

**SOHMED PAIN RELIEVER- acetaminophen, aspirin, and caffeine tablet**  
**SOHM Inc.**

*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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**SohMed™ Pain Reliever**

***Drug Facts***

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

\* This Product is not manufactured or distributed by Novartis Consumer Healthcare, Inc. Owner of registered trademark Excedrin®.

**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.

Although rare, possible reactions to consumption of acetaminophen include three serious skin diseases whose symptoms can include rash, blisters and, in the worst case, widespread damage to the surface of the skin. If you are taking this product and develop a rash or other skin reaction, stop taking this product immediately and seek medical attention.

**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.

- adult takes more than 8 caplets in 24 hours, which is the maximum daily amount.
- Child takes more than 5 caplets 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 product.
- take more or for a longer time than directed.

### **Caffeine warning**

The recommended dose of this product contains about as much as 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 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 a liver disease
- stomach bleeding warning applies to you
- you have not been drinking fluids
- 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
- you have lost a lot of fluids due to vomiting or diarrhea

### **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 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 appear **if pregnant or breast-feeding**, ask 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.**

### **Overdose Warning**

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 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: asks a doctor.

### **Other information**

- store at controlled room temperature 20°-25°C(68°-77°F)
- See end flap or expiration date and lot number.

### **Inactive ingredients**

benzoic acid, carnauba wax, FD&C blue#1, hydroxypropylcellulose, Hypromellose, light mineral oil, microcrystalline cellulose, polysorbate 20, Povidone, propylene glycol, simethicone emulsion, Sorbitan monolaurate, stearic acid, titanium dioxide.

### **Question and comment?**

1(856) 2863646

**Distributed by : Sohm, Inc.**

6920 Knott Ave., Suit A-C, Buena Park, CA 90621

### **PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton**

**SohMed™**

**NDC XXXXXXXXXX**

**\*Compare to the active ingredients in Excedrin®**

***Extra Strength  
Pain Reliever***

**Acetaminophen 250 mg,  
Aspirin 250 mg (NSAID) Caffeine 65 mg**



acetaminophen, aspirin, and caffeine tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50405-008
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Acetaminophen</b> (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	250 mg
<b>Aspirin</b> (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	250 mg
<b>Caffeine</b> (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	65 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>HYDROXYPROPYL CELLULOSE (TYPE H)</b> (UNII: RFW2ET671P)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POVIDONES</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	CRX
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-008-24	1 in 1 CARTON		
1		24 in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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**Labeler** - SOHM Inc. (009303848)

Revised: 8/2013

SOHM Inc.