug, or are under a doctor's care for any serious condition <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> an allergic reaction occurs. Seek medical help right away. you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> 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 or 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms</p>

Drug Facts (Continued)
<p>Directions</p> <ul style="list-style-type: none"> do not use more than directed drink a full glass of water with each dose adults and children 12 years of age and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours children under 12 years: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> each caplet contains 2.5 mg of caffeine store at 20-25°C (68-77°F) close cap tightly after use <p>Inactive ingredients</p> <p>croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polydioxane, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, potassium hydroxide, sodium lauryl sulfate, sodium phosphate dibasic, stearic acid, titanium dioxide, xanthan gum</p> <p>Questions or comments: Call 1-888-423-0139</p>

TOPCARE EXTRA STRENGTH HEADACHE RELIEF
 acetaminophen, aspirin, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-142

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K30 (UNII: U725QWY32X)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (Oblong)	Size	18mm
Flavor		Imprint Code	S142
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-142-01	1 in 1 CARTON	11/09/2023	
1		100 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 Drug	505G(a)(3)	11/09/2023	

