



Wellpoint New Jersey

P. O. Box 62509

Virginia Beach, VA 24466-2509

<Date>

<Parent or Guardian of>

<Member Name>

<Member Address>

<Member City, State ZIP>

Dear Member or Parent/Guardian of <Member Name>:

We have important Medical Device Correction information about your prescription for Omnipod 5, Omnipod DASH, and/or Omnipod Eros Pods.

Our records show that you may have recently filled a prescription for this product.

On May 26, 2026, Insulet Corporation issued a Medical Device Correction of certain lot numbers of Omnipod 5, Omnipod DASH, and Omnipod Eros Pods.

According to Insulet Corporation, this Medical Device Correction was issued due to a manufacturing issue Insulet Corporation identified through ongoing product monitoring, that could result in insulin under-delivery. This action is separate from the Medical Device Correction issued on March 12, 2026 and April 30, 2026 affecting certain Omnipod 5 Pods in the US.

According to Insulet Corporation, Insulet identified that some Pods from specific lots may have a small tear in the tubing (cannula) just above the skin, between the Pod and the point where the cannula enters the body. If this occurs, insulin may leak outside of the Pod instead of being fully delivered into the body as intended, potentially leading to under-delivery of insulin. If a patient is using an affected Pod, they may notice wetness on their skin or Pod adhesive or detect the smell of insulin. However, in some cases, this issue may be difficult to detect and go unnoticed.

If insulin leakage occurs, the patient's blood glucose levels may rise and may not respond as expected to insulin delivery. If using Omnipod 5 in Automated Mode, this

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1091494NJMESWLP 06/26

OMHC# 078-25-59

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could trigger an Automated Delivery Restriction alert, advising them to troubleshoot.

However, this issue may happen without triggering any alert, meaning patients could receive less insulin than needed without realizing it. Patients should not rely only on Pod alerts to know if something is wrong.

Product: Omnipod 5 Starter Kit (Part # PT 001659)

NDC: 08508-3000-01

Lot Number: PK00315, PK00389, PK00316, PK00390, PK00319, PK00394, PK00324, PK00396, PK00327, PK00401, PK00331, PK00407, PK00350, PK00415, PK00354, PK00417, PK00359, PK00420, PK00365, PK00425, PK00370, PK00432, PK00371, PK00509, PK00381, PK00513, PK00383, PK00518, PK00389

Product: Omnipod 5 Starter Kit (Part # PT-001998)

NDC: 08508-3000-88

Lot Number: PK00522, PK00523

Product: Omnipod 5 Pod

NDC: 08508-3000-21, 08508-3000-42

Lot Number: PH1U01032521, PH1U09212421, PH1U12102421, PR1U02132611, PR1U11262521, PH1U02042521, PH1U01102521, PH1U09262411, PH1U12122421, PR1U02132641, PR1U11262541, PH1U04092521, PH1U01132521, PH1U09262421, PH1U12132422, PR1U11182531, PR1U12012521, PH1U04112521, PH1U01172521, PH1U10042421, PH1U12172421, PR1U11182541, PR1U12022521, PH1U10142421, PH1U01222521, PH1U10102421, PH1U12182421, PR1U11192531, PR1U12032521, PH1U10152421, PH1U01232522, PH1U10112422, PR1U01132621, PR1U11192532, PR1U12102522, PH1U10162421, PH1U02132511, PH1U10122421, PR1U01152621, PR1U11192541, PR1U12112521, PH1U11212421, PH1U02212521, PH1U10172522, PR1U01162621, PR1U11192542, PR1U12122521, PH1U11222421, PH1U02222521, PH1U10182521, PR1U01172621, PR1U11202521, PR1U12132511, PH1U11252421, PH1U03202521, PH1U10202521, PR1U01202621, PR1U11202532, PR1U12132521, PH1U11262421, PH1U03262521, PH1U10212521, PR1U01212621, PR1U11202533, PR1U12152521, PH1U01302522, PH1U03282521, PH1U10222521, PR1U01222621, PR1U11202541, PR1U12162521, PH1U01312511, PH1U03312521, PH1U10232521, PR1U01232621, PR1U11202542, PH1U09172421, PH1U02032521, PH1U04032521, PH1U10242521, PR1U01272621, PR1U11212521, PR1U12172521,



PH1U04102521, PH1U04042521, PH1U10252521, PR1U01302641, PR1U11222521, PH1U01092621, PH1U09182421, PH1U04302524, PH1U11152521, PR1U01312631, PR1U11222531, PH1U02202521, PH1U09192421, PH1U05012521, PH1U11172511, PR1U02022641, PR1U11222541, PH1U04222521, PH1U09202421, PH1U05022521, PH1U11172521, PR1U02032631, PR1U11232541, PH1U04232511, PH1U10172421, PH1U05052521, PH1U11182521, PR1U02032641, PR1U11242521, PH1U04232521, PH1U06282422, PH1U11192511, PR1U02042641, PR1U11242531, PH1U10182422, PH1U09112421, PH1U11192521, PR1U02052631, PR1U11252512, PH1U11142521, PH1U09122421, PH1U12022421, PR1U02052641, PR1U11252521, PH1U12042521, PH1U09122422, PH1U12092421, PR1U02062631, PR1U11252531, PH1U12052521, PH1U09162421, PH1U12102412, PR1U02112641, PR1U11252541, PH1U01312521

