Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

30 March 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 13 2023 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – ETHIGEN LTD – BRIVIACT 75MG FILM COATED TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 30 March 2023 EL (23)A/13 Our Ref: MDR 221-03/23

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

Active Pharmaceutical Ingredient: brivaracetam

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.

Medicines & Healthcare products Regulatory Agency

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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk