

Mlungisi Wondo - URGENT MEDICINE RECALL - Class I, Type B: Paraspén IV

From: "Aspen Pharmacare" <medinfo@aspenpharma.com>
To: WondoM@health.gov.za
Date: 2015/02/24 12:35 PM
Subject: URGENT MEDICINE RECALL - Class I, Type B: Paraspén IV



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Dear Health Care Professional

Class I

Class I is for defective/dangerous/potentially life-threatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

Type B

A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

URGENT MEDICINE RECALL

Class: I Type: B

We hereby inform you that we are recalling the following batches of Paraspén IV (registration number 45/2.7/0375):

Product	Pack size	Batch Number	Expiry Date
Paraspén IV	10's	B9037	2015/06
Paraspén IV	10's	B9078	2015/06
Paraspén IV	10's	B9079	2015/06
Paraspén IV	10's	B9096	2015/08
Paraspén IV	10's	C9224	2015/12
Paraspén IV	10's	C9225	2015/12
Paraspén IV	10's	C9226	2015/12
Paraspén IV	10's	C9227	2015/12
Paraspén IV	10's	C9231	2016/01
Paraspén IV	10's	C9232	2016/01
Paraspén IV	10's	C9236	2016/01
Paraspén IV	10's	C9237	2016/01
Paraspén IV	10's	C9239	2016/01
Paraspén IV	10's	C9240	2016/01
Paraspén IV	10's	C9292	2016/02
Paraspén IV	10's	C9293	2016/02
Paraspén IV	10's	C9370	2016/03
Paraspén IV	10's	C9371	2016/03
Paraspén IV	10's	C9374	2016/03
Paraspén IV	10's	C9375	2016/03
Paraspén IV	10's	C9377	2016/03
Paraspén IV	10's	C9378	2016/03
Paraspén IV	10's	C9379	2016/03
Paraspén IV	10's	C9380	2016/03
Paraspén IV	10's	C9381	2016/03

This recall is initiated as a result of a product quality complaint logged at Aspen Pharmacare due to the presence of small black particles and yellow discolouration of the solution. The investigation of the complaint revealed that oxidation of the solution had occurred due to residual oxygen left in the vial as a result of an incomplete vacuum. The oxidative degradation process of the product results in discolouration of the solution and in some instances, the formation of insoluble black particles.

We request that you immediately return the affected batches of Paraspren IV stock to your supplying wholesaler or distributor for full credit.

For further product information or medical queries, please call:

Aspen Pharmacare's Medical Information Line: 0800 118 088

We would like to thank you for your co-operation in this matter and apologise for any inconvenience that this may create.

Yours Sincerely



Lorraine Hill
Responsible Pharmacist

NOTE: Kindly retain this letter in a prominent position for one month, in case there is still stock in transit and inform your customers where possible.

directors mg attridge* (chairman) sm capozzio* m geysler n gullwe
sb saod* * non-executive
company secretary r verster