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**IMMEDIATE MESSAGE TO:**

1. Directors of Pharmacy
2. Medical Directors NHS Boards

17 June 2021

Dear Healthcare Professional,

**DRUG ALERT CLASS 2 - 14 2021 – CLASS 2 MEDICINES RECALL – ACTION WITHIN 48 HOURS – BRISTOL LABORATORIES LIMITED, BROWN & BURK UK LTD, TEVA UK LTD, IRBESARTAN CONTAINING AND LOSARTAN CONTAINING PRODUCTS**

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 RECALL

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy/Wholesaler Level Recall

Date: 17 June 2021

EL (21)A/14

Our Ref: MDR 050-10/20

Dear Healthcare Professional,

### Bristol Laboratories Limited

#### Irbesartan 75 mg Film Coated Tablets

**PL 17907/0421**

Batch Number	Expiry Date	Pack Size	First Distributed
POM0007	February 2023	28	8 Dec 2020
POM0008	February 2023	28	13 Jan 2021
POM0009	February 2023	28	18 Feb 2021
POM0010	February 2023	28	20 Apr 2021

#### Irbesartan 150 mg Film Coated Tablets

**PL 17907/0422**

Batch Number	Expiry Date	Pack Size	First Distributed
PON0005	January 2023	28	15 Feb 2021
PON0006	January 2023	28	8 Mar 2021
PON0007	January 2023	28	29 Mar 2021
PON0008	January 2023	28	12 Apr 2021
PON0009	January 2023	28	20 Apr 2021

#### Irbesartan 300 mg Film Coated Tablets

**PL 17907/0423**

Batch Number	Expiry Date	Pack Size	First Distributed
POO0005	February 2023	28	30 Nov 2020

Active Pharmaceutical Ingredient: irbesartan

### Brown and Burk UK Ltd

#### Irbesartan 75mg Film Coated Tablets

**PL 25298/0073**

Batch Number	Expiry Date	Pack Size	First Distributed
IAAG017	May 2022	28	15 Nov 2019
IAAG018	May 2022	28	14 Oct 2019
IAAG019	May 2022	28	13 Feb 2020
IAAG022	Aug 2022	28	19 Mar 2020
IAAG023	Aug 2022	28	17 Nov 2020

#### Irbesartan 150mg Film Coated Tablets

**PL 25298/0074**

Batch Number	Expiry Date	Pack Size	First Distributed
IABG033	May 2022	28	09 Sep 2019
IABG034	May 2022	28	16 Sep 2019



IABG035	May 2022	28	22 Oct 2019
IABG037	July 2022	28	05 Dec 2019
IABG038	July 2022	28	17 Feb 2020
IABG039	July 2022	28	13 Feb 2020
IABG051	Jan 2023	28	27 May 2020

**Irbesartan 300mg Film Coated Tablets**

**PL 25298/0075**

Batch Number	Expiry Date	Pack Size	First Distributed
IACG027	Jun 2022	28	22 Nov 2019
IACG028	Jun 2022	28	17 Dec 2019
IACG032	Jun 2022	28	27 Feb 2020
IACG035	Sep 2022	28	09 Mar 2020
IACG036	Sep 2022	28	15 Apr 2020
IACG037	Sep 2022	28	19 May 2020

Active Pharmaceutical Ingredient: irbesartan

**Irbesartan/Hydrochlorothiazide 150mg/12.5mg Film Coated Tablets**

**PL 25298/0070**

Batch Number	Expiry Date	Pack Size	First Distributed
IZAG020	May 2023	28	10 Nov 2020

**Irbesartan/Hydrochlorothiazide 300mg/12.5mg Film Coated Tablets**

**PL 25298/0071**

Batch Number	Expiry Date	Pack Size	First Distributed
IZCG010	Aug 2022	28	23 Dec 2019

**Irbesartan/Hydrochlorothiazide 300mg/25mg Film Coated Tablets**

**PL 25298/0072**

Batch Number	Expiry Date	Pack Size	First Distributed
IZBG008	Jul 2022	28	14 May 2020

Active Pharmaceutical Ingredient: irbesartan

**Teva UK Ltd**

**Losartan Potassium 50mg Film Coated Tablets**

**PL 00289/0964**

Batch Number	Expiry Date	Pack Size	First Distributed
108885	May 2023	28	04 Nov 2020

**Losartan Potassium 100mg Film Coated Tablets**

**PL 00289/0965**

Batch Number	Expiry Date	Pack Size	First Distributed
106077	October 2022	28	18 Mar 2020

Active Pharmaceutical Ingredient: losartan potassium



### **Brief description of the problem**

Bristol Laboratories Limited, Brown & Burk UK Ltd and Teva UK Ltd are recalling the above batches of products as a precautionary measure due to contamination with an impurity called 5-(4'-(azidomethyl)-[1,1'-biphenyl]-2-yl)-1H-tetrazole, which has mutagenic potential. These batches are being recalled as the level of contamination is above the acceptable limit.

### **Advice for healthcare professionals**

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Patients are advised not to stop taking their medication prior to consultation with their doctor or pharmacist, as the health risk of discontinuing the medicine is higher than the potential risk presented by the impurity. This recall is being undertaken as a precautionary measure to prevent further exposure to this impurity in the affected medicines whilst the investigation is ongoing.

There are no anticipated shortages of irbesartan-containing and losartan-containing products in the UK as a result of this recall. However, this is a developing issue and MHRA is working with Marketing Authorisation Holders and other medicines regulators to determine any possible impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.

### **Further Information**

#### Bristol Laboratories Limited

For more information or medical information queries please contact [notifications@bristol-labs.co.uk](mailto:notifications@bristol-labs.co.uk)

For supply queries, please contact [notifications@bristol-labs.co.uk](mailto:notifications@bristol-labs.co.uk)

#### Brown & Burk UK Ltd

For more information or medical information queries please contact [pv@bbukltd.com](mailto:pv@bbukltd.com)

For supply queries, please contact [customercare@bbukltd.com](mailto:customercare@bbukltd.com) or 0203 384 7188

#### Teva UK Limited

For more information or medical information queries please contact Teva Medical Information at [medinfo@tevauk.com](mailto:medinfo@tevauk.com) or 0207 540 7117

For supply queries, please contact Teva Customer Solutions at [customer.services@tevauk.com](mailto:customer.services@tevauk.com) or 0800 590502

Recipients of this Medicines Recall 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.



Medicines & Healthcare products  
Regulatory Agency



Yours faithfully

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