

Safety Notice

Medical Devices

Animas Vibe Insulin Pumps

Priority 3 – Advisory



HPRA Safety Notice: SN2018(03)

Issue Date: 24th January 2018

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|-------------------------|---------------------|
| Animas | SD24520 |

ISSUE

The HPRA wishes to raise awareness of the discontinuation of Animas Vibe Insulin infusion Pumps as a result of the manufacturer's decision to exit the insulin pump market. Animas is currently communicating this information to customers in Ireland and has indicated to the HPRA that there will be no further sales of these pumps in Ireland. Animas has also advised that existing pump users will experience no immediate change.

Please see the accompanying communications issued by the manufacturer for further information, including details of the transition plan.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying manufacturer's communications.
2. Discuss future treatment alternatives with your healthcare professional.
3. Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advise that healthcare professionals:

1. Inform all pump users of the information contained in the accompanying manufacturer's communications.
2. Forward a copy of this safety notice and the manufacturer's communications to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
3. Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

For those seeking an alternative insulin pump, the following Safety Notice may be of interest:

- [HPRA Safety Notice SN2015\(02\) Devices In The Home](#)

Please also continue to maintain awareness of the following safety information previously published by the HPRA:-

- [HPRA Safety Notice SN2016\(31\) Animas Vibe Insulin Infusion Pumps](#)
- [HPRA Safety Notice SN2015\(20\) Animas Vibe Insulin Infusion Pump](#)
- [HPRA Safety Notice SN2014\(42\) Insulin Infusion Pumps](#)

| TARGET GROUPS | |
|----------------------------|-------------------------------|
| Carers | Nursing homes |
| Community care managers | Outpatient clinics |
| Community nurses | Paediatricians |
| Community therapists | Pharmacists |
| Diabetes clinics | Practice nurses |
| Diabetes nurse specialists | Private medical practitioners |
| Endocrinology units | Risk managers |
| General practitioners | School nurses |
| Hospital managers / CEOs | Supplies managers |
| Medical directors | |

| BACKGROUND |
|---|
| <p>Animas has advised that customers will continue to receive customer service, training and warranty support, including pump supplies through a transition period to avoid any insulin treatment disruptions. Animas' goal is to transition all patients to another insulin delivery system and to exit the market-by September 2019.</p> <p>Animas has also confirmed that existing pump users whose pumps are within their 4 year warranty will continue to receive replacement pumps where necessary during the transition period.</p> <p>The HPRA is issuing this safety notice to raise awareness of the discontinuation of Animas Vibe Insulin infusion Pumps. Please refer to the accompanying Animas communications for further information.</p> |

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Animas Corporation
Animas UK & Ireland

Telephone: 1800-812-715
E-mail: AnimasUK@its.jnj.com
Website: <https://www.animascorp.co.uk/>

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
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie