

SOHMED EXTRA STRENGTH- acetaminophen 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.

SohMed™ Extra Strength

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Use

- temporarily relieves minor aches and pains due to :
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. 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

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.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.**Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. 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 take more than directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none">▪ take 2 caplets every 6 hours while symptoms last.▪ do not take more than 6 caplets in 24 hours, unless directed by a doctor▪ do not use for more than 10 days unless directed by a doctor.
children under 12 years	ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- See end flap for expiration date and lot number

Inactive ingredients

carnauba wax¹, castor oil¹, corn starch, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, polyethylene glycol¹, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium starch glycolate, titanium dioxide.

Contains No Aspirin

¹ *contains one or more of these ingredients

Questions or comments?

1(856) 2863646

Distributed by : **Sohm, Inc.**
6920 Knott Ave., Suit A-C,
Buena Park, CA 90621

PRINCIPAL DISPLAY PANEL - 24 Tablet Bottle Carton

NDC XXXXXXXXXX

SohMed™

***Compare to the active ingredient of Extra Strength Tylenol® Caplets**

Extra Strength

Pain Relief

Acetaminophen

Acetaminophen 500 mg

Pain reliever • Fever reducer

contains no aspirin

24 Caplets

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

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Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?

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*This Product is not manufactured or distributed by McNeil Consumer Healthcare, owner of registered trademark Extra Strength Tylenol® Caplets.

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



www.sohm.com

NDC XXXXXXXXXX



*Compare to the active ingredient of Extra Strength Tylenol® Caplets

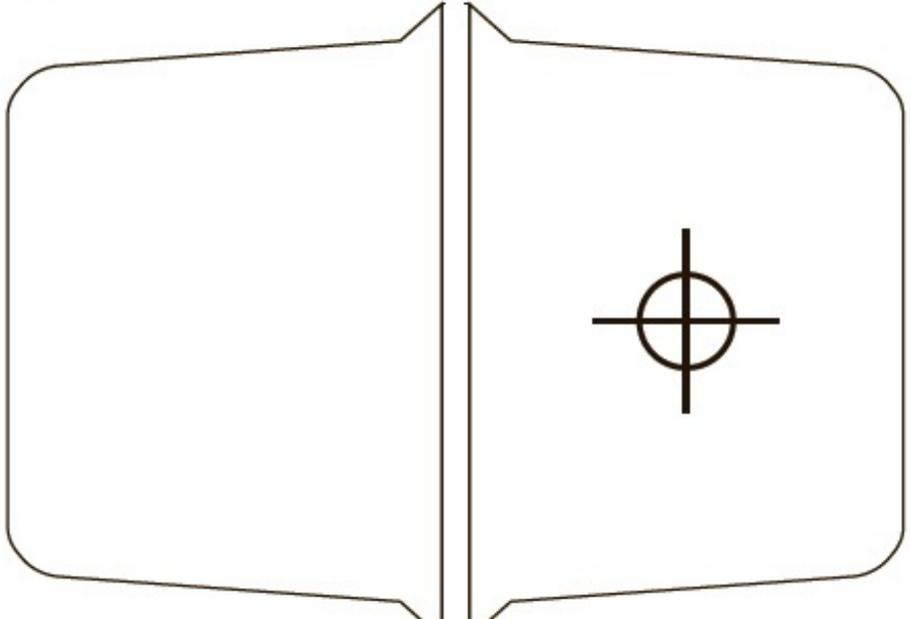
**Extra Strength
Pain Relief**

Acetaminophen

Acetaminophen 500 mg

**Pain reliever • Fever reducer
contains no aspirin**

24 Caplets



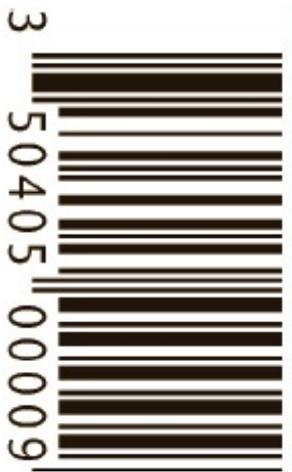
24 Caplets
Pain reliever • Fever reducer
contains no aspirin

