# ARTHRITIS PAIN RELIEVER - acetaminophen tablet, film coated, extended release AvPAK

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#### **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
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache
- 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

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.

#### 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).

#### INACTIVE INGREDIENTS

croscarmellose sodium, D&C red no. 30 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

## **QUESTIONS?**

call 1-855-361-3993

**Contains No Aspirin** 

## Keep the carton. It contains important information.

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Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**NDC** 50268-052-15

Acetaminophen Extended-release Tablets USP

Arthritis Pain Relief

650 mg

50 Tablets (5 X 10) Unit Dose

**NDC** 50268-052-15

Acetaminophen Extended-release Tablets USP

Arthritis Pain Relief

650 mg

50 Tablets (5 X 10) Unit Dose

## DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN.

Use only as directed.

Manufactured for: AvKARE, Inc. Pulaski, TN 38478

Mfg. Rev. R0315 AV 02/16 (P)

#### **AvPAK**

A PRODUCT OF AvKARE



Acetaminophen Extended-release Tablets USP

Arthritis Pain Relief 650 mg

50 Tablets (5 X 10) Unit Dose



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**Arthritis Pain Relief** 



50 Tablets (5 X 10) Unit Dose



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Use only as directed.

## Drug Facts

Uses

• temporarily relieves minor aches and pains due to:

• minor pain of arthritis





N/02/16 (P)

## Drug Facts (continued)

- · muscular aches
- · backache
- · premenstrual and menstrual cramps
- · the common cold
- · headache
- · toothache
- · temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen.

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blisters

· rash

If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, as 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

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- . fever gets worse or lasts more than 3 days
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Drug Facts (continued) 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		
	than directed (see overdose warning)	
adults	take 2 tablets, every 8 hours with water     swallow whole; do not crush, chew, split or dissolve     do not take more than 6 tablets 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).		
Inactive ingredients croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide.		
Questions? call 1-855-361-3993		

Contains No Aspirin

## ARTHRITIS PAIN RELIEVER

acetaminophen tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50268-052(NDC:51660- 333)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	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)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				

STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PO VIDO NES (UNII: FZ989 GH94E)	

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

ı	Packaging						
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date			
ı	1 NDC:50268-052-15	50 in 1 BOX, UNIT-DOSE					
ı	1 NDC:50268-052-11	$1\mbox{in}1\mbox{BLISTER}$ PACK; Type 0: Not a Combination Product					

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	03/07/2016	

# **Labeler -** AvPAK (832926666)

Revised: 3/2016 AvPAK