Product: Omnipod DASH Pod

NDC: 08508-2000-05

Lot Number: PD1U09062421, PD1U10282421, PD1U01082621, PD1U10292521, PD1U11032521, PD1U09092421, PD1U10292421, PD1U02152521, PD1U10302521, PD1U11042521, PD1U09102421, PD1U10312421, PD1U02192521, PD1U10312521, PD1U11052421, PD1U10242421, PD1U11042421, PD1U04242522, PD1U11012421, PD1U10252421, PD1U11192421, PD1U10282522, PD1U11022421

Product: Omnipod (Eros) Pod

NDC: 08508-1120-05

Lot Number: L72514

Talk to your doctor before you stop taking any medication. Stopping a drug without a replacement could have health risks. Your doctor can talk to you about other options that are right for you.

What you need to do next:

- Check your prescriptions to see if you have Omnipod 5, Omnipod DASH, and/or Omnipod Eros Pods.
- To see if you have affected product, check the lot number. The lot number is on the side of the packaging, circled in red or on the pod itself.

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1091494NJMESWLP 06/26

OMHC# 078-25-59

105-CNMCD26071WLPNJ 060226

- If your product has a different lot number, it's not affected by this Medical Device Correction.
- Insulet Corporation advises that you should discontinue use of any impacted Pod immediately. If the Pod you are currently using is from an affected lot, it is important that you immediately change your Pod to resume insulin delivery. When changing your Pod, confirm that the new Pod is not from an affected lot.
- Talk with your doctor about other products to use instead.
- Find more information about this Medical Device Correction at [fda.gov/medwatch](https://www.fda.gov/medwatch).

We're here to help

If you have questions about the Medical Device Correction, please call Insulet Product Support, the manufacturer, at 1-800-641-2049, available 24/7. Or visit <https://www.omnipod.com/mdc-5-26>. You can contact the FDA toll-free at **888-INFO-FDA (888-463-6332)** or visit [fda.gov](https://www.fda.gov) for more information.

You can also call your doctor or pharmacist if you have questions about the product or about this letter. If you have questions about your prescription drug benefits, please call Pharmacy Member Services at the phone number on your member ID card (TTY users can call **711**).

Sincerely,

Your Wellpoint service team

Enclosures: Language assistance sheet
Nondiscrimination notice

This information is provided for educational purposes only and should not be considered medical advice. Talk to your physician for specific treatment options and recommendations best suited for you and before beginning any lifestyle program.



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P. O. Box 62509

Virginia Beach, VA 24466-2509

<Date>

<Padre o tutor de>

<Member Name>

<Member Address>

<Member City, State ZIP>

Estimado/a miembro o padre/tutor de <Member Name>:

Tenemos información importante del retiro de medicamento sobre su receta para las bombas de Omnipod 5, Omnipod DASH y Omnipod Eros.

Nuestros registros muestran que usted tal vez ha surtido recientemente una receta de este producto.

El 26 de mayo de 2026, Insulet Corporation emitió una corrección de dispositivos médicos de determinados números de lote de bombas de Omnipod 5, Omnipod DASH y Omnipod Eros.

Insulet Corporation emitió esta corrección de dispositivos médicos debido a un problema de fabricación que Insulet Corporation identificó a través del monitoreo continuo del producto, que podría resultar en una administración insuficiente de insulina. Esta acción es independiente de la corrección de dispositivos médicos emitida el 12 de marzo de 2026 y el 30 de abril de 2026 que afecta a ciertas bombas de Omnipod 5 en los EE. UU.

Según Insulet Corporation, identificaron que algunas bombas de lotes específicos pueden tener un pequeño desgarramiento en el tubo (cánula) justo encima de la piel, entre la bomba y el punto donde la cánula ingresa al cuerpo. Si esto ocurre, la insulina puede filtrarse fuera de la bomba en lugar de administrarse por completo en el cuerpo según lo previsto, lo que podría provocar una administración insuficiente de insulina. Si un paciente está usando una bomba afectada, puede notar humedad en

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1091494NJMESWLP 06/26

OMHC# 078-25-59

105-CNMCD26071WLPNJ 060226

la piel o en el adhesivo de la bomba o detectar el olor de la insulina. Sin embargo, en algunos casos, este problema puede ser difícil de detectar y puede pasar desapercibido.

Si se produce una filtración de insulina, los niveles de glucosa en sangre del paciente pueden aumentar y es posible que no responda como se esperaba a la administración de insulina. Si utiliza Omnipod 5 en modo automatizado, esto podría activar una alerta automatizada de administración restringida y aconsejar que se solucione el problema. Sin embargo, este problema podría ocurrir sin activar ninguna alerta, lo que significa que los pacientes podrían recibir menos insulina de la necesaria sin darse cuenta. Los pacientes no deben confiar solo en las alertas de la bomba para saber si algo no funciona.

