



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 3-6 April 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. Albiglutide – Acute kidney injury (EPITT no 18778)

Summary of product characteristics

4.4 – Special warnings and precautions for use

Dehydration

Dehydration, sometimes leading to renal impairment and acute renal failure, has been reported in patients treated with albiglutide and has occurred in patients without gastrointestinal side effects. Patients treated with albiglutide should be advised of the potential risk of dehydration, and take precautions to avoid fluid depletion.

Package leaflet

2 - What you need to know before you use Eperzan

Warnings and precautions

When initiating treatment with albiglutide, you may experience fluid loss from vomiting, nausea, diarrhoea or dehydration. It is important to avoid dehydration by drinking plenty of fluids.



2. Leflunomide; teriflunomide – Falsely decreased ionised calcium levels (EPITT no 18787)

Summary of product characteristics

4.4 - Special warning and precautions for use

Interference with determination of ionised calcium levels

The measurement of ionised calcium levels might show falsely decreased values under treatment with leflunomide and/or teriflunomide (the active metabolite of leflunomide) depending on the type of ionised calcium analyser used (e.g. blood gas analyser). Therefore, the plausibility of observed decreased ionised calcium levels needs to be questioned in patients under treatment with leflunomide or teriflunomide. In case of doubtful measurements, it is recommended to determine the total albumin adjusted serum calcium concentration.

Package leaflet

2 - What you need to know before you take {Drug Name}

Warnings and precautions

Talk to your doctor before taking {Drug Name}

- if you are due to have a specific blood test (calcium level). Falsely low levels of calcium can be detected.

3. Temozolomide – Meningoencephalitis herpetic (EPITT no 18785)

Summary of product characteristics

4.4 - Special warnings and precautions for use

Meningoencephalitis herpetic

In post marketing cases, meningoencephalitis herpetic (including fatal cases) has been observed in patients receiving TMZ in combination with radiotherapy, including cases of concomitant steroids administration.

4.8 - Undesirable effects

Infections and infestations

Frequency 'uncommon': Meningoencephalitis herpetic (including cases with fatal outcome)

Package leaflet

4 - Possible side effects

Other side effects:

New or reactivated (recurring) cytomegalovirus infections and reactivated hepatitis B virus infections have been uncommonly reported. Cases of brain infections caused by herpes virus (meningoencephalitis herpetic), including fatal cases, have been uncommonly reported.