

ACETAMINOPHEN- acetaminophen tablet, extended release
Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.

Acetaminophen ER 650 mg

Drug Facts

Active Ingredients (In each caplet)

Active ingredient (in each caplet)	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650mg Pain reliever/fever reducer.

Uses

- temporarily relieves minor aches and pain due to:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- 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 non-prescription). 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 if 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 of 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 of 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 between 20-25°C (68-77°F)
- do not use if foil inner seal imprinted with "SAFETY SEAL" is broken or missing.

Inactive ingredients

hydroxyethyl cellulose, maize starch, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate, FD&C yellow no. 6 aluminum lake and FD&C yellow no. 10 aluminum lake.

Questions or comments?

Call: 1.866.901.DRUG (3784) (toll-free)

Manufactured for

Heritage Pharmaceuticals Inc.,

Eatontown, NJ 07724

1.866.901.DRUG (3784)

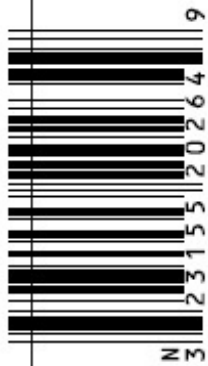
Made in India

Rev.08/16

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL Carton



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 24 Caplets Label



TO OPEN: PUSH AND TURN CAP

← READ THE LABEL →

NDC 23155-202-64

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN.

Acetaminophen Extended-release Tablets, USP 650 mg

*Pain Reliever/Fever Reducer
For Up to 8 Hours Relief of Minor Muscle Aches & Pain
24 Caplets* * Capsule Shaped Bi-Layer Tablets*

Area for
Pharmacode

M. L. No.: 651

Manufactured for
Heritage Pharmaceuticals Inc.,
Eatontown, NJ 07724
1.866.901.DRUG (3784)
Made in India

Artwork Code

PEEL
HERE

• **Keep out of reach of children.** • **Overdose warning:** In case of overdose, get medical help or contact a Poison Control of 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 of 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 between 20–25°C (68–77°F). • do not use if foil inner seal imprinted with “SAFETY SEAL” is broken or missing. • **Inactive ingredients:** hydroxyethyl cellulose, maize starch, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate, FD&C yellow no. 6 aluminum lake and FD&C yellow no. 10 aluminum lake.

Questions or comment?
Call 1.866.901.DRUG (3784)

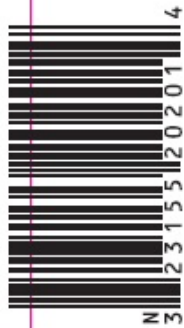
Active ingredient (in each caplet)	Purpose
Acetaminophen 650 mg	Pain reliever/Fever reducer

Uses • temporarily relieves minor aches and pain due to: • muscular aches • backache • minor pain of arthritis • toothache • premenstrual and menstrual cramps • headache • the common cold • 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 non-prescription). 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 if present. These could be signs of a serious condition. **If pregnant or breast-feeding, ask a health professional before use.**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 100 Caplets label



• **Keep out of reach of children.** • **Overdose warning:** In case of overdose, get medical help or contact a Poison Control of 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 of 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 between 20-25°C (68-77°F). • do not use if foil inner seal imprinted with "SAFETY SEAL" is broken or missing. • **Inactive**

Manufactured for Heritage Pharmaceuticals Inc.,
Eatontown, NJ 07724
1.866.901.DRUG (3784)
Made in India

Ingredients: hydroxyethyl cellulose, maize starch, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulfate, FD&C yellow no. 6 aluminum lake and FD&C yellow no. 10 aluminum lake.
Questions or comment? Call 1.866.901.DRUG (3784)

TO OPEN: PUSH AND TURN CAP

← READ THE LABEL →

NDC 23155-202-01

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN.

Acetaminophen Extended-release Tablets, USP 650 mg

Pain Reliever/Fever Reducer For Up to 8 Hours Relief of Minor Muscle Aches & Pain

100 Caplets*

*Capsule Shaped Bi-Layer Tablets

Active ingredient (in each caplet)

Purpose

Acetaminophen 650 mg Pain reliever/Fever reducer

Uses • temporarily relieves minor aches and pain due to: • muscular aches • backache • minor pain of arthritis • toothache • premenstrual and menstrual cramps • headache • the common cold • 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 non-prescription). 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 if present. These could be signs of a serious condition. **If pregnant or breast-feeding, ask a health professional before use.**

M. L. No.: 651

Area for Pharmacode

Atwork Code

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 2000 Tablets

NDC 23155-202-18

PLD PRODUCT
CODE : **BK000397**



**ACETAMINOPHEN 650MG
EXTENDED RELEASE TABLET USP BULK**

LOT : 

XXXXXXX

<p>EXP. DATE :</p>  <p style="text-align: center;">MM/YYYY</p>	<p>QTY. PER CONTAINER:</p> <p style="text-align: center;">20000 Tablets</p>
---	--

Manufactured by: Micro Labs Limited, Goa-403 722. INDIA. M.L.: 651

Storage: Store between 20-25°C (68-77°F)

Caution: For further manufacturing, processing or repackaging. USO-206/A

ACETAMIOPHEN

acetaminophen tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:23155-202
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
-----------------	----------

HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	WHITE (caplet)	Score	no score
Shape	CAPSULE (yellow layer and white coloured plain layer)	Size	19mm
Flavor		Imprint Code	511
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-202-64	1 in 1 CARTON	06/01/2018	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:23155-202-65	1 in 1 CARTON	06/01/2018	
2		750 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:23155-202-01	1 in 1 CARTON	06/01/2018	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:23155-202-18	20000 in 1 CONTAINER; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207035	06/01/2018	

Labeler - Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

Registrant - Heritage Pharma Labs Inc. d/b/a Avet Pharmaceuticals Labs Inc. (189630168)

Establishment

Name	Address	ID/FEI	Business Operations
Micro Labs Limited		915793658	MANUFACTURE(23155-202)

Revised: 6/2023

Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.