Producto: Kit inicial de Omnipod 5 (pieza n.º PT 001659)

NDC: 08508-3000-01

Número de lote: PK00315, PK00389, PK00316, PK00390, PK00319, PK00394, PK00324, PK00396, PK00327, PK00401, PK00331, PK00407, PK00350, PK00415, PK00354, PK00417, PK00359, PK00420, PK00365, PK00425, PK00370, PK00432, PK00371, PK00509, PK00381, PK00513, PK00383, PK00518, PK00389

Producto: Kit inicial de Omnipod 5 (pieza n.º PT-001998)

NDC: 08508-3000-88

Número de lote: PK00522, PK00523

Producto: Bomba de Omnipod 5

NDC: 08508-3000-21, 08508-3000-42

Número de lote: PH1U01032521, PH1U09212421, PH1U12102421, PR1U02132611, PR1U11262521, PH1U02042521, PH1U01102521, PH1U09262411, PH1U12122421, PR1U02132641, PR1U11262541, PH1U04092521, PH1U01132521, PH1U09262421, PH1U12132422, PR1U11182531, PR1U12012521, PH1U04112521, PH1U01172521, PH1U10042421, PH1U12172421, PR1U11182541, PR1U12022521, PH1U10142421, PH1U01222521, PH1U10102421, PH1U12182421, PR1U11192531, PR1U12032521, PH1U10152421, PH1U01232522, PH1U10112422, PR1U01132621, PR1U11192532, PR1U12102522, PH1U10162421, PH1U02132511, PH1U10122421, PR1U01152621, PR1U11192541, PR1U12112521, PH1U11212421, PH1U02212521, PH1U10172522, PR1U01162621, PR1U11192542, PR1U12122521, PH1U11222421, PH1U02222521, PH1U10182521, PR1U01172621, PR1U11202521, PR1U12132511, PH1U11252421, PH1U03202521,



PH1U10202521, PR1U01202621, PR1U11202532, PR1U12132521, PH1U11262421, PH1U03262521, PH1U10212521, PR1U01212621, PR1U11202533, PR1U12152521, PH1U01302522, PH1U03282521, PH1U10222521, PR1U01222621, PR1U11202541, PR1U12162521, PH1U01312511, PH1U03312521, PH1U10232521, PR1U01232621, PR1U11202542, PH1U09172421, PH1U02032521, PH1U04032521, PH1U10242521, PR1U01272621, PR1U11212521, PR1U12172521, PH1U04102521, PH1U04042521, PH1U10252521, PR1U01302641, PR1U11222521, PH1U01092621, PH1U09182421, PH1U04302524, PH1U11152521, PR1U01312631, PR1U11222531, PH1U02202521, PH1U09192421, PH1U05012521, PH1U11172511, PR1U02022641, PR1U11222541, PH1U04222521, PH1U09202421, PH1U05022521, PH1U11172521, PR1U02032631, PR1U11232541, PH1U04232511, PH1U10172421, PH1U05052521, PH1U11182521, PR1U02032641, PR1U11242521, PH1U04232521, PH1U06282422, PH1U11192511, PR1U02042641, PR1U11242531, PH1U10182422, PH1U09112421, PH1U11192521, PR1U02052631, PR1U11252512, PH1U11142521, PH1U09122421, PH1U12022421, PR1U02052641, PR1U11252521, PH1U12042521, PH1U09122422, PH1U12092421, PR1U02062631, PR1U11252531, PH1U12052521, PH1U09162421, PH1U12102412, PR1U02112641, PR1U11252541, PH1U01312521

Producto: Bomba de Omnipod DASH

NDC: 08508-2000-05

Número de lote: PD1U09062421, PD1U10282421, PD1U01082621, PD1U10292521, PD1U11032521, PD1U09092421, PD1U10292421, PD1U02152521, PD1U10302521, PD1U11042521, PD1U09102421, PD1U10312421, PD1U02192521, PD1U10312521, PD1U11052421, PD1U10242421, PD1U11042421, PD1U04242522, PD1U11012421, PD1U10252421, PD1U11192421, PD1U10282522 PD1U11022421

Producto: Bomba de Omnipod (Eros)

NDC: 08508-1120-05

Número de lote: L72514

Hable con su médico antes de dejar de tomar cualquier medicamento. Dejar de tomar un medicamento sin un reemplazo podría tener riesgos para la salud. Su

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1091494NJMESWLP 06/26

OMHC# 078-25-59

105-CNMCD26071WLPNJ 060226



y recomendaciones que mejor se adapten a usted antes de comenzar cualquier programa de estilo de vida.

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1091494NJMESWLP 06/26

OMHC# 078-25-59

105-CNMCD26071WLPNJ 060226