

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy / Wholesaler Level

Dear Healthcare Professional

Ethigen Limited

Briviact 75 mg film-coated tablets

PLPI 18716/0146

SNOMED Code 37622711000001100

LOT Number	Expiry Date	Pack Size	First Distributed
340132	30/09/2024	56	15-Nov-22
332075	28/02/2025	56	06-Dec-22

Briviact 100 mg film-coated tablets

PLPI 18716/0147

SNOMED Code 37622711000001101

LOT Number	Expiry Date	Pack Size	First Distributed
332076	28/02/2025	56	09-Mar-22
329941	31/12/2024	56	09-May-22
337225	30/04/2025	56	30-May-22
332072	31/03/2025	56	01-Jun-22
329491	31/12/2024	56	08-Jun-22
337216	31/05/2025	56	09-Jun-22
339975	30/06/2025	56	27-Jun-22
337216	31/05/2025	56	29-Jul-22
343194	30/09/2025	56	14-Nov-22
349497	31/10/2025	56	16-Nov-22
343190	30/09/2025	56	12-Dec-22
349527	30/11/2025	56	14-Feb-23

Brief description of the problem

Ethigen Limited have informed MHRA that due to a formatting error of the Patient Information Leaflet (PIL), incorrect and missing information about the colorant ingredients of the tablet coating was listed in Section 6 of the PIL:

Briviact 75mg film-coated tablets:

The erroneous PIL packed with the affected batches of Briviact 75mg film-coated tablets contains the following text:

Coating:

poly(vinyl alcohol), titanium dioxide (E171), macrogol (3350), talc, iron oxide yellow (E172), iron oxide black (E172)

The correct version of the PIL should include the following text (missing information in **bold**):

Coating:

poly(vinyl alcohol), titanium dioxide (E171), macrogol (3350), talc, iron oxide yellow (E172), **iron oxide red (E172)**, iron oxide black (E172).

Briviact 100 mg film-coated tablets:

The erroneous PIL packed with the affected batches of Briviact 100mg film-coated tablets contains the following text:

Coating:

poly(vinyl alcohol), titanium dioxide (E171), macrogol (3350), talc, iron oxide yellow (E172), iron oxide red (E172)

The correct version of the PIL should include the following text (correct information in **bold**):

Coating:

poly(vinyl alcohol), titanium dioxide (E171), macrogol (3350), talc, iron oxide yellow (E172), **iron oxide black (E172)**.



Advice for healthcare professionals

There is no risk to product quality as a result of this issue. Healthcare professionals are advised to exercise caution when dispensing the above batches of the product. Where possible, please provide an updated copy of the PIL to the patient and remind the patient to read the leaflet in its entirety before using the medicine. These are available on the [MHRA website](#) by entering the product licence (PLPI) numbers. Alternatively, these may also be accessed via the links below:

[Briviact 75mg film-coated tablets](#)

[Briviact 100mg film-coated tablets](#)

Upon request, Ethigen Limited will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information.

Advice for patients

This notification relates to a typographical error in the Patient Information Leaflet (PIL) relating to the ingredients of the tablet coating of the medicine. Patients do not need to take any action as the medicine itself is not affected.

Any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).



Further Information

For medical information and stock control queries please contact the Regulatory Affairs Department at regulatory@ethigen.co.uk.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

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30th March 2023

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