臺北醫學大學附設醫院
TAIPEI MEDICAL UNIVERSITY HOSPITAL

藥物不良反應工作小組藥物安全警訊通告 107.02

加拿大衛生部(Health Canada)用藥安全資訊風險溝通：

加拿大衛生部警告抗腫瘤藥品Tecentriq®(Atezolizumab)可能引起心肌炎

摘要說明:

Tecentriq® 於 2017 年 7 月經衛生服利部核准上市，適應症為局部晚期或轉移性泌尿道上皮癌及非小細胞肺癌。

加拿大衛生部(Health Canada)發佈由廠商安全性資料庫所提供之臨床試驗及上市後資料，確認有兩例非致命性心肌炎(myocarditis)，其中一例已經由檢體檢查確定。截至 2016 年 11 月，已約有 8000 名病人接受臨床試驗及 5000 名病人於上市後使用 Tecentriq®。

醫療人員注意事項:

1) 醫療人員需提醒病人及其照護者，接受 Tecentriq® 的治療期間若有以下症狀，應立即就醫或諮詢醫療人員:
   - ✓ 胸痛
   - ✓ 心跳不規則
   - ✓ 休息或在運動時感到呼吸短促
   - ✓ 體液滯留:腿部感到腫脹
   - ✓ 運動的耐力降低
2) 醫療人員應監測病人有關心肌炎的症狀及生理數值，若為二級心肌炎病人應暫停使用；三、四級心肌炎病人應禁止使用。
3) 醫療人員若懷疑病人因為使用藥品導致不良反應發生時，請立即線上通報藥物不良反應。

院內品項：

Tecentriq® (Atezolizumab) 1200mg/20mL/vial 癌自禦注射劑

北醫藥物不良反應工作小組 敬啟
臨床藥學組 呂懷恩 藥師
(分機 8443/8444)

Health Canada 原文：

TECENTRIQ (atezolizumab) - Risk of Myocarditis

- **Starting date:February 14, 2018**
- **Posting date:February 14, 2018**
- **Type of communication:Dear Healthcare Professional Letter**
- **Subcategory:Biologic/vaccine**
- **Source of recall:Health Canada**
- **Issue:Product SafetyAudience:Healthcare Professionals, Hospitals**
- **Identification number:RA-65990**

Audiences

Healthcare professionals including oncologists, uro-oncologists, urologists, oncology nurses, oncology pharmacists, emergency room staff, and other healthcare professionals providing care to cancer patients, including those working in hospitals, cancer centers, oncology clinics, and pharmacies.

Key messages

- **Severe cases of myocarditis have been reported in patients being treated with TECENTRIQ (atezolizumab) in clinical trials.**
- **Healthcare professionals are advised to:**
  - **monitor patients receiving TECENTRIQ for signs and symptoms of myocarditis.**
  - **withhold TECENTRIQ therapy in patients with Grade 2 myocarditis.**
  - **permanently discontinue TECENTRIQ treatment in patients with Grade 3 or 4 myocarditis.**
  - **administer corticosteroids and/or additional immunosuppressive agents as clinically indicated to TECENTRIQ treated patients who develop myocarditis.**
- **The Canadian Product Monograph has been updated to include this new safety information.**

Issue

Severe cases of myocarditis have been reported in patients receiving TECENTRIQ treatment.

Products affected

TECENTRIQ (atezolizumab), concentrate for solution for infusion, 60 mg / mL in 20 mL single use vials.

Background information

TECENTRIQ has been issued marketing authorization with conditions, pending the results of studies to verify its clinical benefit.

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- have disease progression during or following platinum-containing chemotherapy.
- have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy.

As of February 20, 2017, a cumulative analysis of the company's safety database, which includes data from clinical trials and the post-marketing setting, identified 2 non-fatal cases of myocarditis, including one case with biopsy confirmation. No Canadian cases of myocarditis related to TECENTRIQ treatment have been identified as of February 2017. Approximately 8,000 patients in clinical trials and 5,000 patients in the post-market setting have been exposed to TECENTRIQ as of November 2016.

Who is affected

Information for consumers

TECENTRIQ is used to treat a type of bladder cancer called urothelial carcinoma that cannot be removed by surgery or has spread to other parts of the body. TECENTRIQ is used after patients have tried chemotherapy and it did not work or is no longer working.

In some patients, TECENTRIQ has been associated with the risk of developing myocarditis. Myocarditis is an inflammation of the heart muscle, leading to possible reduction in the heart's pumping function and to possible irregular heartbeat.

Patients should contact their healthcare professional if they develop the following signs and symptoms during treatment with TECENTRIQ:

- Chest pain
- Irregular heartbeat
- Shortness of breath, at rest or during physical activity
- Fluid retention with swelling of legs, ankles and feet
- Decreased exercise tolerance

Patients and caregivers should discuss any questions or concerns about this information with their healthcare professional.

Patients receiving TECENTRIQ should also inform their healthcare professional if they experience any other side effects.

Information for healthcare professionals

Healthcare professionals are advised to:

- monitor patients receiving TECENTRIQ for signs and symptoms of myocarditis.
- withhold TECENTRIQ therapy in patients with Grade 2 myocarditis.
- permanently discontinue TECENTRIQ treatment in patients with Grade 3 or 4 myocarditis.

- administer corticosteroids and/or additional immunosuppressive agents as clinically indicated to TECENTRIQ treated patients who develop myocarditis.

Action taken by Health Canada

Health Canada in collaboration with Hoffmann-La Roche Limited has updated the TECENTRIQ Product Monograph. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication update will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of myocarditis or other serious or unexpected side effects in patients receiving TECENTRIQ should be reported to Hoffmann-La Roche Limited or Health Canada.

參考來源：

http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/65990a-eng.php