Acetaminophen 500 mg

Acetaminophen

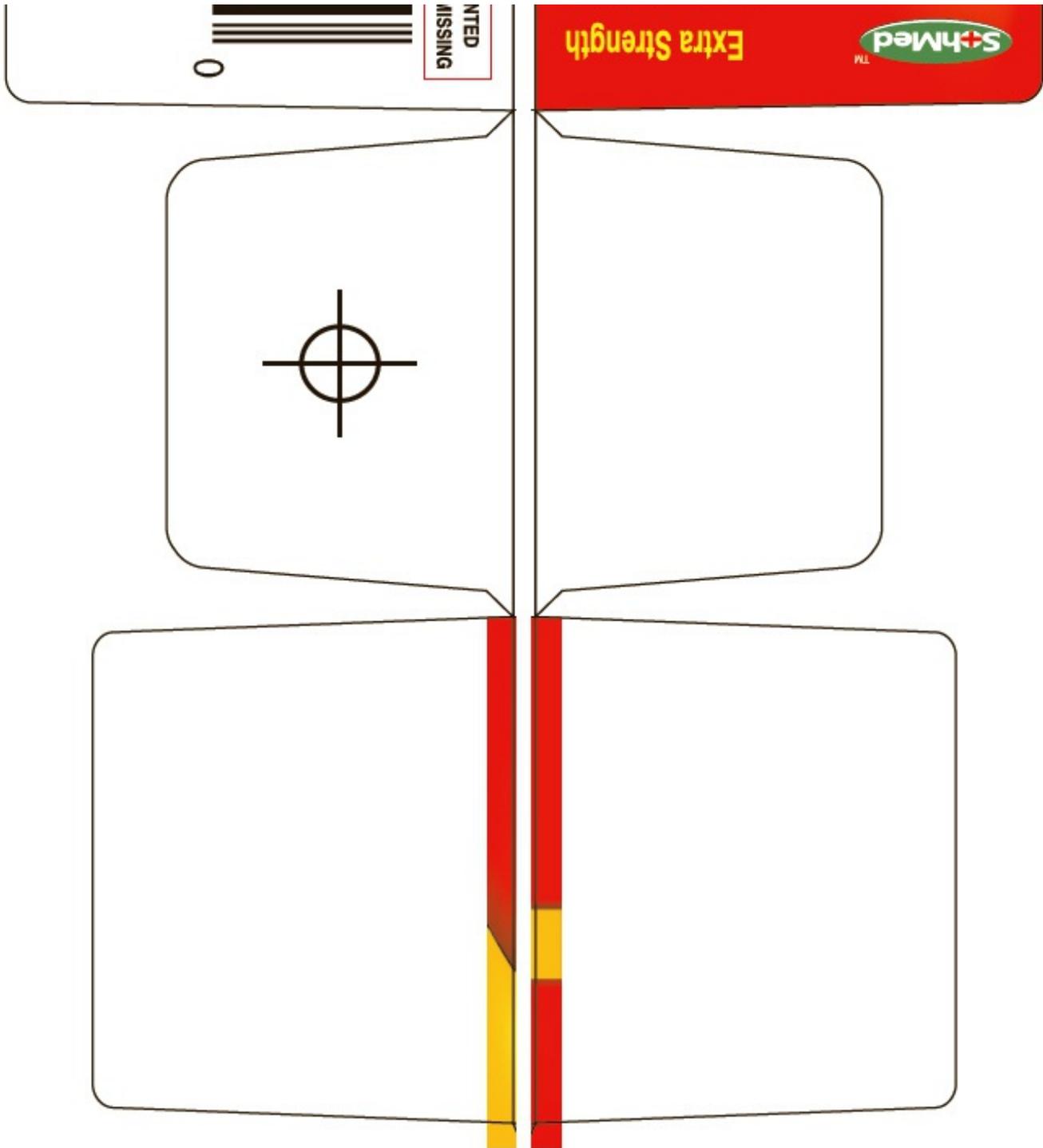
Pain Relief

TAMPER EVIDENT: DO NOT USE IF IMPRINT
SAFETY SEAL UNDER CAP IS BROKEN OR I



LOT NO.

EXP.



SOHMED EXTRA STRENGTH			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50405-001
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	500 mg
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Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CASTOR OIL (UNII: D5340Y2I9G)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	2 pieces
Shape	OVAL	Size	18mm
Flavor		Imprint Code	CRX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-001-24	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
OTC MONOGRAPH NOT FINAL	part343	08/25/2013	

Labeler - SOHM Inc. (009303848)