6 August 2018[1]
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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 9-12 July 2018 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found ***here*** (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Antiretrovirals – Autoimmune hepatitis (EPITT no 18956)

List of antiretrovirals: abacavir; abacavir, dolutegravir, lamivudine; abacavir; abacavir, lamivudine, zidovudine; atazanavir; atazanavir, cobicistat; bictegravir, emtricitabine, tenofovir alafenamide; darunavir; darunavir, cobicistat; darunavir, cobicistat, emtricitabine, tenofovir alafenamide; didanosine; dolutegravir; dolutegravir, rilpivirine; efavirenz ; efavirenz, emtricitabine, tenofovir disoproxil; elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide; elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil; emtricitabine; emtricitabine, rilpivirine, tenofovir alafenamide; emtricitabine, rilpivirine, tenofovir disoproxil; emtricitabine, tenofovir alafenamide; emtricitabine, tenofovir disoproxil; enfuvirtide; etravirine; fosamprenavir; indinavir; lamivudine; lamivudine, tenofovir; lamivudine, zidovudine; lopinavir, ritonavir; maraviroc; nevirapine; raltegravir; rilpivirine; ritonavir; saquinavir; stavudine; tenofovir disoproxil; tipranavir; zidovudine

Summary of product characteristics

4.4. Special warnings and precautions for use

Immune reactivation syndrome

In HIV infected patients with severe immune deficiency at the time of initiation of combination antiretroviral therapy (CART), an inflammatory reaction to asymptomatic or residual opportunistic

[1] Intended publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Typically, such reactions have been observed within the first few weeks or months of initiation of CART. Relevant examples are cytomegalovirus retinitis, generalised and/or focal mycobacterial infections, and Pneumocystis jirovecii pneumonia. Any inflammatory symptoms should be evaluated and treatment instituted when necessary. Autoimmune disorders (such as Graves' disease and autoimmune hepatitis) have also been reported to occur in the setting of immune reactivation; however, the reported time to onset is more variable and these events can occur many months after initiation of treatment.

4.8. Undesirable effects

Immune reactivation syndrome

In HIV infected patients with severe immune deficiency at the time of initiation of CART, an inflammatory reaction to asymptomatic or residual opportunistic infections may arise. Autoimmune disorders (such as Graves' disease and autoimmune hepatitis) have also been reported; however, the reported time to onset is more variable and these events can occur many months after initiation of treatment (see section 4.4).

2. Human normal immunoglobulin for intravenous administration (IVIg) – Lupus-like syndrome and related terms (EPITT no 19098)

Summary of product characteristics

4.8. Undesirable effects

Cases of reversible aseptic meningitis and rare cases of transient cutaneous reactions (including cutaneous lupus erythematosus - frequency unknown) have been observed with human normal immunoglobulin.