

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

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

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

**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

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**

Suspension for intramuscular injection

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

10 Single-dose 0.5-mL Syringes



 10 Single-dose 0.5-mL Syringes

**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

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

10 Single-dose 0.5-mL Syringes

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

Suspension for  
intramuscular injection



5

5

10 Single-dose 0.5-mL Syringes

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

Suspension for  
intramuscular injection

**REFRIGERATE**

10 Single-dose 0.5-mL Syringes


Store at 2-8°C (36-46°F). DO NOT FREEZE. Protect from light.  
 DOS AGE: 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  
 U.S. Govt. Lic. No. 0002

Copyright © 2012 Merck & Co., Inc.  
 Rahway, NJ, USA and its affiliates.  
 All rights reserved.

MERCK

LOT  
613  
86  
MLD



human papillomavirus 9-valent vaccine, recombinant injection, suspension

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	white (white, cloudy)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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)

Revised: 12/2024

Bamboo US BidCo LLC