

MSD (Pty) Ltd
(Reg. No. 1996/003791/07)
117 - 16th Road
Private Bag 3
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South Africa
Tel: +27(0)11-655-3000
Fax: +27(0)11-655-3180



URGENT: DRUG RECALL

1 February 2011

Ref: DP-2011-151

Dear Pharmacist:

This is to inform you of a product recall involving Polaramine Expectorant.

This recall has been initiated due to an error in the dosing recommendation for children aged 2 to 6 that is printed on the bottle label.

The **incorrect** dosing recommendation printed on the bottle label states: *Children 2 to 6 years: one quarter to **one** teaspoonful 3 or 4 times a day.*

The **correct** dosing recommendation, which is printed on the carton and insert, states: *Children 2 to 6 years: one quarter to **one-half** teaspoonful 3 or 4 times a day.*

This error could cause up to double the recommended dose to be administered. According to the Prescribing Information for this product, the most common side effect associated with an overdose is sedation; however signs of stimulation and atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; hyperthermia; and gastrointestinal symptoms) are also likely in children.

The bottle label with this error has been in use since January 2009.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall is being carried out to the pharmacy level.

Batches that are being recalled are:

- Batch No.: 0AGEJ02002
- Batch No.: 0AGEJ04001
- Batch No.: 0AGEJ06001
- Batch No.: 8AGEJ11003
- Batch No.: 9AGEJ09001
- Batch No.: 9AGEJ10001
- Batch No.: 9AGEJ11001

Please make sure that the parents/caregivers of patients you have dispensed this product to are aware of the correct dosing information. Your assistance is appreciated and necessary to help prevent dosing errors.

If you have any questions, please contact Cathy Otieno, Laborex Kenya Ltd at +254 20 693 9110/7333 333 888

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This recall is being made with the knowledge of the Pharmacy and Poisons Board.

Yours faithfully
MSD (PTY) LTD

A handwritten signature in black ink, appearing to read "Dorcas Peta", is written over a horizontal line.

DR DORCAS PETA
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