Pembrolizumab

【IKEY】Keytruda Injection 100mg/4mL/Vial *ATC Code：L01XC18*

中文名： 吉舒達注射劑 «MSD»

適應症： 1.黑色素細胞瘤。2.非小細胞肺癌。3.典型何杰金氏淋巴瘤。4.頭頸部鱗狀細胞癌。 5.泌尿道上皮癌。6.胃癌。7.原發性縱膈腔 B 細胞淋巴瘤。8.高微衛星不穩定性或錯誤配對修復功能不足性癌症。9.高微衛星不穩定性或錯誤配對修復功能不足性大腸直腸癌。10.肝細胞癌。11.子宮頸癌。12.腎細胞癌。13.子宮內膜癌。14.食道癌。15.三陰性乳癌。16.高腫瘤突變負荷量癌症。

藥理分類： Antineoplastic Agent, Anti-PD-1 Monoclonal Antibody; Immune Checkpoint Inhibitor.

用法用量：

Administration:

IV infuse over 30 minutes through a 0.2 to 5 micron sterile, nonpyrogenic, low-protein binding inline or add-on filter. Do not infuse other medications through the same infusion line.

Interrupt or slow the infusion for grade 1 or 2 infusion-related reactions; permanently discontinue for grade 3 or 4 infusion-related reactions.

Indications and dosage regimens:

1. **Cervical cancer** (recurrent or metastatic):
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
2. **Endometrial carcinoma (advanced):**
   IV: 200 mg once every 3 weeks (in combination with lenvatinib) until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
3. **Esophageal cancer (**recurrent locally advanced or metastatic):
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
4. **Gastric cancer (**recurrent locally advanced or metastatic):
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
5. **Head and neck cancer, squamous cell,** (unresectable/recurrent or metastatic), single-agent therapy:
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
6. **Head and neck cancer, squamous cell, (**unresectable/recurrent or metastatic), combination therapy:
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months (initially in combination with 6 cycles of fluorouracil and either carboplatin or cisplatin).
7. **Hepatocellular carcinoma** (advanced):
   IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
8. **Hodgkin lymphoma, classical** (relapsed or refractory):

IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.

9. **Melanoma (adjuvant treatment):**
   IV: 200 mg once every 3 weeks until disease recurrence, unacceptable toxicity, or for up to 12 months in patients without disease recurrence.
10. **Melanoma** (unresectable or metastatic):
    IV: 200 mg once every 3 weeks until disease progression or unacceptable toxicity.
    Off-label dosing: 2 mg/kg once every 3 weeks until disease progression or unacceptable toxicity.
11. **Merkel cell carcinoma**, recurrent or metastatic:
    IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
    Off-label dosing: 2 mg/kg once every 3 weeks for up to 2 years or until complete response, or until disease progression or unacceptable toxicity.
12. **Microsatellite instability-high cancer** (unresectable or metastatic):
    IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
13. **Non-small cell lung cancer** (stage III or metastatic), single-agent therapy:
    IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
    Off-label dosing (in patients with metastatic NSCLC with disease progression following platinum-containing chemotherapy): 2 mg/kg once every 3 weeks for 24 months or until disease progression or unacceptable toxicity.
14. **Non-small cell lung cancer** (metastatic, nonsquamous), combination therapy:
    IV: 200 mg once every 3 weeks (in combination with pemetrexed and either cisplatin or carboplatin) for 4 cycles, followed by pembrolizumab monotherapy of 200 mg once every 3 weeks (with or without optional indefinite pemetrexed maintenance therapy) until disease progression, unacceptable toxicity, or (in patients without disease progression) for a total duration of pembrolizumab therapy of up to 35 cycles or 24 months.
15. **Non-small cell lung cancer (**metastatic, squamous), combination therapy:
    IV: 200 mg once every 3 weeks (in combination with carboplatin and either paclitaxel or paclitaxel [protein bound]) for 4 cycles, followed by pembrolizumab monotherapy of 200 mg once every 3 weeks until radiographic disease progression, unacceptable toxicity, or (in patients without disease progression) for a total duration of pembrolizumab therapy of up to 35 cycles.
16. **Primary mediastinal large B-cell lymphoma** (relapsed or refractory):
    IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.
17. **Renal cell carcinoma** (advanced):

IV: 200 mg once every 3 weeks (in combination with axitinib) until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.

18. Small cell lung cancer (metastatic):

IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.

19. Urothelial carcinoma (locally advanced or metastatic):

IV: 200 mg once every 3 weeks until disease progression, unacceptable toxicity, or (in patients without disease progression) for up to 24 months.

藥品調製與保存： 1.抽取所需藥量注入 NS 或 D5W 的輸注液袋，以輕輕翻轉的方式將稀釋溶液混合均勻。使最終濃度為 1~10 mg/mL。 2.溶液安定性: 室溫，6 小時(包括於室溫下，IV 袋中之輸注溶液的存放時間、以及輸注所需要的時間。)。 2~8˚C，24 小時，投藥前應先讓稀釋後的溶液回復至室溫。

不良反應： 週邊水腫，疲勞，頭痛，寒戰，失眠，頭暈，食慾降低。

交互作用：

- Antibiotics: ↓ the therapeutic effect of Immune Checkpoint Inhibitors.
- Corticosteroids (Systemic): ↓ the therapeutic effect of Immune Checkpoint Inhibitors.
- Desmopressin: ↑ the hyponatremic effect of Desmopressin.
- Ketoconazole (Systemic): ↑ the hepatotoxic effect of Ketoconazole (Systemic).

注意事項： 1.使用含過濾器的管線。2.每 3 週一次，每次以靜脈輸注 30 分鐘。

懷孕期： 目前並無任何可說明發生胚胎胎兒毒性風險的人體試驗資料。應告知懷孕的婦女，其胎兒可能面臨的風險。

授乳期： 目前並不確知 KEYTRUDA 是否會分泌進入人類的乳汁。應囑咐女性病人在使用本藥治療期間及使用最後一劑藥物後的 4 個月期間要停止餵哺母乳。

健保規定： (節錄) 1.每位病人每個適應症限使用一種免疫檢查點抑制劑且不得互換，亦不可合併使用標靶藥物，無效後則不再給付該適應症相關之標靶藥物。2.使用總療程以 52 週為上限。3.需經單筆電子申請事前審查核准後使用(不適用緊急報備)。4.初次申請以 12 週為限。5.用藥後每 12 週評估一次。6.須於療程結束或停止使用藥品後 28 天內，於事前審查系統登錄結案，否則核刪最後一次事前審查申請之藥費。