

**HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet  
Dolgenercorp, Inc. (DOLLAR GENERAL & REXALL)**

*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 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
  - sinusitis
  - toothache
  - premenstrual & 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:**

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 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 are taking a diuretic
- you have asthma

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

taking

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- 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 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 appear

### **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 (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 use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years 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**

- store at controlled room temperature 20°-25°C (68°-77°F)
- excursions permitted to 15°C to 30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing
- \*\*This product is not manufactured or distributed by Novartis Consumer Health, owner of the registered trademark Excedrin® Extra Strength.

### **Inactive ingredients**

hypromellose, maltodextrin, microcrystalline cellulose, polydextrose, polyvinylpyrrolidone, pregelatinized starch, silica, starch, stearic acid, talc, titanium dioxide, and triglycerides

### **Questions or comments?**

**1-888-309-9030**

### **Principal Display Panel**

Compare to active ingredients in Excedrin® Extra Strength\*\*

**EXTRA STRENGTH**

**HEADACHE RELIEF**

**Acetaminophen 250 mg**

Aspirin 250 mg (NSAID)\* and Caffeine 65 mg

Pain Reliever/Pain Reliever Aid

**SEE NEW WARNINGS INFORMATION**

**CAPLETS**

Distributed by Dolgencorp, LLC

100 Mission Ridge, Goodlettsville, TN 37072

MADE IN U.S.A

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

**Package Label**

02789171



100453Q3

PRINT SIDE GLUE

V60x4

NO PRINT  
NO VARNISH  
NO COATING

NO PRINT  
NO VARNISH  
NO COATING

**Drug Facts (continued)**

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 aspirin/acetaminophen 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, or kidney disease. You are taking a diuretic. You have asthma.

**Ask a doctor or pharmacist before use if you are** taking (prescription or nonprescription) a blood thinning drug (anticoagulant) or steroid drug, a prescription drug for diabetes, gout, or arthritis, or any other drug, or taking any other drug containing an NSAID.

**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 in the unborn child or complications during delivery.

**Drug Facts (continued)**

**Warnings**

**Eye'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:** Aspirin may cause a severe allergic reaction (anaphylaxis) which may be fatal. Symptoms of allergic reaction include rash, hives, itching, dizziness, trouble breathing, and swelling of the face, lips, tongue, or throat. Stop using the product and get medical help right away.

**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, you have had stomach ulcers or bleeding problems, or take a blood-thinning (anticoagulant) or steroid drug, or the 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.

**Uses**

Temporarily relieves minor aches and pains due to: headache, a cold, or arthritis; muscular aches; sinusitis; toothache; premenstrual & menstrual cramps.

**Active Ingredients (in each caplet)**

Acetaminophen 250 mg (NSAID)  
Aspirin 250 mg (NSAID)  
Caffeine 65 mg  
Nonsteroidal anti-inflammatory drug  
Pain reliever aid  
Pain reliever

**Purposes**

Pain reliever  
Pain reliever  
Pain reliever

**Drug Facts (continued)**

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.

**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, you have had stomach ulcers or bleeding problems, or take a blood-thinning (anticoagulant) or steroid drug, or the other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others). Have 3 or more alcoholic drinks every day while using this product.

**Extra Strength Headache Relief**  
Acetaminophen 250mg, Aspirin 250mg (NSAID)\* and Caffeine 65mg  
Pain Reliever/Pain Reliever Aid  
100 Caplets

**Compare to active ingredients in Excedrin® Extra Strength\*\***

**Extra Strength Headache Relief**  
Acetaminophen 250mg, Aspirin 250mg (NSAID)\* and Caffeine 65mg  
Pain Reliever/Pain Reliever Aid  
SEE NEW WARNINGS INFORMATION  
100 Caplets

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

A0545

59722615210 5

Lot No.:  
Exp. Date:

**Drug Facts (continued)**

children even if you do not notice any signs or symptoms.

**Directions**

do not use more than directed

drink 8 full glasses of water with each dose. Adults and children 12 years 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**

store at controlled room temperature 20°-25° C (68°-77° F); excursions permitted to 15° to 30° C (59°-86° F). Do not use if imprinted.

**Questions or comments? 1-888-309-9030**

**Drug Facts (continued)**

Exceldrin® Extra Strength  
Consumer Health, owner of the registered trademark product is not manufactured or distributed by Novartis safety seal under cap is broken or missing. This

**100% Guaranteed Quality**  
(888) 309-9030

DISTRIBUTED BY DOLGENCORP LLC  
100 MISSION RIDGE, GOODLETTSVILLE, TN 37072  
MADE IN U.S.A.  
PLD-A  
FC000576

Headache Relief Extra Strength Caplets

<b>HEADACHE RELIEF EXTRA STRENGTH</b> acetaminophen, aspirin, caffeine tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:559 10-184

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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE K15 (UNII: E54VE15114)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	

### Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	2793
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-184-01	1 in 1 BOX	07/08/2013	07/08/2020
1		100 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	07/08/2013	07/08/2020

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)