

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-200

FINAL PRINTED LABELING

marge

76-200

AP 3/19/02



NDC 64720-116-50

Lasts Up To 8 Hours

Acetaminophen

Extended-Release

Tablets

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

650 mg

Pain Reliever

500 Tablets

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

MAR 19 2002

Active Ingredient (in each tablet) Acetaminophen 650 mg..... Pain Reliever

Uses temporarily relieves minor aches and pains due to arthritis the common cold headache toothache muscular aches backache menstrual cramps

Warnings Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers. Acetaminophen may cause liver damage. Do not use with any other product containing acetaminophen

Stop use and ask a doctor if new symptoms occur redness or swelling is present pain gets worse or lasts for more than 10 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. 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 adults: take 2 tablets every 8 hours with water swallow whole - do not crush, chew 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 do not use if printed foil inner seal is broken. store at 20-25°C (68-77°F) avoid excessive heat at 40°C (104°F)

Inactive ingredients croscarmellose sodium, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide.

Questions? Call 1-877-646-5227

Manufactured by: Corepharma LLC Middlesex, NJ 08846 MF# 174

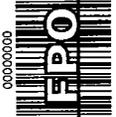
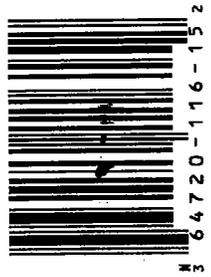


Lot No:

Exp. Date:

Non Varnish Area

Batch No. 1201 Expiration Date:



Drug Facts

Active ingredient
(in each tablet) **Purpose**
Acetaminophen 650 mg..... Pain Reliever

Uses temporarily relieves minor aches and pains due to:

- arthritis
- headache
- muscular aches
- menstrual cramps
- the common cold
- toothache
- backache

Warnings

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers. Acetaminophen may cause liver damage.

Do not use ■ with any other product containing acetaminophen

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 10 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Drug Facts (continued)

Directions ■ do not take more than directed

- adults
- take 2 tablets every 8 hours with water
 - swallow whole - do not crush, chew 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

- do not use if carton is opened or printed foil inner seal is broken.
- store at 20 - 25° C (68 - 77° F)
- avoid excessive heat at 40° C (104° F)
- see end panel for lot number and expiration date

Inactive ingredients

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

Questions? Call 1-877-646-5227

Manufactured by: Corepharma LLC
MF# XXX Middlesex, NJ 08846

150 Tablets

Pain Reliever

650 mg

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Acetaminophen
Extended-Release
Tablets

Lasts Up To 8 Hours

NDC 64720-116-15

150 Tablets

Pain Reliever

650 mg

FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

Acetaminophen
Extended-Release
Tablets

Lasts Up To 8 Hours

NDC 64720-116-15

APPROVED
MAR 19 2002