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EMA/PRAC/611010/2017
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 27-30 November 2017 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. Insulin (pre-filled pens and cartridges): insulin aspart; insulin bovine; insulin degludec; insulin degludec, insulin aspart; insulin degludec, liraglutide; insulin detemir; insulin glargine; insulin glulisine; insulin human (rDNA); insulin human, insulin isophane; insulin lispro; insulin porcine – Potential increased risk of medication error associated with withdrawing insulin from pre-filled pens and cartridges, leading to dysglycaemia (EPITT no 18893)

Standard (100 units/mL) and lower (< 100 units/mL) strength insulin products

The text to be adapted to individual products is **in bold**.

Summary of product characteristics

6.6. Special precautions for disposal and other handling

The following text and any related package leaflet text should be removed: 'If the <pen / infusion pump> malfunctions (see instructions for using the pen / infusion pump), the solution may be drawn from the cartridge into a syringe (suitable for an insulin with 100 units/mL) and injected.'

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4.2. Posology and method of administration, and/or 4.4. Special warnings and precautions for use

<<Product name in cartridges> is only suitable for subcutaneous injections from a reusable pen.

< If administration by syringe, <intravenous injection> or <infusion pump> is necessary, a vial should be used.>>

<<Product name in pre-filled pen> is only suitable for subcutaneous injections.

<If administration by syringe, <intravenous injection> or <infusion pump> is necessary, a vial should be used.>>

Package leaflet

2. What you need to know before you use <product name>, and 3. How to use <product name>

<Product name in cartridges> is only suitable for injecting just under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.

<Product name in pre-filled pen> is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

2. Tofacitinib – Angioedema (EPITT no 18904)

Summary of product characteristics

4.4. Special warnings and precautions for use

Hypersensitivity

In post-marketing experience, cases of hypersensitivity associated with tofacitinib administration have been reported. Allergic reactions included angioedema and urticaria; serious reactions have occurred. If any serious allergic or anaphylactic reaction occurs, tofacitinib should be discontinued immediately.

4.8. Undesirable effects

Immune system disorders

Frequency 'not known': hypersensitivity; angioedema; urticaria

Package leaflet

4. Possible side effects

Other side effects which have been observed with XELJANZ are listed below.

Not known (frequency cannot be estimated from the available data): hives (itchy, bumpy rash)