

ARTHRITIS PAIN RELIEVER- acetaminophen tablet, film coated, extended release
Aidarex Pharmaceuticals LLC

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:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - toothache
 - the common cold
 - premenstrual and menstrual cramps
- 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	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
under 18 years of age	ask a doctor

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 (*Applicable only for Bottle Carton*)
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**
- **THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN. (*for non CRC packages*)**

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**

Contains No Aspirin

Keep the carton. It contains important information.

Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

Repackaged By :

Aidarex Pharmaceuticals LLC,
Corona, CA 92880

PRINCIPAL DISPLAY PANEL

NDC 33261-0665-50

EASY TO OPEN BOTTLE

Use only as directed.

See New Warnings Information

Lasts up to 8 hours

Arthritis Pain Relief

Acetaminophen Extended-Release Tablets, USP 650 mg

Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

50 CAPLETS*

650 mg EACH

(*capsule-shaped tablets)

†Compare to the active ingredient of Tylenol® Arthritis Pain

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

Repackaged By :

Aidarex Pharmaceuticals LLC,

Corona, CA 92880

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)	Packaged and Distributed by: AIDAREX PHARMACEUTICALS LLC.	ACETAMINOPHEN ER 650 mg	PEEL HERE INITIAL PATIENT LOG CHART PEEL HERE TIP
	ACETAMINOPHEN ER	NDC: 33261-0665-50 RX 1001024529 50	
	650 mg	ACETAMINOPHEN ER 650 mg	
	50 TABS	NDC: 33261-0665-50 RX1001024529 50	
	EACH TABLET CONTAINS THE FOLLOWING ACTIVE INGREDIENTS: ACETAMINOPHEN.....650 mg EXTENDED-RELEASE	ACETAMINOPHEN ER 650 mg NDC: 33261-0665-50 RX1001024529 50	
	GENERIC FOR : TYLENOL AR NDC: 33261-0665-50	ACETAMINOPHEN ER 650 mg NDC: 33261-0665-50 RX1001024529 50	
	TAKE _____ EVERY _____ HOURS _____ TIMES A DAY TOME _____ CADA _____ HORAS _____ VECES AL DIA	ACETAMINOPHEN ER 650 mg NDC: 33261-0665-50 RX 1001024529 50	
	MFG: FOR: OHM LABORATORIES INC. NORTH BRUNSWICK, NJ 08902		

ARTHRITIS PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-665(NDC:51660-333)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL (Capsule Shaped)	Size	19mm
Flavor		Imprint Code	cor116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-665-50	50 in 1 BOTTLE, PLASTIC		

Marketing Information

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

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 11/2013

Aidarex Pharmaceuticals LLC