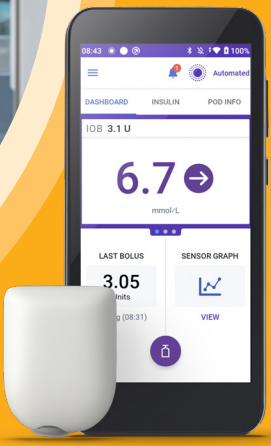
Omnipod® 5

AUTOMATED INSULIN DELIVERY SYSTEM



INDICATION: FOR PEOPLE WITH INSULIN REQUIRING **TYPE 1 DIABETES** AGED 2 YEARS AND OLDER

omnipod® 5
automated insulin delivery system

Screen image is an example, for illustrative purposes only. Pod shown without necessary adhesive.

OMNIPOD® 5:

Automated insulin delivery simplified

Omnipod 5[a] with **SmartAdjust™ technology** proactively manages insulin delivery every 5 minutes using a customised glucose target to help **minimise time in hyperglycaemia and hypoglycaemia**[1,b,c,d].

- Choice of glucose targets by time of day, throughout the day; adjustable from 6.1-8.3 mmol/L in 0.55 mmol/L increments (110mg/dL-150 mg/dL in 10mg/dL increments)[e]
- The only tubeless AID System with **SmartBolus Calculator**, informed by sensor value and trend[j]

Adjustments on the go[1,b,c]

No more multiple daily injections, tubing or finger pricks[1,h]

- Tubeless, waterproof,[i] Pod with built-in SmartAdjust™ technology
- Integrated with the leading sensor brands[j]

Omnipod 5 pivotal study results[3,4]

- Adults reported **lower stress** when eating compared to prior therapy[c,g]
- Parents of children reported **better sleep** quality compared to prior therapy[c,g]
- Adult users and parents of children felt confident in **staying safe** from the risk of hypoglycaemia compared to prior therapy[c,g]

Omnipod 5 improved glycaemic control in adults, adolescents and children with type 1 diabetes (T1D) in pivotal studies[c,d,f,1,2]

76%

time in range (TIR) at a target of 6.1 mmol/L in adults and adolescents (14–70 years) and **68%** overall TIR in children (2-13.9 years)[1]

HbA1c

was significantly reduced in very young children (2.0–5.9 years), children (6–13.9 years), adults and adolescents (14–70 years) by 0.5%, 0.7% and 0.4% respectively[1]

HbA1c = glycated hemoglobin

33%

reduced time in hyperglycaemia in children, and **24%** in adults and adolescents[1]

60%

reduction in hypoglycaemia overnight and **46%** overall in adults and adolescents[1]

Omnipod® 5—simple design, sophisticated technology, improved results

- Improved glycaemic control across all age groups from age 2 in two pivotal studies, while time in hypoglycaemia remained low[1,2,b,c,d,f]
- No more multiple daily injections (MDI), tubing or finger pricks[1,h]
- Tubeless, waterproof[i] Pod with built-in SmartAdjust™ technology

For more information visit **omnipod.com**

Important Safety Information: The Omnipod 5 Automated Insulin Delivery System is indicated for use by individuals with type 1 diabetes mellitus in persons 2 years of age and older. The Omnipod 5 System is intended for single patient, home use and requires supervision of the user's healthcare provider. The Omnipod 5 System is compatible with the following U-100 insulins: NovoLog®/NovoRapid®, Humalog®, Trurapi®/Insulin aspart Sanofi®, Kirsty®, and Admelog®/Insulin lispro Sanofi®. Refer to the Omnipod® 5 Automated Insulin Delivery System User Guide and www.omnipod.com/safety for complete safety information including indications, contraindications, warnings, cautions, and instructions.

