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 Pharmacist

We wish to advise you that the batches listed below of **Viridal Duo 10 micrograms/ml and Viridal Duo 40 micrograms/ml, Powder and Solvent for Solution for Injection,** are being recalled with immediate effect.

This recall is going to **patient level**.

This action has been agreed with the Health Products Regulatory Authority.

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

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.

Please immediately perform the following actions:

1. **Immediately quarantine any units from the batches listed above which you have in your possession**. For hospital pharmacies, this includes wards, clinics and any other relevant locations within your facility. Quarantined units will be uplifted by United Drug.

2. **Check dispensing records, to obtain prescriber details of all units dispensed from 21st June 2016, to-date and contact the relevant prescriber(s) to inform them of the recall.** The attached Dear Doctor letter can be sent to them, or they can be directed to www.hpra.ie, where it will also be available.

P.T.O.

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3. **Complete the attached fax-back form indicating the number of units which require uplift.**

4. **Please proceed to recall units from patients, as follows:**

   - Check your dispensing records to identify patients to whom the product has been dispensed, from 21st June 2016 to date. Please note that 21st June 2016 is the date on which the impacted batches were first distributed to pharmacies.

   - Endeavour to contact those patients by telephone, to ascertain if they have any remaining unused units from the affected batches. If units are identified by the patient, please request that they return the units to you at their earliest opportunity.

   - Check the pack(s) on return to ensure that the batch numbers stated on the packs are included in the above-listed batch numbers

   - Quarantine any packs that are returned to you by a patient

   - Contact United Drug Distributors at 01 463 2300 to arrange uplift of further units returned by patients

If you have supplied units from these batches to a GP, clinic, another pharmacy or any other party, please forward a copy of this letter to them so that they can perform the requested actions.

While limited, unaffected stocks of Viridal Duo are available, manufacturing of all strengths is currently ceased, therefore an out of stock situation will likely occur and patients are advised to consult their treating physicians to discuss suitable alternative medicines.

No adverse events or complaints from the market have been reported to UCB to-date, which could be linked to this issue. Nevertheless, if patients have any concerns, they should be advised to contact their treating physicians.

We apologise for any inconvenience this action may cause. Should you have any queries or want to report an adverse event, please contact:

UCB contact information

UCB Medical Information:

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Yours sincerely,

Dr Bharat Karbal

Head of Medical and Business Integrity