



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 27-30 October 2025 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 on the webpage for [PRAC recommendations on safety signals](#) (in English only).

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

1. Bosutinib – Cutaneous vasculitis (EPITT no 20184)

Summary of product characteristics

4.8 Undesirable effects

Skin and subcutaneous tissue disorders

Frequency "Uncommon":

Cutaneous vasculitis

Package leaflet

4. Possible side effects

Uncommon (may affect up to 1 in 100 people):

Inflammation of blood vessels in the skin which may result in a rash or bruising (cutaneous vasculitis).

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



2. Datopotamab deruxtecan – Anaphylactic reaction (EPITT no 20181)

Summary of product characteristics

4.4 Special warnings and precautions for use

Hypersensitivity

Serious, anaphylactic reactions have been observed with datopotamab deruxtecan. Patients should be observed closely for hypersensitivity/allergic reactions, which may have the same clinical presentation as an infusion-related reaction. Medicinal products to treat such reactions, as well as emergency equipment, should be available for immediate use. In the event of a serious hypersensitivity reaction, datopotamab deruxtecan treatment must be immediately and permanently discontinued.

4.8 Undesirable effects

Tabulated list of adverse reactions

Table 3

Immune system disorders

Frequency: not known

Anaphylactic reaction

Package leaflet

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

Warnings and precautions

Datroway may also cause:

- allergic reactions, including anaphylaxis: allergic reactions which can be serious can occur during or shortly after the infusion. Your doctor will observe you closely while you are being given Datroway. For signs and symptoms of allergic reactions see section 4. Possible side effects.

If you experience a serious allergic reaction your doctor will permanently stop your treatment.

4. Possible side effects

[...]

Some side effects may be serious, and possibly fatal. **Speak with your doctor or nurse immediately** if you notice any of the following:

[...]

Not known (frequency cannot be estimated from the available data)

- Allergic reaction, including anaphylaxis: may include signs and symptoms such as rash, severe itching, flushing, dizziness, swelling of the face, lips, tongue and/or throat (angioedema), difficulty breathing or swallowing, and/or low blood pressure.

3. Epcoritamab – Hypogammaglobulinaemia (EPITT no 20174)

Summary of product characteristics

4.4 Special warnings and precautions for use

Serious infections

[...]

Hypogammaglobulinaemia has also been reported in patients receiving epcoritamab (see section 4.8). Immunoglobulin (Ig) levels should be monitored prior to and during treatment. Patients should be treated according to local institutional guidelines, including infection precautions and antimicrobial prophylaxis.

[...]

4.8 Undesirable effects

Table 7

Immune system disorders

Frequency “Very common” for all grades and “Uncommon” for grades 3-4:

Hypogammaglobulinaemia

Package leaflet

2. What you need to know before you use Tepkinly

Warnings and precautions

[...]

Your doctor or nurse will do blood tests, prior and during your treatment with epcoritamab, to check your antibody levels, which may indicate your risk of infection and the need for specific treatment.

[...]

4. Possible side effects

Other side effects

[...]

Very common: may affect more than 1 in 10 people

[...]

Shown in blood tests

[...]

- low levels of immunoglobulins, which may lead to infections