# SFDA
# Safety communication

**[17 /03/2022]**

## Potential Risk of Optic neuritis Associated with the Use of Pembrolizumab

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals about the potential risk of optic neuritis associated with the use of pembrolizumab.

Pembrolizumab approved by SFDA for the treatment of advanced melanoma in adults, metastatic non-small cell lung carcinoma, relapsed or refractory classical Hodgkin lymphoma , locally advanced or metastatic urothelial carcinoma and treatment of recurrent or metastatic head and neck squamous cell carcinoma. Optic neuritis (ON) is an inflammatory optic neuropathy affecting optic nerves, causing vision loss, reduced color vision, and pain on movement of the eye with recovery over weeks to a month, in most cases.

We reviewed published literature and post marketing databases to assess the association between potential risk of optic neuritis with pembrolizumab use. Our review found five published case reports suggesting a possible association between ON and pembrolizumab use. In addition, we identified 54 spontaneous case reports of ON with pembrolizumab use in the World Health Organization (WHO) database, reported between 1999 and January 2022. Most reported cases was from the United States and 52 cases were serious. The cases involved 31 males and 21 females, and the rest of cases were unknown. Age ranges in most cases were between 45 to 75 years old. Time to onset in most cases ranged from 4 days up to 8 months following pembrolizumab use.

Therefore, the SFDA requests to update the product information of pembrolizumab containing products by adding ON as a post marketing adverse event.

**Call for reporting:**

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662 SFDA

Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa