



DRUG ALERT

CLASS 1 MEDICINES RECALL

Action Now – including out of hours
Pharmacy Level Recall

Date: 10 July 2018

EL (18)A/11 - revision 1

Our Ref: MDR 094-06/18

Dear Healthcare Professional,

VALSARTAN 40MG CAPSULES, HARD	DEXCEL PHARMA LIMITED	PL 14017/0192
VALSARTAN 80MG CAPSULES, HARD	DEXCEL PHARMA LIMITED	PL 14017/0193
VALSARTAN 160MG CAPSULES, HARD	DEXCEL PHARMA LIMITED	PL 14017/0194
VALSARTAN 40MG FILM-COATED TABLETS	ACTAVIS GROUP PTC EHF	PL 30306/0109
VALSARTAN 80MG FILM-COATED TABLETS	ACTAVIS GROUP PTC EHF	PL 30306/0110
VALSARTAN 160MG FILM-COATED TABLETS	ACTAVIS GROUP PTC EHF	PL 30306/0111
VALSARTAN 320MG FILM-COATED TABLETS	ACTAVIS GROUP PTC EHF	PL 30306/0405
VALSARTAN/HYDROCHLOROTHIAZIDE 160/12.5MG TABLETS	ACTAVIS GROUP PTC EHF	PL 30306/0342

Brief description of the problem

The Drug Alert EL (18)A/11 issued on 5 July 2018 is now superseded by this revised alert EL (18)A/11 – revision 1 because Actavis (now Accord) has provided new information that an additional product (Valsartan/Hydrochlorothiazide 160/12.5mg Film-Coated Tablets) is also affected and is being recalled. Accord apologises for any inconvenience this may cause.

All batches of the above products are being recalled from pharmacies as a precautionary measure at a European level. This is due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.



This is an emerging issue; the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible impact.

Healthcare professionals and wholesalers

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

If you receive queries about this issue from patients, encourage them not to stop taking their medication. They should speak to their doctor to help identify alternatives.

An investigation into other potentially impacted products is currently being undertaken and further updates will be provided as the investigation progresses.

Company contacts for further information

Dexcel:

Cheryl Haynes – Responsible Person
cheryl.haynes@dexcel.com
Telephone: 01327 314830 or 07827 895061

Actavis (now Accord):

- For Actavis stock control: Customer Services Team on 0800 373573
- For medical information enquires please contact Accord Medical Information on 01271 385257

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to relevant clinics, general practitioners, hospitals and community pharmacists for information.

Yours faithfully

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