



Medicines Authority
Inspectorate and Enforcement Division
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Drug Alert

CLASS I MEDICINES RECALL

ACTION WITHIN 24 HOURS

Date: 20th November, 2015

Our Ref: MDR6-11/2015

Dear Wholesale Dealer/Managing Pharmacist

Serolf Trading Agency Ltd., Malta

Polygynax vaginal capsule x 12 caps

MA 093/00401

Batch Number	Expiry date	Pack size	First distributed
31810	04/2007	12 caps	17/09/2015
32188	05/2017	12 caps	n/a

The Inspectorate and Enforcement Directorate within the Medicines Authority were informed of a Medicinal Product Defect dated 18th November 2015 by the French National Drug Safety Agency (ANSM). The reason for the recall concerned cases of mix up of capsules (capsules of a given product discovered in the batch of another product), which occurred at the pharmaceutical plant "Catalent France Beinheim SA", participating as a subcontractor in the manufacture of soft capsules for many pharmaceutical companies.

The recall is being carried out under the supervision of the Medicines Authority and has been classified as a Class I recall up to Pharmacy level.

Thanks and regards

Christopher Attard
Medicines Inspector