

Safety Notice

Medical Devices

Durex Real Feel & Durex Latex Free Condoms

Priority 1 – For Immediate Action



HPRA Safety Notice: SN2018(25)

Issue Date: 30 July 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Reckitt Benckiser Healthcare (UK) Limited, United Kingdom	V36620

ISSUE
<p>Reckitt Benckiser recently became aware that a number of Durex Real Feel ‘Latex-Free’ and Durex Latex Free Polyisoprene condoms manufactured in 2018 do not pass the requirements for burst pressure towards the end of the shelf life for the product. The expiry date of the affected batches is between December 2020 and February 2021. There could be an increase in the number of condoms that burst during application or use for the batches of condoms affected by this issue.</p> <p>A recall of the affected batch numbers has been initiated by Reckitt Benckiser.</p>

ACTION OR RECOMMENDATIONS
<p>The HPRA advises that consumers:</p> <ol style="list-style-type: none"> 1 Check the bottom of the outer pack and on the foil wrapping of the individual condoms to see if the batch numbers listed on the field safety notice are the same as those outlined on the product in your possession.

- 2 If you have product with the affected batch numbers, immediately discontinue the use of the affected product.
- 3 Return the affected products to the store where they were purchased from for a full refund.
- 4 If you have any health concerns, please consult your pharmacist / general practitioner for their advice.
- 5 Report any concerns regarding this device or incidents involving this device to the manufacturer and the HPRA.

The HPRA advises that **wholesalers / distributors / pharmacies / retail outlets:**

- 1 Check the bottom of the outer pack to see if the batch numbers listed above are the same as those outlined on the product in your possession.
- 2 If you have product with the affected batch numbers, immediately quarantine and discontinue sale of the affected products.
- 3 Ensure that affected product is returned to the wholesaler / manufacturer.
- 4 Report any concerns regarding this device or incidents involving this device to the manufacturer and the HPRA.

TARGET GROUPS

Consumer public Pharmacies	Retail outlets Sexual health clinics
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BACKGROUND

Reckitt Benckiser recently became aware that a number of Durex Real Feel 'Latex-free' and Durex Latex Free Polyisoprene condoms manufactured in 2018 do not pass the requirements for burst pressure towards the end of the shelf life for the product. The expiry date of the affected batches is between December 2020 and February 2021. There could be an increase in the number of condoms that burst during application or use for the batches of condoms affected by this issue.

A recall of these products have been initiated. The following batch numbers have been confirmed to be on the Irish market:

Description	SKU Code	Batch Number	Expiry Date
Durex Latex Free 12 Pack	3014272	1000444367	Feb-2021
		1000433145	Jan-2021
Durex Real Feel 12 Pack	3014277	1000419930	Jan-2021
		1000444367	Feb-2021
		1000416206	Dec-2020

The following batch numbers have been placed on the UK market. The HPRa is proactively requesting consumers to also check the below list of batch numbers. Although the HPRa have received no confirmation to date that the following batch numbers are on the Irish market, we strongly believe these products may have reached the Irish market:

Description	SKU Code	Batch Number	Expiry Date
Durex Real Feel 6 Pack	3040039	1000438054	Jan-2021
Durex Real Feel 12 Pack	3014278	1000444370	Feb-2021
	3014277	1000474804	Feb-2021
Durex Real Feel 18 Pack	3030444	1000434066	Jan-2021
		1000430479	Jan-2021
Durex Real Feel 18 Pack (RF Tag)	3030445	1000430479	Jan-2021

You will find the batch number on the bottom of the pack and on the foil wrapping of individual condoms. Please see the example below:



Full details of the recall can be found on the Durex website www.durex.ie. Please also refer to the accompanying field safety notice for further details.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Tracy Crooks
 Reckitt Benckiser Healthcare (UK) Limited
 Dansom Lane
 Hull
 East Yorkshire HU8 7DS
 United Kingdom

Telephone: 01-630-5429
 E-mail: consumer.relations-hcukroi@rb.com
 Website: www.durex.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie