



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Encube Ethicals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210986
Application:	ANDA
DUNS:	11-698-2244
Proprietary Name (if Applicable) and Established Name:	Diclofenac Sodium Topical Gel, 1%
Selling Unit NDC:	21922-009-09
Individual Unit NDC:	2192200909
UPC:	32192200909
UDI	
CVX Code:	
MXV Code:	
Description:	Diclofenac Sodium Topical Gel, 1% is a opaque white smooth homogeneous gel base, free from lumps, foreign particles and leakage, packed in Aluminum collapsible tube fitted with Cylindrical pp white cap and legible label.
Active Ingredient(s):	Diclofenac Sodium USP
URL for Additional Product Information:	
Address:	200 Meredith Avenue, Suite 101A
City:	Durham
State:	NC
Zip:	27713
Key Contact:	Kamesh Venugopal
Phone Number:	+1-269-806-2796
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Dipti Kamani
Number:	+1-781-789-0567
Group E-mail:	usreg@encubeethicals.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device? reverse numbered? co-licensed?	No
Is the Product... Is the Product...	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	21922-009-09
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	100 g
Strength:	1%
Dosage Form:	Topical Gel
Product Shape:	
Product Color:	A opaque white smooth homogeneous gel
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	21922-009-09
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input checked="" type="checkbox"/> Tube	Minimum order quantity?
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	Prescription (will appear in OB post approval)
II. Generic Equivalent to What Brand?:	VOLTAREN GEL (diclofenac sodium topical gel) 1%
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	890600527
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.290128	6.6929	2.0866	1.7716	24.7411117	1
Case:	5.791537	10.98423	7.0866	6.49605	505.658017	18
Pallet:	24.53742	14.64564	13.7795	111.4173	22485.0803	72
UPC:	544.7616	47.4018	34.51568	38.91725	63672.7213	1440
Case:	30321922009096					
Carton:	00321922009095					

GTIN PRODUCT INFORMATION						
Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Item	Saleable Unit		
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	1	00321922009095
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	18	10321922009092
<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	72	30321922009096
					1440	50321922009090

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			