

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلانية
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No... 2.6... dated 09/02/2012 Regarding NCMDR Recall of
AQUACEL EXTRA from (ConvaTec).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للأجهزة الطبية
والرقابة الدوائية
مسقط

Circular No. 26/2021

26-06 -1442 H

09-02-2021

Recall of AQUACEL EXTRA from ConvaTec.

Source	NCMDR- National Centre Medical Device Reporting http://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15517
Product	AQUACEL EXTRA.
Description	Sterile, non-woven dressing.
Manufacturer	ConvaTec.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	ICC Code: 420673 SAP Code: 1704596 Product Description: AQUACEL™ Extra 15x15cm (1x5pk) Lot Number: 0C01702 Date of Mfg: 24 Mar 2020.
Reason	In some instances dressing has been found attached to the seam of the primary packaging (figure 3) therefore breaching the sterile barrier and making the product unable to be used.
Action	1. Immediately stop distributing and quarantine all of the affected LOT.(See attached FSN). 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



Description of the problem:

ConvaTec are voluntarily initiating a field action for the above-stated product because in some instances dressing has been found attached to the seam of the primary packaging (figure 3) therefore breaching the sterile barrier and making the product unable to be used. Using a non-sterile device on a patient may potentially expose the patient to infectious agents.

Product Identification Procedure:

- Confirmation of Specific Product Code and LOT:
 - This issue is limited to product code 420673.
 - Only the identified product code and LOT within this notice may have a potential breach in the sterile barrier packaging. Only 82 dressings from this same batch are known to be affected.
 - For this reason and to address any potential risk of harm, the affected product 420673 from LOT 0C01702 should not be used.
 - The only way to identify affected product is by comparing Product code/REF and LOT/Batch number (see Attachment 2) to the product list (see Attachment 1). There is no other discernible difference between affected and unaffected product.

DISTRIBUTOR ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed the Corrective Action Response Form and return it to the address on the response form. Return the attached Corrective Action Response Form even if no affected product is in inventory.
3	You will be reimbursed for the product. Please ensure your account number is correctly identified on the attached Corrective Action Response Form.
4	If you have distributed this product to other wholesalers, then forward this letter to them and ask that they follow these Distributor Actions and return the attached Corrective Action Response Form to the address listed on the form.
5	Send a copy of this market action package to all other consignees: Retailers, if applicable, hospitals and end users. <i>It is extremely important to identify the responsible individual, who is in charge of corrective action activities, at hospital locations. This will make the field action process more effective and eliminate confusion and duplicated effort.</i>
6	Send a complete list of all consignees to the <i>ConvaTec</i> Coordinator. This information is required to allow <i>ConvaTec</i> to perform corrective action effectiveness checks.

RETAILER ACTIONS:

1	Immediately stop distributing and quarantine all of the affected LOT.
2	Perform a count of affected product currently in inventory. Complete the enclosed Corrective Action Response Form and return it to the address on the response form. Return the attached Corrective Action Response Form even if no affected product is in inventory. It is important that you send a copy of the Corrective Action Response Form to your distributor in order to receive reimbursement for the returned product.
3	Post page one of this Field Safety Corrective Action notice in a conspicuous location in your store.

Figure 1: AQUACEL™ Extra 15 x 15cm Carton Secondary Packaging



Figure 2: AQUACEL™ Extra 15 x 15cm Dressing

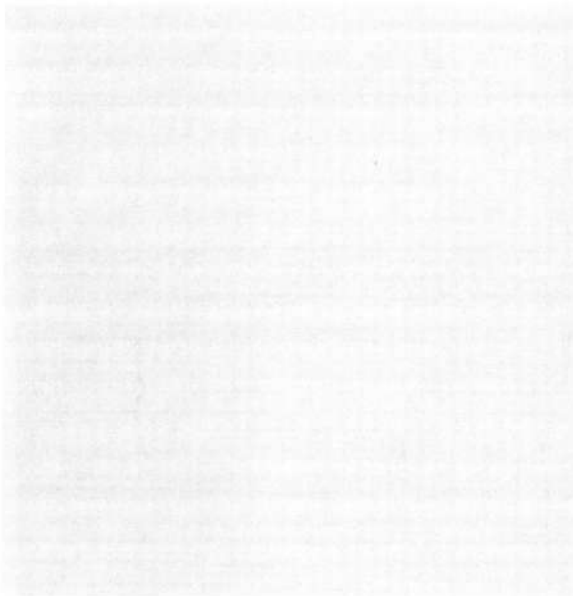


Figure 3: AQUACEL™ Extra 15 x 15cm Foil Primary Packaging



Attachment 1 Product Details:

ICC Code	SAP Code	Product Description	Lot Number	Date of Mfg	Market Unit Qty
420673	1704596	AQUACEL™ Extra Dressing 15 x 15cm	0C01702	24 Mar 2020	82 units

Attachment 2 Examples of Labelling and Affected Product:

The shipper labelling will include the product REF/ICC code and the product LOT number (see example to the right).

Shipper Label:

Batch Record - PINK final packaging


Location(s) Affected: Dueside

INT/INDC CODE **420673**

DESCRIPTION
AQUACEL EXTRA
15X15CM (1X5PK) STERILE EUR

REF/ICE INSTRUCTIONS
STORE AT ROOM TEMPERATURE
AVOID REFRIGERATION AND
EXPOSURE TO HIGH HUMIDITY

Made in UK




(10)001702

(1)7250001


(01)10768455125651

CONVATEC

1704596




LOT NUMBER
0C01702



EXP. DATE 2025-03-01

QUANTITY
20 x 5



LABEL SERIAL NO.
0000

ConvaTec 