a When used in automated mode with a compatible sensor, the Omnipod 5 System adjusts insulin delivery every 5 minutes based on the user's current sensor value, glucose values predicted 60 minutes in the future, glucose trend and past insulin delivery to bring glucose to a user-defined target. **b** Requires a compatible sensor. **c** Prospective pivotal trial in 240 participants with T1D aged 6–70 yrs (128 adolescents/adults aged 14–70 years and 112 children aged 6.0–13.9 years). Study included a 14-day ST phase followed by a 3-month Omnipod 5 HCL phase. The incidence rates of severe hypoglycemia and diabetic ketoacidosis during the AID phase were 4.8 and 1.2 events per 100 person-years, respectively.[1] **d** Mean time in range (70–180 mg/dL [3.9–10.0 mmol/L]) as measured by sensor in adults/adolescents and children ST vs 3-month Omnipod 5: 64.7% vs 73.9%, P<0.0001; 52.5% vs 68.0%, P<0.0001, respectively. Mean HbA1c: baseline vs Omnipod 5 use in adults/adolescents and children, respectively (7.16% vs 6.78%, P<0.0001; 7.67% vs 6.99%, P<0.0001). Mean time above range (>180 mg/dL [10.0 mmol/L]) as measured by sensor in adults/adolescents and children ST vs 3-month Omnipod 5: 32.4% vs 24.7%; 45.3% vs 30.2%, P<0.0001, respectively. Median time below range (<70 mg/dL [3.9 mmol/L]) as measured by sensor in adults/adolescents and children ST vs 3-month Omnipod 5: 2.0% vs 1.1%, P<0.0001; 1.4% vs 1.5%, P=0.8153, respectively. Median time below range (<70 mg/dL [3.9 mmol/L]; 12–6AM) as measured by sensor in adults/adolescents and children ST vs 3-month Omnipod 5: 2.07% vs 0.82%, p<0.0001; 0.78% vs 0.78%, P=0.0456, respectively. Comparisons are relative changes.[1] **e** Glucose targets can be adjusted in up to 8 segments per day. **f** Prospective trial in 80 participants with T1D aged 2.0–5.9 yrs. Study included a 14-day ST phase followed by a 3-month Omnipod 5 HCL phase. Mean time in range (70–180 mg/dL [3.9–10.0 mmol/L]) in very young children as measured by sensor: ST=57.2%, 3-month Omnipod 5=68.1%, P<0.05. Mean HbA1c: ST vs Omnipod 5 use in very young children 7.4% vs 6.9%, P<0.05. Median time below range (<70 mg/dL [3.9 mmol/L]) as measured by sensor: ST vs Omnipod 5 use in very young children (2.2% vs 1.9%, P<0.05).[2] **g** Prior therapy in adults and children, respectively: 15.6% MDI, 84.4% CSII; 9.6% MDI, 90.4% CSII. During the Omnipod 5 pivotal trial, adults aged 18–70 years (N=111) experienced an improvement in eating distress survey score after 3 months of Omnipod 5 use compared to ST: mean T1-DDS Eating Distress Subscale: 1.74 vs 1.97, respectively. Parents of children aged 6.0–11.9 years (N=82) and adults aged 18–70 years (N=111) experienced an improvement in hypoglycaemia confidence survey score after 3 months of Omnipod 5 use compared to ST: mean HCS score=3.59 vs 3.34; and 3.65 vs 3.52, respectively. Parents of children 6.0–11.9 years (N=82) experienced an improvement in sleep quality survey score after 3 months of Omnipod 5 use compared to ST: mean PSQI Overall Sleep Quality Subscore=0.70 vs 1.13, respectively.[1] **h** If glucose alerts and readings from the compatible sensor do not match symptoms or expectations, a blood glucose metre should be used to make diabetes treatment decisions. **i** The Pod has an IP28 rating for up to 7.6 metres (25 feet) for 60 minutes. The controller is not waterproof. Consult sensor manufacturer user guide for sensor waterproof rating. **j** Compatible sensor sold and prescribed separately.

AID, automated insulin delivery; CGM/sensor, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; DKA, diabetic ketoacidosis; HbA1c, glycated hemoglobin; HCL, hybrid closed loop; MDI, multiple daily injection; ST, standard therapy; T1D, type 1 diabetes.

References: 1. Brown S et al. Multicenter trial of a tubeless, on-body automated insulin delivery system with customisable glycemic targets in pediatric and adult participants with type 1 diabetes. Diabetes Care. 2021;44(7):1630-1640. 2. Sherr JL et al. Safety and glycemic outcomes with a tubeless automated insulin delivery system in very young children with type 1 diabetes: a single-arm, multicenter clinical trial. Diabetes Care. 2022; doi: 10.2337/dc21-2359 3. Hood KK, et al. Pediatric Diabetes 2023 (in press) 4. Polonsky WH et al. Diabetes Res Clin Pract 2022;190:109998

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