



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2023¹
EMA/PRAC/477437/2023
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 23-26 October 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. Dapagliflozin; dapagliflozin, metformin; dapagliflozin, saxagliptin – Acquired phimosis and phimosis (EPITT no 19935)

For dapagliflozin monoproducts

Summary of product characteristics

4.8 – Undesirable effects

Description of selected adverse reactions

Vulvovaginitis, balanitis and related genital infections

[New paragraph to be added at the end of this section]

<...>

Cases of phimosis/acquired phimosis have been reported concurrent with genital infections and in some cases, circumcision was required.

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



For dapagliflozin and metformin combination products

Summary of product characteristics

4.8 – Undesirable effects

Description of selected adverse reactions

Vulvovaginitis, balanitis and related genital infections

[New paragraph to be added at the end of this section]

<...>

Cases of phimosis/acquired phimosis have been reported with dapagliflozin concurrent with genital infections and in some cases, circumcision was required.

For dapagliflozin and saxagliptin combination products

Summary of product characteristics

4.8 – Undesirable effects

Description of selected adverse reactions

Vulvovaginitis, balanitis and related genital infections

[New paragraph to be added at the end of this section]

<...>

Cases of phimosis/acquired phimosis have been reported with dapagliflozin concurrent with genital infections and in some cases, circumcision was required.