

**DRUG ALERT**  
**CLASS 1 MEDICINES RECALL**

**Action Now – including out of hours**  
**Pharmacy Level Recall**

Dear Healthcare Professional

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



**Brief description of the problem**

**The Drug Alert PHC/11/2018 (MPS 2516) issued on 5 July 2018 is now superseded by this revised alert PHC/13/2018 (MPS 2518) because Actavis (now Accord) has provided new information that an additional product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](mailto: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**

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**11<sup>th</sup> July 2018**

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