SUNMARK ARTHRITIS 8 HOUR- acetaminophen tablet, film coated, extended release Sunmark

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Acetaminophen USP, 650 mg

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - minor pain of arthritis
 - backache
- temporarily reduces fever

WARNINGS

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

- more than 6 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

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: 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	take 2 caplets every 8 hours with water swallow whole - do not crush, chew, split or dissolve do not take more than 6 caplets in 24 hours do not use for more than 10 days unless directed by a doctor
children under 12 years	do not use

OTHER INFORMATION

- store at 20 25° C (68 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

INACTIVE INGREDIENTS

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

QUESTIONS?

call 1-800-406-7984

Keep the carton. It contains important information.

Contains No Aspirin.

Distributed By McKesson

One Post Street, San Francisco, CA 94104

www.sunmarkbrand.com

PRINCIPAL DISPLAY PANEL

sunmark[®]

NDC 49348-924-09

See New Warnings Information

Lasts up to 8 hour

8 hour pain relief

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

FOR UP TO 8 HOUR RELIEF OF MINOR MUSCULAR ACHES & PAIN

Use only as directed.

50 CAPLETS*650 mg EACH

(*capsule-shaped tablets)

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

[†]COMPARE TO TYLENOL® 8 HOUR ACTIVE INGREDIENT

[†]This product is not manufactured or distributed by McNeil Consumer Healthcare, Inc. The owner of the registered trademark Tylenol® is The Tylenol Company.



SUNMARK ARTHRITIS 8 HOUR

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-924
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	650 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
PO VIDO NE (UNII: FZ989 GH94E)			
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics			
Color	white	Score	no score
Shape	OVAL (Capsule shaped)	Size	19 mm
Flavor		Imprint Code	cor116
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-924-09	50 in 1 BOTTLE		
2	NDC:49348-924-10	100 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	04/30/2002	

Labeler - Sunmark (177667227)

Registrant - Ohm Laboratories Inc. (051565745)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(49348-924)

Revised: 8/2012 Sunmark