



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 09 Aug 2021

EL (21)A/19

Our Ref: MDR 050-10/20

Dear Healthcare Professional,

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	Jul 2022	28	11 Dec 2019
9A118	Oct 2022	28	27 Mar 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**	Apr 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

**Per correction by Aventis Pharma Limited T/A Sanofi, update made on 13 Aug 2021 to reflect Apr 2023 as the correct expiry date

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 k.s.

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 300 mg/12.5 mg 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 or 0800 854 430

For more information or medical information queries, please contact 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

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

MPT Pharma Limited

For more information or medical information queries, please contact ga@cstpharma.co.uk or tel 01477 549310

For supply queries, please contact: ga@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

For supply queries, please contact Jason Ogle at jogle@nippharma.co.uk

Gowrie Laxmico Ltd T/A B&S Healthcare

For more information or medical information queries, please contact medinfo@bnsheathcare.com

For supply queries, please contact customerservice@bnshealthcare.com

Zentiva Pharma UK Ltd

For more information or medical information queries, please contact 0800 0902408 or UKmedinfo@zentiva.com

For supply queries, please contact 0844 8793188 or gfd-customerservices@zentiva.com. Please contact 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.

Yours faithfully

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