

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

Acetaminophen Extended-release Tablets USP

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.

0115

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

NDC 50268-052-15

**Acetaminophen
Extended-release
Tablets USP**

Arthritis Pain Relief

650 mg

50 Tablets (5 X 10) Unit Dose



5026805215

NDC 50268-052-15

**Acetaminophen
Extended-release
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Arthritis Pain Relief

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5026805215

DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN
Use only as directed.

Drug Facts

Active Ingredient (in each tablet)	Purpose
Acetaminophen USP, 650 mg	Pain reliever/ fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- minor pain of arthritis

Manufactured for AvKARE, Inc. - Pineda, TN 38478
Ntg. Box 80015

N 02/14 (P)

AVPAK
A PRODUCT OF AvKARE

Peel
Here

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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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

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
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Drug Facts (continued)	
If pregnant or breast-feeding, ask a health professional before use.	
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Directions	
• do not take more than directed (see overdose warning)	
adults	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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		
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: 70097M6130)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			

STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-052-15	50 in 1 BOX, UNIT-DOSE	03/07/2016	
1	NDC:50268-052-11	1 in 1 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: 1/2024

AvPAK