**EXTRA STRENGTH NIGHT TIME PAIN RELIEF- acetaminophen, diphenhydramine hcl tablet, coated**
**AMERISOURCE BERGEN**

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**GNP 224B (324)**

## Active Ingredients

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

## Purposes

Pain Reliever

Sleep aid

## Uses

for the temporary relief of occasional headaches and minor ache and pains along 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 • 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. • with any other product containing diphenhydramine, even one used on skin • in children under 12 years of age • if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have** • liver disease • a breathing problem such as emphysema or chronic bronchitis • glaucoma • difficulty urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are taking** • the blood thinning drug warfarin

• sedatives or tranquilizers

**When using this product** • drowsiness will occur • do not drive a motor vehicle or operate machinery after use • avoid alcoholic drinks

**Stop use and ask a doctor if** • sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness. • pain gets worse or lasts for more that 10 days • fever gets worse or lasts more than 3 days • new symptoms occur • redness or swelling is present.These may 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 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 directed (see overdose warning)
• adults and children 12 years and over: take 2 caplets at bedtime. Do not take more than 2 caplets of this product in 24 hours.
• children under 12 years: do not use

## Other information

• store at controlled room temperature 20-25 °C (68-77° F)

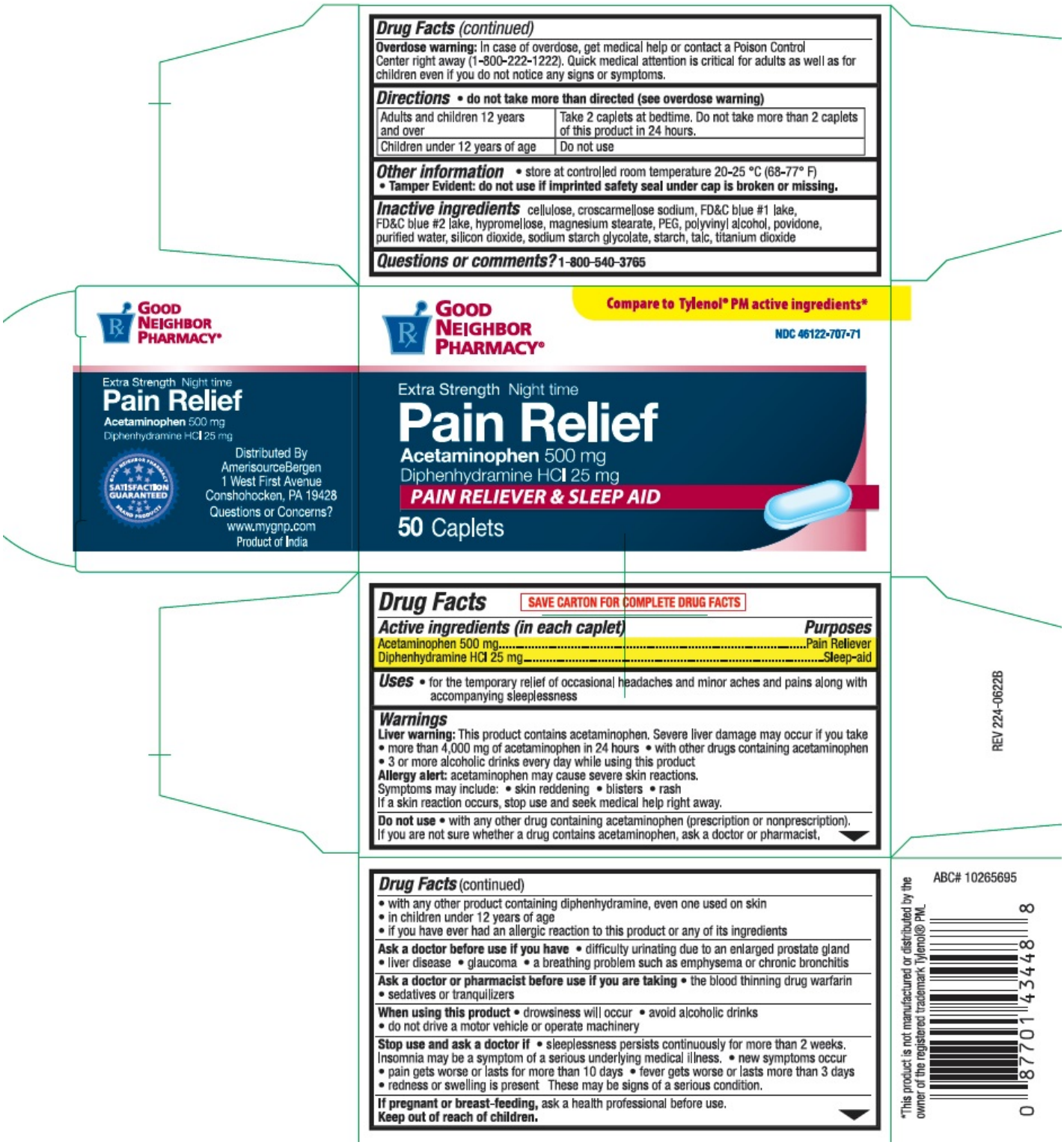
## Inactive ingredients

cellulose, croscarmellose sodium, FD&C blue #1 lake, FD&C blue #2 lake, hypromellose, magnesium stearate, PEG, polyvinyl alcohol, povidone, purified water, silicon dioxide, sodium starch glycolate, starch, talc, titanium dioxide

## Questions or comments?

**1-800-540-3765**

## package Label




# EXTRA STRENGTH NIGHT TIME PAIN RELIEF

acetaminophen, diphenhydramine hcl tablet, coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:46122-707 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 500 mg |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **TALC** (UNII: 7SEV7J4R1U) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue | **Score** | no score |
| **Shape** | CAPSULE | **Size** | 18mm |
| **Flavor** | | **Imprint Code** | P525 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:46122-707-78 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2022 | |
| **2** | NDC:46122-707-71 | 1 in 1 CARTON | 09/16/2022 | |
| **2** | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:46122-707-62 | 1 in 1 CARTON | 10/05/2022 | |
| **3** | | 24 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 Drug | M013 | 06/01/2022 | 02/28/2026 |

## Labeler - AMERISOURCE BERGEN (007914906)

## Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 11/2024 AMERISOURCE BERGEN