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Media and Public Relations

News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 25-28 November 2024

Doxycycline: currently available evidence not supporting link with risk of suicidality

EMA's safety committee (PRAC) has concluded that the currently available evidence is not sufficient to establish a causal relationship between the use of the antibiotic doxycycline and the risk of suicidality.

Doxycycline is a broad-spectrum antibiotic, widely used to treat a wide range of infections caused by bacteria such as acne, urinary and lower respiratory tract infections, dental infections, and skin infections. It is also used to prevent the development of certain infections, such as malaria

A safety signal on the risk of suicidality, suicidal thoughts or actions with doxycycline was raised based on cases reported to the Finnish national competent authority, as well as further cases reported to EudraVigilance, the centralised European database of suspected side effects reports, and the medical literature.

The PRAC started its review in November 2023 and also requested the marketing authorisation holders for doxycycline to perform a cumulative review of the data from all relevant sources.

The PRAC also requested a study based on real-world evidence, which includes data from electronic health records and disease registries, through DARWIN EU to facilitate the assessment of the signal. After reviewing all available evidence from spontaneous reports, the literature, the discussion on possible mechanisms and the study performed via DARWIN EU, the PRAC considered that the evidence is not sufficient to establish a causal relationship and that no update to the product information of doxycycline is warranted.

Suicide-related events in relation to doxycycline will be closely monitored and any new evidence will be discussed in the Periodic Safety Update Reports (PSURs).

New safety information for healthcare professionals

Veoza (fezolinetant): new recommendations to minimise risk of liver injury

The PRAC has agreed to a direct healthcare professional communication (DHPC) informing of the risk of drug-induced liver injury (DILI) with Veoza (fezolinetant) and has recommended monitoring of liver function before and during treatment.

Veoza is a medicine used to treat moderate-to-severe vasomotor symptoms (also referred to as hot flushes or night sweats) associated with menopause.

The committee considered a review of the potential risk of fezolinetant to cause drug-induced liver injury based on information from all available sources, including reports of suspected side effects and studies published in the scientific literature.

Severe elevations of the liver enzymes alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) (>10x upper limit of normal) with concurrent elevations in bilirubin and/or alkaline phosphatase (ALP) have been reported post marketing in women taking Veoza. In some cases, elevated liver function tests (LFTs) were associated with signs or symptoms suggestive of liver injury such as fatigue, pruritus, jaundice, dark urine, decreased appetite, or abdominal pain.

PRAC recommends LFTs must be performed before treatment is started. During the first three months of treatment, monthly LFTs must be performed, and thereafter based on clinical judgement. During treatment, LFTs must be performed if symptoms suggestive of liver injury occur. Monitoring of liver function should be maintained until they have normalised.

Treatment should be discontinued in certain cases of transaminase and bilirubin elevations or if liver enzyme elevations are accompanied by symptoms suggestive of liver injury.

The summary of product characteristics and package leaflet of Veoza are being updated to reflect the new risk information and recommendations.

Once adopted, the DHPC for Veoza will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.