Zepbound™ (tirzepatide) injection 0.5 mL

2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg

IMPORTANT DOSING AND PRODUCT INFORMATION FOR PHARMACISTS

Attention:
Pharmacies, Pharmacists, and Pharmacy Staff, on behalf of Lilly USA, LLC

Subject:
Stocking and product information for Zepbound™ (tirzepatide)

Eli Lilly and Company is pleased to announce that Zepbound was approved by the U.S. Food and Drug Administration on November 8, 2023.

Lilly anticipates beginning shipment of Zepbound to Lilly Authorized Distributors of Record on or after [<November 24, 2023>].

Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Select Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

Lilly

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STARTING AND CONTINUING ZEPBOUND

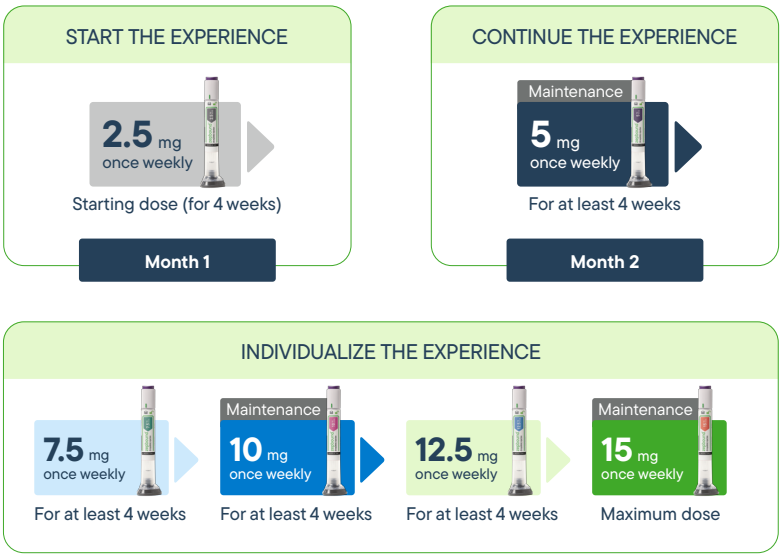
A once-weekly, subcutaneous injection[1]

Recommended maintenance dosages are 5 mg, 10 mg, or 15 mg[1]:

- Initiate with the 2.5-mg dose
- After 4 weeks, increase to the 5-mg dose
- You can continue to increase the dose by 2.5-mg increments after at least 4 weeks on the current dose. The maximum dose is 15 mg
- Consider treatment response and tolerability when selecting maintenance dosage. If not tolerated, consider a lower maintenance dosage

For adults with obesity (BMI of ≥30 kg/m^2) or with overweight (BMI of ≥27 kg/m^2) with at least 1 weight-related comorbidity.[1]

The 2.5-mg dosage is for treatment initiation and is not intended for chronic weight management.[1]



HOW SUPPLIED[1]

Package Size (4 pens per package)	Carton Dimensions (L x W x H, inches)	Carton Weight (lb)	NDC and UPC	Individual Package GTIN
2.5 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2506-80 **UPC:** 300022506802	00300022506802
5 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2495-80 **UPC:** 300022495809	00300022495809
7.5 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2484-80 **UPC:** 300022484803	00300022484803
10 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2471-80 **UPC:** 300022471803	00300022471803
12.5 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2460-80 **UPC:** 300022460807	00300022460807
15 mg/0.5 mL in a single-dose pen	6.3 x 5.12 x 2.09	0.44	**NDC:** 0002-2457-80 **UPC:** 300022457807	00300022457807

BMI=body mass index; GTIN=Global Trade Item Number; NDC=National Drug Code; UPC=Universal Product Code.

Select Important Safety Information

Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.

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Zepbound™ (tirzepatide) injection

STORAGE AND HANDLING[1]

Cartons per Case	Case Dimensions (L x W x H, inches)	Case Weight (lb)
20	13.31 x 11.37 x 11.22	10.1

Minimum Order Quantity:	1 carton
Prescription Legend:	Yes
Returned Goods:	Please visit www.trade.lilly.com for further details.
Distribution:	Lilly Authorized Distributors of Record
Storage:	Store Zepbound in a refrigerator at 36°F to 46°F (2°C to 8°C)[1] If needed, each single-dose pen can be stored unrefrigerated at temperatures not to exceed 30°C (86°F) for up to 21 days. If Zepbound is stored at room temperature, it should not be returned to the refrigerator. • Discard if not used within 21 days after removing from the refrigerator. • Do not freeze Zepbound. Do not use Zepbound if frozen. • Store Zepbound in the original carton to protect from light. For questions about storage and transportation, call 1-800-545-5979.
Trade Agreements Act (TAA)–Compliant:	Yes
Country of Origin:	United States

Select Important Safety Information

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

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Questions your patients may have about Zepbound

Q: My Zepbound prescription was rejected because it needs a prior authorization. What does that mean?

