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Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-11080

Trade Name	*Dose Form*	*Strength*	*Identifier*
Tevimbra	Concentrate for injection	100 mg/10mL	
Sponsor	*Application date*	*Registration situation*	*Classification*
BeiGene NZ Unlimited c/o Quigg Partners Level 7, The Bayleys Building 36 Brandon Street Wellington 6011	29/7/2022	Consent given Approval date: 5/12/2024	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
concentrate for injection	Active	
	Tislelizumab 10 mg/mL	Boehringer Ingelheim Biopharmaceuticals (China) Ltd. 1090, Halei Road, Pilot Free Trade Zone Shanghai 201203 CHINA
	Excipient	
	Citric acid monohydrate	
	Histidine	
	Histidine hydrochloride monohydrate	
	Polysorbate 20	
	Sodium citrate dihydrate	
	Trehalose dihydrate	
	Water for injection	

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	BeiGene (Suzhou) Co., Ltd. Building 9, 218 Sangtian St. Suzhou Industrial Park Suzhou Area Pilot Free Trade Zone Suzhou, Jiangsu 215025 CHINA
	Boehringer Ingelheim Biopharmaceuticals (China) Ltd. 1090, Halei Road, Pilot Free Trade Zone Shanghai 201203 CHINA
Manufacture of Final Dose Form	Boehringer Ingelheim Biopharmaceuticals (China) Ltd. 1090, Halei Road, Pilot Free Trade Zone Shanghai 201203 CHINA
Packing	Boehringer Ingelheim Biopharmaceuticals (China) Ltd. 1090, Halei Road, Pilot Free Trade Zone Shanghai 201203 CHINA
Secondary Packaging	Millmount Healthcare Limited Block-7 City North Business Campus Stamullen County Meath K32 YD60 IRELAND
NZ Site of Product Release	Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics 58 Richard Pearse Drive Airport Oaks Mangere AUCKLAND 2022

Packaging

Package	*Contents*	*Shelf Life*
Vial, glass, Type 1 with chlorobutyl rubber stopper	10 mL	36 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) protect from light. Do not shake.

Indications

TEVIMBRA as monotherapy is indicated for the treatment of adult patients with unresectable, recurrent, locally advanced or metastatic OSCC after prior systemic therapy.

TEVIMBRA in combination with pemetrexed and platinum containing chemotherapy is indicated for the first-line treatment of patients with locally advanced or metastatic non-squamous NSCLC, with PD-L1 expression greater than or equal to 50% but no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations.
TEVIMBRA in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of patients with locally advanced or metastatic squamous NSCLC.
TEVIMBRA as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC after prior chemotherapy.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
29/7/2022	New Higher-risk Medicine Application	New higher-risk medicine containing one or more new active substances	Granted 5/12/2024	9/9/2022	