

**68391-850-72**

**DAYTIME NIGHTTIME COLD FLU RELIEF**

**National Drug Code Directory**

The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily.

**68391-850-72 Daytime Nighttime Cold Flu Relief**

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|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Labeler Name</i>            | BJWC (Berkley & Jensen / BJ's)                                                                                                                        | Name of Company corresponding to the labeler code segment of the ProductNDC.                                                                                                                                                                                                                                                                                                   |
| <i>NDC Package Code</i>        | 68391-850-72                                                                                                                                          | The labeler code, product code, and package code segments of the National Drug Code number, separated by hyphens. Asterisks are no longer used or included within the product and package code segments to indicate certain configurations of the NDC.                                                                                                                         |
| <i>Proprietary Name</i>        | Daytime Nighttime Cold Flu Relief                                                                                                                     | Also known as the trade name. It is the name of the product chosen by the labeler.                                                                                                                                                                                                                                                                                             |
| <i>11 Digit NDC Code</i>       | 68391-0850-72                                                                                                                                         | It should be noted that many NDCs are displayed on drug packaging in a 10-digit format. Proper billing of an NDC requires an 11-digit number in a 5-4-2 format. Converting NDCs from a 10-digit to 11-digit format requires a strategically placed zero, dependent upon the 10-digit format.                                                                                   |
| <i>Product NDC</i>             | 68391-850                                                                                                                                             | The labeler code and product code segments of the National Drug Code number, separated by a hyphen. Asterisks are no longer used or included within the product code segment to indicate certain configurations of the NDC.                                                                                                                                                    |
| <i>Product Type Name</i>       | HUMAN OTC DRUG                                                                                                                                        | Indicates the type of product, such as Human Prescription Drug or Human OTC Drug. This data element corresponds to the "Document Type" of the SPL submission for the listing. The complete list of codes and translations can be found at <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.                                |
| <i>Proprietary Name Suffix</i> | Multi Symptom                                                                                                                                         | A suffix to the proprietary name, a value here should be appended to the ProprietaryName field to obtain the complete name of the product. This suffix is often used to distinguish characteristics of a product such as extended release ("XR") or sleep aid ("PM"). Although many companies follow certain naming conventions for suffices, there is no recognized standard. |
| <i>Non Proprietary Name</i>    | Acetaminophen,<br>Dextromethorphan Hbr,<br>Doxylamine Succinate,<br>Phenylephrine Hcl                                                                 | Sometimes called the generic name, this is usually the active ingredient(s) of the product.                                                                                                                                                                                                                                                                                    |
| <i>Package Description</i>     | 1 KIT in 1 KIT (68391-850-72) * 24 BLISTER PACK in 1 CARTON / 1 CAPSULE in 1 BLISTER PACK * 48 BLISTER PACK in 1 CARTON / 1 CAPSULE in 1 BLISTER PACK | A description of the size and type of packaging in sentence form. Multilevel packages will have the descriptions concatenated together. For example: 4 BOTTLES in 1 CARTON/100 TABLETS in 1 BOTTLE.                                                                                                                                                                            |

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| <i>Marketing Category Name</i>      | OTC MONOGRAPH DRUG | Product types are broken down into several potential Marketing Categories, such as NDA/ANDA/BLA, OTC Monograph, or Unapproved Drug. One and only one Marketing Category may be chosen for a product, not all marketing categories are available to all product types. Currently, only final marketed product categories are included. The complete list of codes and translations can be found at <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.                                                                                                                                                                                                                                                                              |
| <i>Application Number</i>           | M012               | This corresponds to the NDA, ANDA, or BLA number reported by the labeler for products which have the corresponding Marketing Category designated. If the designated Marketing Category is OTC Monograph Final or OTC Monograph Not Final, then the Application number will be the CFR citation corresponding to the appropriate Monograph (e.g. "part 341"). For unapproved drugs, this field will be null.                                                                                                                                                                                                                                                                                                                                                                          |
| <i>Product Marketing Start Date</i> | 20191030           | This is the date that the labeler indicates was the start of its marketing of the drug product.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <i>Product Marketing End Date</i>   | 20241231           | This is the date the product will no longer be available on the market. If a product is no longer being manufactured, in most cases, the FDA recommends firms use the expiration date of the last lot produced as the EndMarketingDate, to reflect the potential for drug product to remain available after manufacturing has ceased. Products that are the subject of ongoing manufacturing will not ordinarily have any EndMarketingDate. Products with a value in the EndMarketingDate will be removed from the NDC Directory when the EndMarketingDate is reached.                                                                                                                                                                                                               |
| <i>Dosage Form Name</i>             | KIT                | The translation of the DosageForm Code submitted by the firm. The complete list of codes and translations can be found <a href="http://www.fda.gov/edrls">www.fda.gov/edrls</a> under Structured Product Labeling Resources.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <i>Status</i>                       | Deprecated         | <p>Possible status values:</p> <ul style="list-style-type: none"> <li>&lt;li&gt;&lt;strong&gt;Active&lt;/strong&gt; &lt;br/&gt;Active NDC Code&lt;/li&gt;</li> <li>&lt;li&gt;&lt;strong&gt;Deprecated&lt;/strong&gt; &lt;br/&gt;Deprecated NDC Code&lt;/li&gt;</li> <li>&lt;li&gt;&lt;strong&gt;Unfinished&lt;/strong&gt; (Unapproved) &lt;br/&gt;The following status describes submitted unfinished drugs, including the marketing categories of Active Pharmaceutical Ingredient (API), Drug for Further Processing, Bulk for Human Drug Compounding, and Bulk for Animal Drug Compounding. &lt;br/&gt;&lt;strong&gt;FDA does not review and approve unfinished products. Therefore, all products having "unfinished" status are considered unapproved.&lt;/strong&gt;</li> </ul> |

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| <i>Last Update<br/>Date</i> | 2025-01-01 | The date that a record was last updated or changed. |
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Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Compliance, Immediate Office  
Drug Registration and Listing Team  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002  
Email: [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov)

For all questions regarding this bundle please contact [Support@DataLabs.Health](mailto:Support@DataLabs.Health). Also feel free to let us know about any suggestions or concerns. All additional information as well as customer support is available at <https://www.datalabs.health/>.