



PHA/JFD/IEA.8

5 December 1989

PHA Information Exchange System

ALERT

RECALL OF PRE-OPERATIVE SURGICAL WASH HIBISCRUB^R- OMISSION IN INSTRUCTIONS ON LABEL

The Medicines Control Agency of the United Kingdom has transmitted to the World Health Organization a Drug Alert which it has received from the manufacturer, ICI, concerning erroneous labelling for a pre-operative surgical wash containing chlorhexidine gluconate 4% w/v (Hibiscrub^R). The relevant extract is quoted below:

"ICI PHARMACEUTICALS
HIBISCRUB^R BOTTLES 500 ML
PRODUCT LICENCE: PL 0029/0127
DISTRIBUTED SINCE 1 MARCH 1989

"The company has instituted a recall of Hibiscrub^R 500 ml bottles as a precautionary measure.

"This is because an error has been identified in the labelling of the Hibiscrub^R 500 ml bottles distributed since 1 March 1989. The instructions for use for pre-operative surgical washing omits the phrase "Repeat the wash for two minutes". Unless the correct instructions are followed fully, efficacy in pre-operative surgical handwashing may be compromised.

"Please see attached sheet for full list of batch numbers/countries.

"Please return your existing stocks for credit. The Company have stated that correctly labelled supplies will not be available until the first week in December; in the interim, supplies of correct labels can be made available on request.

"Enquiries should be addressed to the appropriate ICI Customer Services Administrator."

Reference: Drug Alert MDR 6-11/89, Medicines Control Agency, London, 15 November 1989.

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<u>Country</u>	<u>Suffix</u>	<u>Batch numbers</u>
Arab Emirates		OM 637, OA 087, MA 265, HA 026
Bahamas	QE	HA 026
Bahrain		UM 470, HA 026
Barbados	QD	AA 191, OA 051
Belize	QD	AA 191
Bermuda		UM 470, OM 637, PM 567, OA 087, MA 265, HA 026
Curaçao		AA 191, OA 051, OM 621
Cyprus		OM 637, OA 087, MA 265, HA 026
FRG		UM 470, MM 081, MA 265, HA 026
Ghana	QD	AA 191, OA 051
Haiti	QD	AA 191
Hong Kong		UM 470, OA 087, MA 265, HA 026
Ireland		UM 470, OM 637, PM 567, MM 081, OA 081, MA 265, HA 026
Kenya		MA 265
Kuwait	QE	MA 265
Lebanon	QE	HA 026
Malaysia		UM 470, OM 637, PM 567, OA 087, MA 265, HA 026
Malawi		OM 637, PM 567
Mauritius	QE	MA 265, HA 026
Oman		UM 470, OM 637, PM 567, OA 087, MA 265
Qatar	QE	MA 265
Saudi Arabia	FS	UM 470, MM 081, OM 620, SM 390
	AY	IA 273
Singapore	QE	UM 470, OM 637, PM 567, OA 087, MA 265, HA 026
Sri Lanka	QD	OA 051, OM 621
Sudan	QD	AA 191
Uganda	QE	MA 265
Windward I.	QD	AA 191
Zambia	QE	HA 026

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