

DRUG ALERT
CLASS 1 MEDICINES RECALL

Action Now – including out of hours Pharmacy Level Recall

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



Brief description of the problem

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.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 3552
Fax No. 028 9536 3901

6th July 2018

Pharmaceutical website: <http://www.hscbusiness.hscni.net>