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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 8-11 March 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. Anakinra; canakinumab – Drug reaction with eosinophilia and systemic symptoms (DRESS) (EPITT no 19566)

Summary of product characteristics

4.4. Special warnings and precautions for use

- Anakinra

Drug reaction with eosinophilia and systemic symptoms (DRESS)

Drug reaction with eosinophilia and systemic symptoms (DRESS) has rarely been reported in patients treated with Kineret, predominantly in patients with systemic juvenile idiopathic arthritis (sJIA). Patients with DRESS may require hospitalization, as this condition may be fatal. If signs and symptoms of DRESS are present and an alternative aetiology cannot be established, Kineret should be discontinued and a different treatment considered.

- Canakinumab

Drug reaction with eosinophilia and systemic symptoms (DRESS)

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

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Drug reaction with eosinophilia and systemic symptoms (DRESS) has rarely been reported in patients treated with Ilaris, predominantly in patients with systemic juvenile idiopathic arthritis (sJIA). Patients with DRESS may require hospitalization, as this condition may be fatal. If signs and symptoms of DRESS are present and an alternative aetiology cannot be established, Ilaris should not be re-administered and a different treatment considered.

Package leaflet

2. What you need to know before you use <product name>

- Anakinra

Contact your doctor immediately

- if you have ever developed an atypical, widespread rash or skin peeling after taking Kineret.

The serious skin reaction, DRESS (drug reaction with eosinophilia and systemic symptoms), has rarely been reported in association with Kineret treatment, predominantly in patients with systemic juvenile idiopathic arthritis (sJIA). Seek medical attention immediately if you notice an atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes.

- Canakinumab

Contact your doctor immediately

- if you have ever developed an atypical, widespread rash or skin peeling after taking Ilaris.

The serious skin reaction, DRESS (drug reaction with eosinophilia and systemic symptoms), has rarely been reported in association with Ilaris treatment, predominantly in patients with systemic juvenile idiopathic arthritis (sJIA). Seek medical attention immediately if you notice an atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes.

2. COVID-19 vaccine (ChAdOx1-S [recombinant]) (COVID-19 Vaccine AstraZeneca) – Anaphylactic reaction (EPITT no 19668)

Summary of product characteristics

4.4. Special warnings and precautions for use

Hypersensitivity and anaphylaxis

Events of anaphylaxis have been reported.

[…]

4.8. Undesirable effects

Immune system disorders

Frequency 'Not known': Anaphylaxis; Hypersensitivity

Package leaflet

4. Possible side effects

Frequency unknown

- severe allergic reactions (anaphylaxis)

- hypersensitivity

3. Trastuzumab emtansine – Extravasation and epidermal necrosis (EPITT no 19611)

Summary of product characteristics

4.2. Posology and method of administration

Posology

[…] Cases of delayed epidermal injury or necrosis following extravasation have been observed in post-marketing setting (see sections 4.4 and 4.8).

4.4. Special warnings and precautions for use

[…]

Infusion-related reactions

[…]

Injection site reactions:
Extravasation of trastuzumab emtansine during intravenous injection may produce local pain, severe tissue lesions (erythema, vesiculation) and epidermal necrosis. If extravasation occurs, the infusion should be terminated immediately and the patient should be examined regularly as necrosis may occur within days or weeks after the infusion.

4.8. Undesirable effects

Description of selected adverse reactions

[…]

Extravasation

[…] In the post-marketing setting, cases of epidermal injury or necrosis following extravasation have been observed within days to weeks after infusion. Specific treatment for trastuzumab emtansine extravasation is unknown at this time (see section 4.4).

Package leaflet

2. What you need to know before you are given Kadcyla

Tell your doctor or nurse straight away if you notice any of the following serious side effects while you are given Kadcyla:

[…]

Injection site reactions: If you get a burning sensation, feel pain or tenderness at the infusion site, this could indicate that Kadcyla leaks outside the blood vessel. Tell your doctor or nurse immediately. If Kadcyla has leaked outside the blood vessel increased pain, discoloration, blistering and sloughing of your skin (skin necrosis) can occur within days or weeks after the infusion.

4. Possible side effects

Tell your doctor or nurse straight away if you notice any of following serious side effects.

[…]

Frequency not known:
If the Kadcyla infusion solution leaks into the area around the infusion site you may develop pain, discoloration, blistering and sloughing of your skin (skin necrosis) at the infusion site. Contact your doctor or nurse immediately.