

**LEGATRIN PM- acetaminophen, diphenhydramine hci tablet**  
**Church & Dwight Co., Inc.**

*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.*

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**Legatrin PM Pain Reliever/Sleep Aid**

***Active ingredients (in each caplet)***

***Active ingredients (in each caplet)***

Acetaminophen 500 mg

Diphenhydramine HCl 50 mg

***Purposes***

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Acetaminophen - Pain Reliever

Diphenhydramine HCl - Sleep Aid

***Uses***

***Uses***

temporary relief of minor aches and pains, such as leg cramp pain, joint pain, lower backache, and sore feet, with accompanying sleeplessness.

**Warnings**

***Warnings***

**Liver Warning:** this product contains acetaminophen. 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.

**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**

**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.
- with any other product containing diphenhydramine, even one used on skin
- in children under 12 years of age

## Ask Doctor

### Ask a doctor before use if you have

- liver disease
- glaucoma
- breathing problem such as asthma, emphysema, chronic bronchitis or pulmonary disease
- trouble urinating due to an enlarged prostate gland
- heart disease
- high blood pressure
- thyroid disease
- diabetes

### Ask a doctor or pharmacist before use if you are

- taking tranquilizers or sedatives
- taking the blood thinning drug warfarin

## When using this product

### When using this product

- drowsiness will occur
- do not drive a motor vehicle or operate machinery
- avoid alcoholic drinks

## Stop Use

### Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- symptoms do not improve within 7 days or are accompanied by a fever
- new symptoms occur
- redness or swelling is present
- nervousness, dizziness or sleeplessness occur

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

### *Keep out of reach of children*

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

### *Directions*

#### *Directions*

- **Do not exceed recommended dosage.**

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|   |   |
|---|---|
| Adults and children 12 years of age and older | 1 caplet at bedtime as needed, or as directed by a doctor |
| Children under 12 years                       | consult a doctor  |

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## Other Information

### Other information

- store at controlled room temperature 20° to 25° C (68° to 77° F)
- avoid excessive heat and humidity
- tamper evident. Do not use if carton is opened or neck wrap or foil inner seal is broken.
- see end panel for lot number and expiration date.

## Inactive Ingredients

### Inactive ingredients

colloidal silicon dioxide, corn starch, FD&C blue #1, hydroxypropyl methylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid

## Package Label. Principal Display Panel

### LegatrinPM

Just 1 caplet

helps you sleep!

SAFE, NON-HABIT FORMING

Contains **Acetaminophen,**

**Diphenhydramine HCl**

### LegatrinPM

Pain Reliever/Sleep Aid

**Relieves lower**

**body pain**

Leg Cramp Pain

Joint Pain

Lower Backache

Sore Feet

50 Caplets

**DO NOT USE IF NECK WRAP OR FOIL INNER SEAL IS BROKEN.**

| <b>Drug Facts</b>                          |                 |
|--|-----------------|
| <b>Active Ingredients (in each caplet)</b> | <b>Purposes</b> |
| Acetaminophen 500 mg.....Pain Reliever     |                 |
| Diphenhydramine HCl 50 mg.....Sleep Aid    |                 |

**Uses**  
temporary relief of minor aches and pains, such as leg cramp pain, joint pain, lower backache, and sore feet, with accompanying sleeplessness.

**Warnings**  
**Liver Warning:** This product contains acetaminophen. 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.  
**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:  
• skin reddening

| <b>Drug Facts (continued)</b>  |                       |
|--|-----------------------|
| • with any other product containing diphenhydramine, even one used on skin             |                       |
| • In children under 12 years of age  |                       |
| <b>Ask a doctor before use if you have</b>   |                       |
| • liver disease  | • glaucoma            |
| • breathing problem such as asthma, emphysema, chronic bronchitis or pulmonary disease |                       |
| • trouble urinating due to an enlarged prostate gland                                  |                       |
| • heart disease  | • high blood pressure |
| • thyroid disease  | • diabetes            |
| <b>Ask a doctor or pharmacist before use if you are</b>                                |                       |
| • taking tranquilizers or sedatives  |                       |
| • taking the blood thinning drug warfarin  |                       |
| <b>When using this product</b>   |                       |
| • drowsiness will occur  |                       |
| • do not drive a motor vehicle or operate machinery                                    |                       |
| • avoid alcoholic drinks   |                       |
| <b>Stop use and ask a doctor if</b>  |                       |
| • sleeplessness persists continuously for more   |                       |



|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:10237-907 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength             | Strength |
|--|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                   | ACETAMINOPHEN                 | 500      |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 50       |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)             |          |
| POVIDONE (UNII: FZ989GH94E)                            |          |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                     |          |
| STARCH, CORN (UNII: O8232NY3SJ)                        |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                     |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                       |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                        |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)          |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                        |          |

### Product Characteristics

|                 |      |                     |          |
|-----------------|------|---------------------|----------|
| <b>Color</b>    | blue | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL | <b>Size</b>         | 17mm     |
| <b>Flavor</b>   |      | <b>Imprint Code</b> | Legatrin |
| <b>Contains</b> |      |                     |          |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:10237-907-50 | 1 in 1 CARTON                                     | 10/01/2014           |                    |
| 1 |                  | 50 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 10/01/2014           |                    |

**Labeler** - Church & Dwight Co., Inc. (001211952)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

|                           |  |           |                  |
|---------------------------|--|-----------|------------------|
| Church & Dwight Co., Inc. |  | 043690812 | label(10237-907) |
|---------------------------|--|-----------|------------------|

## Establishment

| Name     | Address | ID/FEI    | Business Operations    |
|----------|---------|-----------|------------------------|
| ULTRAtab |         | 151051757 | manufacture(10237-907) |

Revised: 10/2019

Church & Dwight Co., Inc.