

Omnipod® Products Are Designed to Help Simplify Life for People With Diabetes

Insulet provides innovative insulin delivery devices for people who require insulin.

Omnipod® 5 Automated Insulin Delivery System

One prescription is required to obtain the Omnipod 5 Intro Kit. **A separate prescription** is also required to obtain the Dexcom G6 CGM.



Omnipod 5 G6 Intro Kit (Gen 5)
NDC 08508-3000-01



11 Pods
Two 5-packs and 1 training Pod



Controller

Second prescription required for refill 5-packs to continue Pod therapy



Omnipod 5 G6 Pods (Gen 5)
NDC 08508-3000-21

The Omnipod 5 Automated Insulin Delivery System is indicated for people with type 1 diabetes 6 years of age and older

Omnipod DASH® Insulin Management System for people with insulin-requiring diabetes

Only 1 prescription is needed to start Omnipod DASH and the patient gets **all materials in 1 package**.



Omnipod DASH Intro Kit (Gen 4)
NDC 08508-2000-32



11 Pods
Two 5-packs and 1 training Pod



Personal Diabetes Manager

Second prescription required for refill 5-packs to continue Pod therapy



Omnipod DASH Pods (Gen 4)
NDC 08508-2000-05

For type 1 and type 2 insulin-requiring persons of any age

Omnipod Product Ordering Information

Transaction Name	NDC	Manufacturing Model Number	Package Contents	Package Description
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Omnipod 5 Automated Insulin Delivery System*

*Omnipod 5 Automated Insulin Delivery System requires a secondary prescription for the Dexcom G6 to be integrated with the system.

Omnipod 5 G6 Intro Kit (Gen 5)	08508-3000-01	SKT-H001-G-X9	1 Controller and 11 Pods	Box
Omnipod 5 G6 Pods (Gen 5)	08508-3000-21	POD-BLE-525	5 Pods	Box

Omnipod DASH Insulin Management System

Omnipod DASH Intro Kit (Gen 4)	08508-2000-32	PIK-USA-D001-MG	1 Personal Diabetes Manager and 11 Pods	Box
Omnipod DASH Pods (Gen 4)	08508-2000-05	BLE-P1-525	5 Pods	Box

WAC, wholesale acquisition cost.

FDA 510(k) Clearance to Market and Important Safety Information for Omnipod® 5 Automated Insulin Delivery System

The Omnipod® 5 Automated Insulin Delivery System is indicated for use by individuals with Type 1 diabetes mellitus who are 6 years of age and older. The Omnipod® 5 System is intended for single patient, home use and requires a prescription. The Omnipod® 5 System is compatible with the following U-100 insulins: NovoLog®, Humalog®, and Admelog®.

The Omnipod® 5 ACE Pump (Pod) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Omnipod® 5 ACE Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

SmartAdjust™ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and pause delivery of insulin based on current and predicted glucose values.

The Omnipod® 5 SmartBolus Calculator is intended to calculate a suggested bolus dose based on user-entered carbohydrates, most recent sensor glucose value (or blood glucose reading if using fingerstick), rate of change of the sensor glucose (if applicable), insulin on board (IOB), and programmable correction factor, insulin to carbohydrate ratio, and target glucose value.

Warning: SmartAdjust™ technology should NOT be used by anyone under the age of 6 years old. SmartAdjust™ technology should also NOT be used in people who require less than 6 units of insulin per day as the safety of the technology has not been evaluated in this population.

The Omnipod® 5 System is NOT recommended for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, are unable to use the Omnipod® 5 System according to instructions, are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and do NOT have adequate hearing and/or vision to allow recognition of all functions of the Omnipod® 5 System, including alerts, alarms, and reminders. Device components including the Pod, CGM transmitter, and CGM sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. In addition, the Controller and smartphone should be placed outside of the procedure room. Exposure to MRI, CT, or diathermy treatment can damage the components.

Visit www.omnipod.com/safety for additional important safety information.

The Omnipod DASH® Insulin Management System

Important Safety Information: The Omnipod DASH® Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. Additionally, the Omnipod DASH® System is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements. The Omnipod DASH® System has been tested and found to be safe for use with the following U-100 insulin: NovoLog®, Humalog®, Apidra®, Fiasp®, Lyumjev®, or Admelog®. Refer to the Omnipod DASH® Insulin Management System User Guide at omnipod.com/safety for complete safety information including indications, contraindications, warnings, cautions, and instructions.

FDA, US Food and Drug Administration.

Reference: Data on file. Insulet Corporation.

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March 2022 INS-OHS-01-2022-00006 V1.0