# EXTRA STRENGTH MAPAP- acetaminophen tablet Medsource Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

## **Drug Facts**

## Active ingredient (in each tablet)

Acetaminophen 500 mg

## **Purposes**

Pain Reliever/Fever Reducer

Aspirin Free Extra Strength Pain Reliever

#### Uses

for the temporary relief of minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

## **Warnings**

**Liver warning:** This product contains acetaminophen.

The maximum daily dose of this product is 6 tablets (3,000mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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 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 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

This Unit Dose package is not child resistant and is Intended for Institutional Use Only.

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In the 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 the directed (see overdose warning)

## Adults and children 12 years and over:

- Take 2 tablets every 6 hours while symptoms last.
- Do not take more than 6 tablets in 24 hours unless directed by a doctor
- Do not take for more than 10 days unless directed by a doctor

**Children under 12 years:** Do not use adult Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

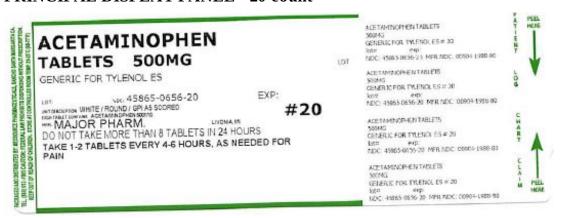
#### Other information

Store at room temperature

### **Inactive ingredients**

Povidone, Pregelatinized Starch, Sodium Starch Glycolate, Stearic Acid

### PRINCIPAL DISPLAY PANEL - 20 count



## EXTRA STRENGTH MAPAP

acetaminophen tablet

| Product Information     |                |                    |                              |  |
|-------------------------|----------------|--------------------|------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:45865-656(NDC:0904-1988) |  |
| Route of Administration | ORAL           |                    |                              |  |

| Active Ingredient/Active Moiety                                           |                   |          |  |  |
|---------------------------------------------------------------------------|-------------------|----------|--|--|
| Ingredient Name                                                           | Basis of Strength | Strength |  |  |
| ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D) | ACETAMINOPHEN     | 500 mg   |  |  |

| Inactive Ingredients                                   |          |  |  |
|--------------------------------------------------------|----------|--|--|
| Ingredient Name                                        | Strength |  |  |
| PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)             |          |  |  |
| STARCH, CORN (UNII: O8232NY3SJ)                        |          |  |  |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) |          |  |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)                        |          |  |  |

| Product Characteristics |                                       |              |          |
|-------------------------|---------------------------------------|--------------|----------|
| Color                   | white                                 | Score        | 2 pieces |
| Shape                   | ROUND (round flat faced beveled edge) | Size         | 12mm     |
| Flavor                  |                                       | Imprint Code | GPI;A5   |
| Contains                |                                       |              |          |

| ı | Packaging              |                                                            |                         |                       |  |
|---|------------------------|------------------------------------------------------------|-------------------------|-----------------------|--|
|   | # Item Code            | Package Description                                        | Marketing Start<br>Date | Marketing End<br>Date |  |
|   | 1 NDC:45865-656-<br>20 | 20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 1/0 1/20 18           |                       |  |
|   | 2 NDC:45865-656-<br>30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 1/0 1/20 18           |                       |  |

| Marketing Information   |                                          |                      |                    |  |
|-------------------------|------------------------------------------|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part343                                  | 05/04/2011           |                    |  |
|                         |                                          |                      |                    |  |

# **Labeler** - Medsource Pharmaceuticals (833685915)

| Establishment             |         |           |                     |  |
|---------------------------|---------|-----------|---------------------|--|
| Name                      | Address | ID/FEI    | Business Operations |  |
| Medsource Pharmaceuticals |         | 833685915 | repack(45865-656)   |  |

Revised: 7/2018 Medsource Pharmaceuticals