## DG HEALTH 8 HR ARTHRITIS PAIN RELIEF- acetaminophen tablet, film coated, extended release Dolgencorp Inc

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#### Dolgencorp, LLC 8 HR Arthritis Pain Relief Drug Facts

#### **Active ingredient (in each caplet)**

Acetaminophen 650 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

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

#### **Warnings**

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

- more than 6 caplets 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.

• 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.

**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:
- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets 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

- store at 20-25°C (68-77°F)
- · do not use if printed foil under cap is broken or missing
- meets the requirements of USP Dissolution Test 2

#### Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose,

magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

#### Questions or comments?

1-888-309-9030

#### **Principal Display Panel**

DG™|health

READ THE LABEL

8 HR Arthritis Pain Relief

Acetaminophen Extended-Release Tablets, 650 mg

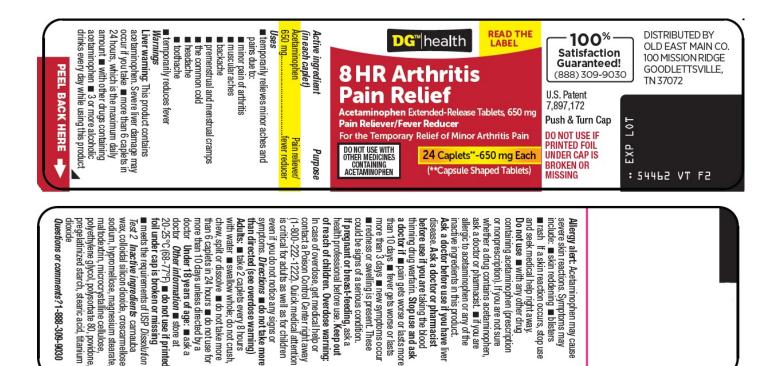
Pain Reliever/Fever Reducer

For the Temporary Relief of Minor Arthritis Pain

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

24 Caplets\*\* - 650 mg Each

(\*\*Capsule Shaped Tablets)



#### DG HEALTH 8 HR ARTHRITIS PAIN RELIEF

acetaminophen tablet, film coated, extended release

#### **Product Information**

| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:55910-828 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | ORAL           |                    |               |

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN (650 mg

| Inactive Ingredients                                |          |
|---|----------|
| Ingredient Name                                     | Strength |
| CARNAUBA WAX (UNII: R12CBM0EIZ)                     |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                  |          |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48)            |          |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)        |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                     |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)       |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H)                   |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)            |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                     |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |

| <b>Product Characteristi</b> | tics  |              |          |
|------------------------------|-------|--------------|----------|
| Color                        | WHITE | Score        | no score |
| Shape                        | OVAL  | Size         | 19mm     |
| Flavor                       |       | Imprint Code | L544     |
| Contains                     |       |              |          |

| P | ackaging             | ing  |                         |                       |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code            | Package Description                                | Marketing Start<br>Date | Marketing End<br>Date |
| 1 | NDC:55910-828-<br>71 | 1 in 1 CARTON                                      | 11/08/2018              |                       |
| 1 |                      | 50 in 1 BOTTLE; Type 0: Not a Combination Product  |                         |                       |
| 2 | NDC:55910-828-<br>78 | 1 in 1 CARTON                                      | 08/19/2019              |                       |
| 2 |                      | 100 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |
| 3 | NDC:55910-828-<br>62 | 1 in 1 CARTON                                      | 03/20/2020              |                       |
| 3 |                      | 24 in 1 BOTTLE; Type 0: Not a Combination Product  |                         |                       |
| 4 | NDC:55910-828-<br>83 | 1 in 1 CARTON                                      | 03/20/2020              |                       |
| 4 |                      | 225 in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |

| Marketing Information |  |                         |                       |
|-----------------------|--|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA075077                               | 11/08/2018              |                       |
| ANDA                  | ANDA075077                               | 11/08/2018              |                       |

### Labeler - Dolgencorp Inc (068331990)

Revised: 5/2023 Dolgencorp Inc