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## Class 2 Medicines Recall: Various Marketing Authorisation Holders and parallel distributor companies, Irbesartan-containing products, EL (21)A/19

Specific batches of products supplied by the Marketing Authorisation Holders and parallel distributor companies are being recalled due to presence of a mutagenic impurity.

From:

Medicines and Healthcare products Regulatory Agency

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9 August 2021

Alert type:

Medicines recall/notification

Medical specialty:

Anaesthetics, Cardiology, Care home staff, Cosmetic surgery, Critical care, Dentistry, General practice, General surgery, Haematology and oncology, Infection prevention, Obstetrics and gynaecology, Ophthalmology, Orthopaedics, Paediatrics, Pathology, Pharmacy, Physiotherapy and occupational therapy, Radiology, Renal medicine, Theatre practitioners, Urology, Vascular and cardiac surgery

Issued:

5 August 2021

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**Company name****Aventis Pharma Limited T/A Sanofi**

Aprovel 75mg Film-Coated Tablets, EU/1/97/046/017

Batch number	Expiry date	Pack size	First distributed
9A111	July 2022	28	11 Dec 2019
9A118	Oct 2022	28	27 March 2020

Aprovel 150mg Film-Coated Tablets, EU/1/97/046/022, (PLGB 04425/0788)

Batch number	Expiry date	Pack size	First distributed
0R258	Jan 2023	28	18 Jun 2020
0R855	Sep 2023	28	04 Nov 2020
8R827	Oct 2021	28	16 Jun 2019
9R217	Dec 2021	28	18 Sep 2019
9R2N7	Aug 2022	28	05 Nov 2019
9R40E	Aug 2022	28	27 Jan 2020

Aprovel 300mg Film-Coated Tablets, EU/1/97/046/027, (PLGB 04425/0789)

Batch number	Expiry date	Pack size	First distributed
0R262	Jan 2023	28	08 Oct 2020
0R263	Jan 2023	28	30 Sep 2020
8R830	Oct 2021	28	09 Aug 2019
9R27A	Jun 2022	28	10 Dec 2019
9R2N9	Aug 2022	28	08 Apr 2020

Co-Aprovel 150mg/12.5mg Film-Coated Tablets, EU/1/98/086/012, (PLGB 04425/0791)

Batch number	Expiry date	Pack size	First distributed
0R824	Apr 2023	28	18 Aug 2020

Co-Aprovel 300mg/12.5mg Film-Coated Tablets, EU/1/98/086/017, (PLGB 04425/0792)

Batch number	Expiry date	Pack size	First distributed
0R16E	May 2023	28	19 Jan 2021
0R2EL	Aug 2023	28	15 Mar 2021
8R962	Oct 2021	28	27 Dec 2018

## Zentiva

Irbesartan Zentiva 75mg Film-Coated Tablets, EU/1/06/376/017

Batch number	Expiry date	Pack size	First distributed
9A111	Jul 2022	28	14 Oct 2019

## Parallel Distributors

### Doncaster Pharmaceuticals Group Ltd

Aprovel 150mg Film-Coated Tablets, EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry date	Pack size	First distributed
FT050	FT050/3218	Mar 2023	28	10 Nov 2020

### MPT Pharma Limited

Aprovel 75mg Film-Coated Tablets, EU/1/97/046/017

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry date	Pack size	First distributed
9A111	CONS 160248	Jul 2022	28	02 Mar 2020
9A118	CONS 162175	Oct 2022	28	01 Sep 2020

### PCO Manufacturing Ltd

Co-Aprovel 300mg/12.5mg Film-Coated Tablets, EU/1/98/086/017

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry date	Pack size	First distributed
FT013	FT013:: RN248	Feb 2023	28	25 Jan 2021

## Gowrie Laxmico Ltd T/A B&S Healthcare

Aprovel 150mg Film-Coated Tablets, EU/1/97/046/004, (PLGB 18799/3988)

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry date	Pack size	First distributed
FT050	10R0284	Mar 2023	28	22 Oct 2020
FT050	05T0767	Mar 2023	28	18 Jun 2021

Co-Aprovel 150mg/12.5mg Film-Coated Tablets, EU/1/98/086/001, (PLGB 18799/3984)

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry date	Pack size	First distributed
FT037	08R0074	Feb 2023	28	23 Oct 2020

Aprovel – active pharmaceutical ingredient: irbesartan

Co-Aprovel – active pharmaceutical ingredients: irbesartan and hydrochlorothiazide

### Brief description of the problem

Specific batches of the above products are recalled by the Marketing Authorisation Holders and parallel distributor companies as a precautionary measure due to contamination with an impurity called 5-(4'-(azidomethyl)-[1,1'-biphenyl]-2yl)-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.
- To confirm if a product has been parallel distributed and repackaged, please check the outer carton and/or affixed label for more details of the respective parallel distributor companies

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 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

## **Sanofi**

For stock control enquiries, please contact [GB-CustomerServices@sanofi.com](mailto:GB-CustomerServices@sanofi.com) or 0800 854 430

For more information or medical information queries, please contact [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com) or 0800 035 25 25

## **Doncaster Pharmaceuticals Group Ltd**

For more information or medical information queries, please contact Richard Gore at 01302 554805 (or 07736 297267 out of hours) or [richard.gore@doncaster-pharm.com](mailto:richard.gore@doncaster-pharm.com)

For supply queries, please contact Rebecca Platts at 01302 552961 (Mon-Fri 8am-4pm) or [rebecca.platts@doncaster-pharm.com](mailto:rebecca.platts@doncaster-pharm.com)

## **MPT Pharma Limited**

For more information or medical information queries, please contact [qa@cstpharma.co.uk](mailto:qa@cstpharma.co.uk) or tel 01477 549310

For supply queries, please contact: [qa@cstpharma.co.uk](mailto:qa@cstpharma.co.uk) or tel 01477 549310

## **PCO Manufacturing Ltd**

For more information or medical information queries, please contact Niamh Clarke at [nclarke@pco.ie](mailto:nclarke@pco.ie)

For supply queries, please contact Jason Ogle at [jogle@nippharma.co.uk](mailto:jogle@nippharma.co.uk)

## **Gowrie Laxmico Ltd T/A B&S Healthcare**

For more information or medical information queries, please contact [medinfo@bnsheathcare.com](mailto:medinfo@bnsheathcare.com)

For supply queries, please contact [customerservice@bnshealthcare.com](mailto:customerservice@bnshealthcare.com)

## **Zentiva Pharma UK Ltd**

For more information or medical information queries, please contact 0800 0902408 or [UKmedinfo@zentiva.com](mailto:UKmedinfo@zentiva.com)

For supply queries, please contact 0844 8793188 or [gfd-customerservices@zentiva.com](mailto:gfd-customerservices@zentiva.com). Please contact [claims@zentiva.com](mailto:claims@zentiva.com) to arrange return and replacement of affected packs in your possession.

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.

## **Download document**

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