8 February 2021[1]
EMA/PRAC/19650/2021
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 11-14 January 2021 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. Adalimumab – Abnormal weight gain (EPITT no 19520)

Summary of product characteristics

4.8. Undesirable effects

Investigations

Frequency 'Not known': Weight increased[2)]

2) The mean weight change from baseline for adalimumab ranged from 0.3 kg to 1.0 kg across adult indications compared to (minus) -0.4 kg to 0.4 kg for placebo over a treatment period of 4-6 months. Weight increase of 5-6 kg has also been observed in long-term extension studies with mean exposures of approximately 1-2 years without control group, particularly in patients with Crohn's disease and ulcerative colitis. The mechanism behind this effect is unclear but could be associated with the anti-inflammatory effect of adalimumab.

Package leaflet

4. Possible side effects

Not known (frequency cannot be estimated from available data)

[…]

- weight gain (for most patients, the weight gain was small)

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Anastrozole – Depressed mood disorders (EPITT no 19592)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

Psychiatric disorders

Frequency 'Very common': Depression

Package leaflet

4 - Possible side effects

Very common side effects (affect more than 1 in 10 people)

[…]

Depression

3. Hydrocortisone (brand name: Alkindi) – Adrenal crisis (EPITT no 19656)

Summary of product characteristics

4.2. Posology and method of administration

Changing from conventional oral glucocorticoid treatment to Alkindi

When changing patients from conventional oral hydrocortisone replacement therapy, crushed or compounded, to Alkindi, an identical total daily dose may be given. Alkindi is therapeutically equivalent to conventional oral hydrocortisone ~~tablets~~ formulations. Where a patient is changed from other oral hydrocortisone formulations to Alkindi, inaccuracy in the dosing possible with other oral hydrocortisone formulations can lead to a relative fall in hydrocortisone exposure on the same nominal dose, leading to symptoms of adrenal insufficiency or crisis (see section 4.4).

4.4. Special warnings and precautions for use

Adrenal crisis

[…]

Adrenal crisis can occur when switching from conventional oral hydrocortisone formulations, crushed or compounded, to Alkindi. Close monitoring of patients is recommended in the first week after switch. Healthcare professionals should inform carers and patients that extra doses of Alkindi should be given if symptoms of adrenal insufficiency are seen. If this is required, then an increase in the total daily dose of Alkindi should be considered and immediate medical advice should be sought.

Package leaflet

2 - What you need to know before you give Alkindi

Warnings and precautions

- When your child is changing to Alkindi from another hydrocortisone preparation.

Differences between hydrocortisone preparations when changing to Alkindi may mean your child could be at risk of receiving an incorrect dose of hydrocortisone in the first week after switching to Alkindi. This may lead to a risk of adrenal crisis. You should watch your child carefully in the week after changing to Alkindi and give extra doses of Alkindi if there are symptoms of adrenal crisis such as unusual tiredness, headache, a raised or low temperature or vomiting. If this happens medical attention should be sought right away.