

**MEDI-FIRST NON-ASPIRIN EXTRA STRENGTH- acetaminophen tablet, film coated
Proficient Rx LP**

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.

Acetaminophen 500 mg

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

For the temporary relief of minor aches and pains associated with

- headache
- toothache
- minor arthritis pain
- muscular aches
- common cold
- menstrual cramps

For the reduction of fever.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 8 tablets 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.

- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

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 using and ask a doctor if

- symptoms do not improve
- pain or fever persists or gets worse
- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding,

ask a health professional before use.

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

Directions

- **do not use more than directed**

Adults and children: (12 years and older)

Take 2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

Children under 12 years:

Do not give this adult strength product to children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- store at room temperature 59°-86°F (15°-30°C)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, hypromellose, maltodextrin*, microcrystalline cellulose*, polyethylene glycol, povidone*, pregelatinized corn starch*, sodium starch glycolate*, stearic acid, titanium dioxide*

* *May contain*

Questions or comments? 1-800-634-7680

Medi-First Plus XS Non-Aspirin Label

8 Tablets

Extra Strength

Non-Aspirin

Acetaminophen/Acetaminofeno 500mg

Pull To Open

Tire Para Abrir

Pain Reliever/Fever Reducer

Alivia el Dolor/Reduce La Fiebre

Compare Active ingredient to:

Extra Strength Tylenol®

Registered Trademark of McNeil Consumer

Tamper Evident Unit Dose Packets

Empaquetado con sellado

Evidente en dosis unitarias

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320



NDC 71205-314-08

Lot #:00000
Exp. 00/00/00
SN#MASTER

Extra Strength Non-Aspirin 500mg

#08 Tablets

Each tablet contains: Acetaminophen 500mg Pain
reliever/ fever reducer

White, round, unscored tablet with imprint code "AZ 235"

Product ID: SA031408

Mfr For: Medique Products Fort Myers, FL 33967

Store at room temperature 59°-86°F (15°-30°C)

Keep medication out of the reach of children

Extra Strength Non-Aspirin 500mg
#08 Tablets
Lot #:00000 SN#MASTER
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Relabeled By Proficient Rx LP
Thousand Oaks, CA 91320

MEDI-FIRST NON-ASPIRIN EXTRA STRENGTH

acetaminophen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-314(NDC:47682-804) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 500 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | white (white) | Score | no score |
| Shape | ROUND (ROUND) | Size | 12mm |
| Flavor | | Imprint Code | AZ;235 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71205-314-04 | 4 in 1 PACKET; Type 0: Not a Combination Product | 09/01/2019 | |
| 2 | NDC:71205-314-08 | 8 in 1 PACKET; Type 0: Not a Combination Product | 02/05/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph not final | part343 | 12/30/2008 | |

Labeler - Proficient Rx LP (079196022)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|------------------|----------------|---------------|--|
| Proficient Rx LP | | 079196022 | REPACK(71205-314) , RELABEL(71205-314) |