

## **EXTRA STRENGTH HEADACHE RELIEF- acetaminophen, aspirin, and caffeine capsule Walgreens**

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

#### ***Drug Facts***

<b><i>Active ingredients (in each softgel)</i></b>	<b><i>Purposes</i></b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

#### **Uses**

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- 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**

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 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 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 and over: take 2 softgels every 6 hours; not more than 8 softgels in 24 hours
- children under 12 years: ask a doctor

### **Other information**

- store at 20° - 25° C (68° - 77° F)
- close cap tightly after use
- read all product information before using.

### **Inactive ingredients**

Beeswax, carboxymethyl cellulose, D&C Yellow No.10, ethanol, FD&C Blue No.1, gelatin, glycerin, HPMC, light liquid paraffin, PEG 400, purified water, shellac, sorbitol sorbitan solution, soya bean oil, soya lecithin, stearic acid, titanium dioxide

### **Questions or comments**

**1-888-333-9792**

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

### **PRINCIPAL DISPLAY PANEL - 80 Softgel Bottle Label**

**NEW**

**Well at  
Walgreens**

NDC 0363-0021-80

**EXTRA STRENGTH**


**Headache  
Relief Softgels**

**Acetaminophen /  
Aspirin (NSAID) /  
Caffeine / Pain Reliever /  
Pain Reliever Aid**

**80 SOFTGELS**

# Compare to Excedrin® Extra Strength active ingredients ##

**NEW**



**EXTRA STRENGTH**

## Headache Relief Softgels

Acetaminophen / Aspirin (NSAID) / Caffeine / Pain Reliever / Pain Reliever Aid

### 80 SOFTGELS

Compare to Excedrin® Extra Strength active ingredients##

NDC 0363-0021-80

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

**Drug Facts**


**Active ingredients (in each softgel)**

Acetaminophen 250 mg.....Pain reliever  
 Aspirin 250 mg (NSAID)\*.....Pain reliever  
 Caffeine 65 mg.....Pain reliever aid  
 \*nonsteroidal anti-inflammatory drug

**Uses** temporarily relieves minor aches and pains due to:  
 ■ headache ■ a cold ■ arthritis  
 ■ muscular aches ■ 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 a warning 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)

**Drug Facts (continued under label)**

DISTRIBUTED BY: WALGREEN CO., 200 W. MONTRO, KEFFER, ILL. 60015  
 100% SATISFACTION GUARANTEED walgreens.com ©2016 Walgreen Co.  
**MADE IN INDIA**  
 ITEM 945065 W10070-0710-L  
 ORG0616-F  
  
 3 11917 18594 1  
 Lot No.:  
 Exp. Date:

**Drug Facts (continued)**

■ 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 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 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  
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**Other information**  
 ■ store at 20° - 25° C (68° - 77° F)  
 ■ close cap tightly after use  
 ■ read all product information before using.

**Inactive ingredients**  
 Beeswax, carbonyl methyl cellulose, D&C Yellow No. 10, ethanol, FD&C Blue No. 1, gelatin, glycerin, HPMC, light liquid paraffin, PEG 400, purified water, shellac, sorbitol sorbitan solution, soya bean oil, soya lecithin, stearic acid, titanium dioxide

**Questions or comments** 1-888-333-9792  
 Walgreens Pharmacist Recommended  
 Walgreens Pharmacist Survey Study, November 2014.  
 †This product is not manufactured or distributed by Novartis Consumer Health, Inc., owner of the registered trademark Excedrin® Extra Strength.

EXTRA STRENGTH HEADACHE RELIEF			
acetaminophen, aspirin, and caffeine capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0021
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: R16C05Y76E) (ASPIRIN - UNII:R16C05Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	
Inactive Ingredients			
Ingredient Name	Strength		
YELLOW WAX (UNII: 2ZA36H0S2V)			
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			

ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL (OBLONG)	Size	21mm
Flavor		Imprint Code	S08
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0021-80	80 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/10/2016	

**Labeler** - Walgreens (008965063)

**Registrant** - Spirit Pharmaceuticals LLC (179621011)

Establishment			
Name	Address	ID/FEI	Business Operations
Medgel Private LTD.		677385498	manufacture(0363-0021)