Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 30 June 2020 EL (20)A/26 Our Ref: MDR 166-06/20

Dear Healthcare Professional,

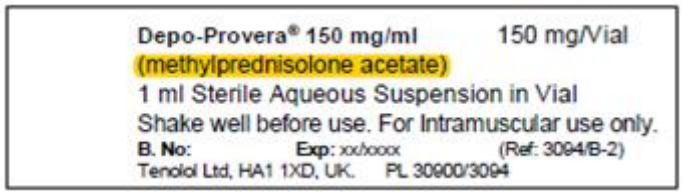
Drugsrus Ltd & Tenolol Ltd

Depo-Provera 150mg/ml Injection (1ml Vial) PLPI 30900/3094

Batch Number	Expiry Date	Pack Size	First Distributed
AT0604	04/2023	1	22/04/2020
X44095	02/2023	1	21/02/2020

Active pharmaceutical ingredient: medroxyprogesterone acetate

Brief description of the problem
Drugsrus Ltd (distributor) / Tenolol Ltd (MA Holder) has informed us of a typographical error in active ingredient stated on the label on the vial. The active ingredient should be “medroxyprogesterone acetate” (a long acting contraceptive) however, it is stated as “methylpredinisolone acetate” (a corticosteroid) in error.



The product is packed as a single vial and is for administration by healthcare professionals. The outer carton and leaflets (Patient leaflet and Healthcare Professional leaflet) have the correct active ingredient (medroxyprogesterone acetate) stated on them, and the brand name on the vial is also correctly stated as “Depo-Provera”.

Advice for healthcare professional
The above batches are not being recalled, as there are no concerns with the quality, safety and efficacy of the product. Existing stock at Drugsrus Ltd has been quarantined and no new stock will be released with the affected issue.

Further Information
For more information or medical information enquiries please contact info@drugsrus.co.uk or call on 020 8423 3800

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 community pharmacists and dispensing general practitioners for information.

Yours faithfully

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