EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 July 2023[1]
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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 3-6 July 2023 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. Olaparib – Hepatocellular damage and hepatitis (EPITT no 19846)

Summary of product characteristics

4.4. Special warnings and precautions for use

Hepatotoxicity

Cases of hepatotoxicity have been reported in patients treated with olaparib (see section 4.8). If clinical symptoms or signs suggestive of hepatotoxicity develop, prompt clinical evaluation of the patient and measurement of liver function tests should be performed. In case of suspected drug-induced liver injury (DILI), treatment should be interrupted. In case of severe DILI treatment discontinuation should be considered as clinically appropriate.

4.8. Undesirable effects

Table 1 Tabulated list of adverse reactions

[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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MedDRA System Organ Class	Frequency of All CTCAE grades
Hepatobiliary disorders	Not known Drug-induced liver injury* Common Transaminases increased[a]

* As observed in the post-marketing setting.

[a] Transaminases increased includes PTs of alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased and hypertransaminasaemia.

Package leaflet

2. What you need to know before you take Lynparza

Warnings and precautions

Talk to your doctor, pharmacist or nurse before or during treatment with Lynparza:

- if you notice yellowing of your skin or the whites of your eyes, abnormally dark urine (brown coloured), pain on the right side of your stomach area (abdomen), tiredness, feeling less hungry than usual or unexplained nausea and vomiting contact your doctor immediately as this may indicate problems with your liver

4. Possible side effects

Other side effects include

not known (cannot be estimated from available data)

- Signs of liver problems, such as yellowing of your skin or the whites of your eyes (jaundice), nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (brown coloured), feeling less hungry than usual, tiredness

Common (may affect up to 1 in 10 people)

- [……] abnormal liver function tests