



# WebCenter Approval Information

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**Project:** PRD-006211-1-Nivolumab-Opdivo-Carton-Malaysia  
**Document:** 2000046A0.pdf  
**Document description:**  
**Version:** 1  
**Version ID:** 00002\_0000043655  
**Downloaded:** Nov 26, 2024 at 11:44 AM GMT+08:00  
**By:** chua, clarissa (CHUAW2)  
**Approval state:**

**Draft**

2 of 5 CODE № 0200004600



40 mg/4 ml  
nivolumab  
concentrate for solution for infusion  
**OPDIVO** 10 mg/ml

Reg No.: MAL17055001ARZ

Product Registration holder  
DKSH Malaysia Sdn Bhd.  
B-11-01, The Ascent, Paradigm  
No.1, Jalan SS7/26A, Kelana Jaya,  
47301 Petaling Jaya  
Selangor, Malaysia.

Manufactured By:  
Vetter Pharma-Fertigung GmbH & Co. KG.  
Mooiswiesen 2, Ravensburg, Germany

Released by:  
Swords Laboratories Unlimited Company  
T/A Bristol-Myers Squibb  
Cruiserath Biologics  
Cruiserath Road  
Mulhuddart, Dublin 15, Ireland

Lot :  
Mfg :  
EXP :



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2000046A0

C037  
BMS286A

Each ml of concentrate contains 10 mg of nivolumab.

Each vial contains 40 mg of nivolumab.

Excipients: sodium citrate, sodium chloride, mannitol (E421), pentetic acid, polysorbate 80, sodium hydroxide, hydrochloric acid, water for injections.

Contains no antimicrobial preservative. For single use only.

Refer to the package insert for dosage and administration instruction before use.

Store at 2°C to 8°C (Refrigerate. Do not freeze). Store in the original package in order to protect from light.

Keep out of the sight and reach of children / Jauhi daripada kanak-kanak. Controlled medicine / Ubat terkawal.

See accompanying package insert for indications and dosing information.

**OPDIVO** 10 mg/ml  
concentrate for solution for infusion

nivolumab

40 mg/4 ml

1 vial

Intravenous use

Bristol Myers Squibb

**OPDIVO** 10 mg/ml  
concentrate for solution for infusion

nivolumab

40 mg/4 ml

Reg No.: MAL17055001ARZ

Bristol Myers Squibb

**MS&T Artwork:** Dublin  
**BAMS Artwork Number:** PRD-006211-1  
**Version:** 01  
**Trade Name:** Opdivo  
**Component:** Carton  
**Market(s):** Malaysia

**Print Swatches:**

- PMS 302
- PMS 5265
- PMS 1665
- PMS 314
- PMS 299
- PMS Process Black

**Non-Print Swatches:**

- Profile
- Technical Info
- Varnish

Confidentiality agreement: Artwork may not be altered in any way without express permission from MS&T Artwork



Bar prints 100mm @ 100%

**MS&T Artwork Dublin**

**Date:** 12 Nov 2024      **Time:** 12:10  
**Superseded Artwork Number:** N/A  
**CMO Artwork Number:** 2000046A0  
**CMO Drawing:** C037  
**BMS Template:** N/A  
**OLV Barcode Type/Value:** 2/5 = 0200004600  
**SITE/CMO:** CATALENT ANAGNI  
**CMO Description:** CTN OPDIVO 40MG VETTER 286A FCT MY

**Font Information**

**Font Family:** Helvetica, Trade Gothic LT Std  
**Body text size:** 7pt  
**Smallest text size:** 7pt (Excluding artwork code)

