0054-0188-13
BUPRENORPHINE AND NALOXONE
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.

0054-0188-13 Buprenorphine And Naloxone

Labeler Name	Hikma Pharmaceuticals USA Inc.	Name of Company corresponding to the labeler code segment of the ProductNDC.
NDC Package Code	0054-0188-13	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.
Proprietary Name	Buprenorphine And Naloxone	Also known as the trade name. It is the name of the product chosen by the labeler.
11 Digit NDC Code	00054-0188-13	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.
Product NDC	0054-0188	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.
Product Type Name	HUMAN PRESCRIPTION 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 www.fda.gov/edrls under Structured Product Labeling Resources.
Non Proprietary Name	Buprenorphine And Naloxone	Sometimes called the generic name, this is usually the active ingredient(s) of the product.
Package Description	30 TABLET in 1 BOTTLE (0054-0188-13)	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.
Marketing Category Name	ANDA	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 www.fda.gov/edrls under Structured Product Labeling Resources.
Application Number	ANDA203326	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.

Product Marketing Start Date	20140627	This is the date that the labeler indicates was the start of its marketing of the drug product.
Dosage Form Name	TABLET	The translation of the DosageForm Code submitted by the firm. The complete list of codes and translations can be found www.fda.gov/edrls under Structured Product Labeling Resources.
Route Name	SUBLINGUAL	The translation of the Route Code submitted by the firm, indicating route of administration. The complete list of codes and translations can be found at www.fda.gov/edrls under Structured Product Labeling Resources.
Substance Name	BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE DIHYDRATE	This is the active ingredient list. Each ingredient name is the preferred term of the UNII code submitted.
Strength Number	2; .5	These are the strength values (to be used with units below) of each active ingredient, listed in the same order as the SubstanceName field above.
Strength Unit	mg/1; mg/1	These are the units to be used with the strength values above, listed in the same order as the SubstanceName and SubstanceNumber.
DEA Schedule	CIII	Schedules of Controlled Substances This is the assigned DEA Schedule number as reported by the labeler. Values are CI, CII, CIII, CIV, and CV. The CSA places each controlled substance—drug or other substance—into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability. The Act also allows substance to be added to or removed from a schedule, and to be rescheduled or transferred from one schedule to another. The basis upon which substances are placed into each of the five schedules is explained below, and examples of drugs' or other substances within the schedules are listed.
Pharmaceutical Classes	Opioid Antagonist [EPC], Opioid Antagonists [MoA], Partial Opioid Agonist [EPC], Partial Opioid Agonists [MoA]	These are the reported pharmaceutical class categories corresponding to the SubstanceNames listed above.

Status	Active	Possible status values: - Active Active NDC Code - Deprecated Deprecated NDC Code Unfinished (Unapproved) 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. FDA does not review and approve unfinished products. Therefore, all products having "unfinished" status are considered unapproved.
Last Update Date	2026-08-05	The date that a record was last updated or changed.

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

For all questions regarding this bundle please contact 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/.