



UCB (Pharma) Ireland Limited

United Drug House, Magna Drive, Magna Business Park, Citywest Rd, Dublin 24

Patient Level Batch Recall

**Viridal Duo 10 micrograms/ml Powder and Solvent for Solution for Injection
PA891/15/1**

**Viridal Duo 40 micrograms/ml Powder and Solvent for Solution for Injection
PA891/15/3**

23 February 2017

Dear Doctor

We wish to advise you that certain batches (listed below) of **Viridal Duo Powder and Solvent for Solution for Injection** are being recalled with immediate effect.

The batches affected are:

Strength	Batch number	Expiry date	Pack size
10 micrograms/ml	5692601	05/2019	2 x 1 ml
40 micrograms/ml	5678701	11/2018	2 x 1 ml
40 micrograms/ml	5678704	11/2018	2 x 1 ml
40 micrograms/ml	5678706	11/2018	2 x 1 ml
40 micrograms/ml	5683201	03/2019	2 x 1 ml
40 micrograms/ml	5683204	03/2019	2 x 1 ml
40 micrograms/ml	5678709*	11/2018	2 x 1 ml

*Denotes UK batch additionally distributed as Exempt Medicinal Product (non-UCB distribution).

This recall notice is going to patient level and the action has been agreed with the Health Products Regulatory Authority.

The reason for the recall is the observation of an integrity issue with the cartridge membrane, in a small number of units of Viridal Duo. Defective membranes may lead to ingress of moisture to the cartridge and, as a result, the sterility of all affected units cannot be assured.

Patients who were dispensed the affected batches, including those prescribed the product by you, are being contacted by their pharmacists to return any remaining units remaining in their possession.



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This recall will mean that there will be an out of stock situation, at least until the full investigation into this issue is completed. Other products containing Alprostadil for intra-cavernous injection and indicated for erectile dysfunction are available.

All adverse events should be reported to :

UCB contact information

UCB Medical Information:

Tel: +353 1 4632371; Fax: +353 14637396; Email: UCBCares.IE@ucb.com

Or

HPRA contact information

HPRA Pharmacovigilance; Earlsfort Terrace; IRL - Dublin 2

Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie;

E-mail: medsafety@hpra.ie

Full information is also available on the HPRA website: www.hpra.ie

Yours sincerely,

Dr Bharat Karbal

Head of Medical and Business Integrity