

GARDASIL 9- human papillomavirus 9-valent vaccine, recombinant injection, suspension
Bamboo US BidCo LLC

These highlights do not include all the information needed to use GARDASIL 9 safely and effectively. See full prescribing information for GARDASIL 9.

GARDASIL[®] 9
(Human Papillomavirus 9-valent Vaccine, Recombinant)
Suspension for intramuscular injection
Initial U.S. Approval: 2014

PRINCIPAL DISPLAY PANEL - 0.5 mL Vial Carton

10 Single-dose 0.5-mL Vials

REFRIGERATE

Human Papillomavirus 9-valent Vaccine, Recombinant

GARDASIL[®] 9

Suspension for intramuscular injection

Each 0.5-mL dose contains human papillomavirus L1 protein of each type adsorbed on amorphous aluminum

hydroxyphosphate sulfate adjuvant as follows:

Type 6 (30 mcg), Type 11 (40 mcg), Type 16 (60 mcg), Type 18 (40 mcg), Type 31 (20 mcg), Type 33 (20 mcg),
Type 45 (20 mcg), Type 52 (20 mcg), Type 58 (20 mcg).

Vaccine is prepared from fermentation cultures of a recombinant strain of yeast *Saccharomyces cerevisiae*

containing the genes for the human papillomavirus L1 protein of each type (6, 11, 16, 18, 31, 33, 45, 52, 58).

Contains no preservative or antibiotics.

Rx only



PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Carton

10 Single-dose 0.5-mL Syringes

REFRIGERATE

Human Papillomavirus

9-valent Vaccine, Recombinant

GARDASIL®9

Suspension for intramuscular injection

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REFRIGERATE

**Human Papillomavirus
9-valent Vaccine, Recombinant
GARDASIL® 9**

Suspension for intramuscular injection

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Rx only

10 Single-dose 0.5-mL Syringes

**Human Papillomavirus
9-valent Vaccine, Recombinant
GARDASIL® 9**

Suspension for
intramuscular injection

5

Encoding area: Space reserved for
2D Serialization Barcode,
Serial Number, Expiry and Lot



REFRIGERATE

10 Single-dose 0.5-mL Syringes

Store at 2-8°C (36-46°F). DO NOT FREEZE. Protect from light.
 DOSAGE: See Package Insert.
 Inject intramuscularly. Discard syringe after use.
 For product and service information, call 1-800-672-6372.

Manufactured and Distributed by:
 Merck Sharp & Dohme LLC
 Rahway, NJ 07065 USA
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LOT
613
86
MLD



human papillomavirus 9-valent vaccine, recombinant injection, suspension

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:83703-047
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HUMAN PAPILOMAVIRUS TYPE 6 L1 CAPSID PROTEIN ANTIGEN (UNII: 61746O90DY) (HUMAN PAPILOMAVIRUS TYPE 6 L1 CAPSID PROTEIN ANTIGEN - UNII:61746O90DY)	HUMAN PAPILOMAVIRUS TYPE 6 L1 CAPSID PROTEIN ANTIGEN	30 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 11 L1 CAPSID PROTEIN ANTIGEN (UNII: Z845VHQ61P) (HUMAN PAPILOMAVIRUS TYPE 11 L1 CAPSID PROTEIN ANTIGEN - UNII:Z845VHQ61P)	HUMAN PAPILOMAVIRUS TYPE 11 L1 CAPSID PROTEIN ANTIGEN	40 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 16 L1 CAPSID PROTEIN ANTIGEN (UNII: 6LTE2DNX63) (HUMAN PAPILOMAVIRUS TYPE 16 L1 CAPSID PROTEIN ANTIGEN - UNII:6LTE2DNX63)	HUMAN PAPILOMAVIRUS TYPE 16 L1 CAPSID PROTEIN ANTIGEN	60 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 18 L1 CAPSID PROTEIN ANTIGEN (UNII: J2D279PEM5) (HUMAN PAPILOMAVIRUS TYPE 18 L1 CAPSID PROTEIN ANTIGEN - UNII:J2D279PEM5)	HUMAN PAPILOMAVIRUS TYPE 18 L1 CAPSID PROTEIN ANTIGEN	40 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 31 L1 CAPSID PROTEIN ANTIGEN (UNII: 53JIL371NS) (HUMAN PAPILOMAVIRUS TYPE 31 L1 CAPSID PROTEIN ANTIGEN - UNII:53JIL371NS)	HUMAN PAPILOMAVIRUS TYPE 31 L1 CAPSID PROTEIN ANTIGEN	20 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 33 L1 CAPSID PROTEIN ANTIGEN (UNII: 759RAC446C) (HUMAN PAPILOMAVIRUS TYPE 33 L1 CAPSID PROTEIN ANTIGEN - UNII:759RAC446C)	HUMAN PAPILOMAVIRUS TYPE 33 L1 CAPSID PROTEIN ANTIGEN	20 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 45 L1 CAPSID PROTEIN ANTIGEN (UNII: 68S8VCN34F) (HUMAN PAPILOMAVIRUS TYPE 45 L1 CAPSID PROTEIN ANTIGEN - UNII:68S8VCN34F)	HUMAN PAPILOMAVIRUS TYPE 45 L1 CAPSID PROTEIN ANTIGEN	20 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 52 L1 CAPSID PROTEIN ANTIGEN (UNII: 55644W68FD) (HUMAN PAPILOMAVIRUS TYPE 52 L1 CAPSID PROTEIN ANTIGEN - UNII:55644W68FD)	HUMAN PAPILOMAVIRUS TYPE 52 L1 CAPSID PROTEIN ANTIGEN	20 ug in 0.5 mL
HUMAN PAPILOMAVIRUS TYPE 58 L1 CAPSID PROTEIN ANTIGEN (UNII: 94Y15HP7LF) (HUMAN PAPILOMAVIRUS TYPE 58 L1 CAPSID PROTEIN ANTIGEN - UNII:94Y15HP7LF)	HUMAN PAPILOMAVIRUS TYPE 58 L1 CAPSID PROTEIN ANTIGEN	20 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9.56 mg in 0.5 mL
HISTIDINE (UNII: 4QD397987E)	0.78 mg in 0.5 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	50 ug in 0.5 mL
SODIUM BORATE (UNII: 91MBZ8H3QO)	35 ug in 0.5 mL
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (white, cloudy)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-047-02	10 in 1 CARTON		
1	NDC:83703-047-01	0.5 mL in 1 SYRINGE, GLASS; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
BLA	BLA125508		12/10/2014	

Labeler - Bamboo US BidCo LLC (119087615)

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Bamboo US BidCo LLC