



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 30 November 2021

EL (21)A/34

Our Ref: MDR 050-10/20

Dear Healthcare Professional,

Aventis Pharma Limited T/A Sanofi

Co-Aprovel 150mg/12.5mg Film-Coated Tablets

EU/1/98/086/012
(PLGB 04425/0791)

Batch Number	Expiry Date	Pack Size	First Distributed
9R1PC	May 2022	28	Jan 2020

Co-Aprovel 300 mg/12.5 mg Film-Coated Tablets

EU/1/98/006/017
(PLGB 04425/0792)

Batch Number	Expiry Date	Pack Size	First Distributed
9R1P9	May 2022	28	Sep 2019

Parallel Distributors

Chemilines Ltd

Aprovel 150mg Tablets

EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT022	FT022/001	Jan 2023	28	Aug 2020
FT022	FT022/002	Jan 2023	28	Oct 2020
FT022	FT022/003	Jan 2023	28	Feb 2021

Aprovel 300mg Tablets

EU/1/97/046/007

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT020	FT020/001	Jan 2023	28	July 2020

Co-Aprovel 150mg/12.5mg Tablets

EU/1/98/086/001

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT020	FT020/001	Feb 2023	28	Aug 2020



Co-Aprovel 300mg/12.5mg Tablets

EU/1/98/086/004

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT037	FT037/001	June 2023	28	Dec 2020

Drugsrus Ltd (Repackaged by P.I.E Pharma Ltd)

Co-Aprovel 150mg/12.5mg Tablets

EU/1/98/086/001

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT020	K/066	Feb 23	28	Oct 2020

Lexon (UK) Ltd

Aprovel 300mg Tablets

EU/1/97/046/007

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT027	FT027	Jan 23	28	Jul 2020

**BR Lewis Pharmaceuticals Ltd
(Repackaged by Doncaster Pharmaceuticals Group Ltd)**

Aprovel 150mg Tablets

EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
ET042	ET042/2156	Mar 2022	28	Oct 2019
FT022	FT022/2994	Jan 2023	28	Aug 2020
FT022	FT022/3112	Jan 2023	28	Oct 2020
FT040	FT040/3218	Mar 2023	28	Nov 2020
FT052	FT052/3228	Mar 2023	28	Nov 2020

Aprovel 300mg Tablets

EU/1/97/046/007

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
FT027	FT027/3124	Jan 2023	28	Aug 2020
FT027	FT027/3079	Jan 2023	28	Jul 2020

Co-Aprovel 150mg/12.5mg Film-Coated Tablets

EU/1/98/086/012

Manufacturer's Batch Number	Parallel Distributor's Batch number	Expiry Date	Pack Size	First Distributed
9R1PC	9R1PC	May 2022	28	Mar 2020



Gowrie Laxmico Ltd T/A B&S Healthcare

Aprovel 150mg Tablets

EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT022	06R1441	Jan 2023	28	Jul 2020
FT022	06T0238	Jan 2023	28	Jun 2021
FT022	07R0792	Jan 2023	28	Aug 2020
FT022	11R0446	Jan 2023	28	Dec 2020
FT049	05T0766	Mar 2023	28	Jun 2021
FT050	05T0767	Mar 2023	28	Jun 2021
FT050	10R0284	Mar 2023	28	Oct 2020

Co-Aprovel 150mg/12.5mg Tablets

EU/1/98/086/001

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT012	06R1475	Jan 2023	28	Jul 2020
FT012	08R0102	Jan 2023	28	Sep 2020
FT020	10R0532	Feb 2023	28	Nov 2020
FT037	08R0074	Feb 2023	28	Oct 2020

Co-Aprovel 300mg/25mg Film-Coated Tablets

EU/1/98/086/024

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT029	05R1210	Jan 2023	28	Jul 2020

Quadrant Pharmaceuticals Ltd (Repackaged by Maxearn Ltd)

Aprovel 150mg Tablets

EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
ET065	7790R	May 2022	28	Nov 2019
ET049	1390T	May 2022	28	Mar 2020
ET049	1655T	May 2022	28	Mar 2020
ET050	1392T	May 2022	28	June 2020
ET050	1652T	May 2022	28	June 2020
FT022	9494T	Jan 2023	28	Sep 2020
FT022	9619T	Jan 2023	28	Sep 2020
FT084	1905U	Jun 2023	28	Nov 2020
ET039	4908R	Mar 2022	28	Sep 2019

Aprovel 300mg Tablets

EU/1/97/046/007

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT020	9486T	Jan 2023	28	Sep 2020



OPD Laboratories Ltd

Aprovel 150mg Tablets

EU/1/97/046/004

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT051	FT051/1	Mar 2023	28	Sep 2020
FT051	FT051/2	Mar 2023	28	Sep 2020
FT051	FT051/3	Mar 2023	28	Nov 2020
FT052	FT052/1	Mar 2023	28	Nov 2020

Co-Aprovel 150mg/12.5mg Tablets

EU/1/98/086/001

Manufacturer's Batch Number	Parallel Distributor's Batch number (Int No.)	Expiry Date	Pack Size	First Distributed
FT020	FT020/1	Feb 2023	28	Mar 2021

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.

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



Chemilines

For more information or medical information queries, please contact Ashutosh Pradhan at Ashutosh.pradhan@chemilines.com

For supply queries, please contact Nisha Brar at Nisha.brar@chemilines.com

BR Lewis Pharmaceuticals Ltd / Doncaster Pharmaceuticals Group Ltd

For more information or medical information queries, please contact Richard Gore at 01302 554805 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

Drugsrus Ltd

For more information or medical information / supply queries, please contact Drugsrus Limited at recall@drugsrus.co.uk or +44 (0)208 423 3800

Lexon (UK) Ltd

For more information or medical information queries, please contact Yogesh Patel at yogesh.patel@lexonuk.com or 07515 765513

For supply queries, please contact Heather Jordan at heather.jordan@lexonuk.com

Gowrie Laxmico Ltd T/A B&S Healthcare

For more information or medical information queries, please contact medinfo@bnsheathcare.com or 0800 049 9401 ext 941

For supply queries, please contact customerservice@bnshealthcare.com

Quadrant Pharmaceuticals Ltd

For all enquiries please contact Radoslaw Bandomir at radoslaw.bandomir@maxearn.co.uk

OPD Laboratories Ltd

For more information or medical information queries, please contact Sasi Vimalaranjithan / Hemang Patel at 01923 332 796 or sasi@sigmaplc.com / hemang@sigmaplc.com

For supply queries, please contact Vasanth Samson / Krina Shah at qa@sigmaplc.com

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574