D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy and Dispensing Clinic Level

Date: 08 January 2014 EL (14)A/01 Our Ref: MDR 64-12/13

Dear Healthcare Professional,

Teva Pharma B.V. (Trading as Teva UK Ltd)

Irbesartan / Hydrochorothiazide Teva 300/12.5mg Film-coated tablets **EU/1/09/583/0077**

Irbesartan / Hydrochorothiazide Teva 300/25mg Film-coated tablets **EU/1/09/583/0078**

Teva UK Ltd has informed MHRA that an incorrect dosing instruction is present in the Patient Information Leaflet for Irbesartan / Hydrochorothiazide, Teva strength combinations 300/12.5 mg & 300/25 mg.

The recommended dose of Irbesartan / Hydrochlorothiazide Teva is one tablet a day.

The Patient Information Leaflet incorrectly states one or two tablets a day. If taken according to the wrong recommendation in the Patient Information Leaflet, patients are at risk of overdose. No cases of overdose with the combination of irbesartan with hydrochlorothiazide have been reported to date.

Irbesartan / Hydrochorothiazide Teva is prescribed by a healthcare professional and patients following the prescribing advice provided are not at risk.

For further information, please telephone Teva UK Ltd medical information on 020 7540 7117 or by email to medinfo@tevauk.com.

Distribution of affected stock has ceased and this issue is being corrected by the manufacturer, however to avoid an impact to supply affected product will remain in the market for a short period of time.

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

Yours faithfully

Adam Burgess

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Medicines and Healthcare Products Regulatory Agency