A: Sometimes prescribers are required to get approval from your pharmacy insurance provider for a medication to be covered. This process is called a prior authorization, or PA. Your prescriber will need to fill out paperwork to explain why you need Zepbound. The pharmacy can fill a prescription for Zepbound with or without a PA, but if your insurance requires a PA and the PA is not approved, your out-of-pocket costs are likely to be higher than they otherwise would be.

Q: Will my prescriber need to complete a PA in order for me to receive Zepbound coverage?

A: It depends on what kind of pharmacy insurance you have. Most patients will need their prescriber to complete a PA to be eligible for coverage of Zepbound. The requirements for a PA vary by pharmacy insurance provider and may be subject to change. If you are covered by Medicare, you likely do not currently have coverage for anti-obesity medications.

Q: What type of information will my prescriber need to submit a PA?

A: If your pharmacy insurance requires a PA, your prescriber may need to share some of the following clinical information, which may include:

- Diagnosis
- Disease-specific ICD-10 code(s) based on your diagnosis
- BMI (kg/m^2)
- Other health conditions you may have
- Current and past diet and exercise attempts and programs
- Current and past use of other anti-obesity medications

Requirements vary by plan. Information listed above includes common information that may be requested.

Q: What happens if my PA is rejected?

A: If your PA is rejected, you should call your pharmacy insurance provider to clarify why it rejected the PA. You can then let your prescriber know what additional information will be needed prior to resubmitting a PA to your pharmacy insurance provider.

Q: Will I need more authorizations over time?

A: You may be subject to re-authorization requirements. If re-authorization is necessary, speak with your prescriber about additional information that may be needed, including documented weight loss progress (weight loss from baseline).

- **Is your patient unsure if Zepbound is covered? Please advise patients to check with their pharmacy insurance provider to confirm if Zepbound is covered**
- **Formulary access alone may not guarantee patient coverage. A patient's employer may also need to opt in to coverage of Zepbound even if Zepbound is on formulary**
- **Patients enrolled in Medicare likely do not have coverage for anti-obesity medications**

ICD-10=International Classification of Diseases (10th revision).

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Explore Savings Eligibility

For eligible and commercially insured patients

With coverage for Zepbound

Pay as little as

$25 for a 1-month, 2-month, or 3-month prescription if eligible and commercially insured with coverage for Zepbound

OR

Without coverage for Zepbound

Save up to

$563 for a 1-month prescription of Zepbound if eligible, commercially insured, and not covered for Zepbound

Governmental beneficiaries excluded, terms and conditions apply.

One month is defined as 28 days and 4 pens. Two months is defined as 56 days and 8 pens. Three months is defined as 84 days and up to 12 pens.

Prior to receiving specific ID and RxBIN numbers, patients will need to enroll by visiting the Zepbound™ Savings Card website or using the QR code below

HAVE PATIENTS SCAN THE CODE FOR
ZEPBOUND SAVINGS INFORMATION

TERMS AND CONDITIONS

Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Zepbound Savings Card Program ("Card" or "Program") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2024. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.**

MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial drug insurance coverage for Zepbound: You must have commercial drug insurance that covers Zepbound™ (tirzepatide) and a prescription consistent with FDA-approved product labeling to pay as little as $25 for a 1-month, 2-month, or 3-month prescription fill of Zepbound. Month is defined as 28-days and up to 4 pens. Card savings are subject to a maximum monthly savings of up to $150 per 1-month prescription, $300 per 2-month prescription, or $450 per 3-month prescription fill and separate maximum annual savings of up to $1,800 per calendar year. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024.

For patients with commercial drug insurance who do not have coverage for Zepbound: You must have commercial drug insurance that does not cover Zepbound and a prescription consistent with FDA-approved product labeling to obtain savings of up to $563 off your 1-month prescription fill of Zepbound. Month is defined as 28-days and up to 4 pens. Card savings are subject to a maximum monthly savings of up to $563 and a separate maximum annual savings of up to $7,319 per calendar year. Subject to Lilly's right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024.

ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees and any amount that exceeds the monthly or annual maximum benefits. Card may be used for a maximum of up to 13 prescription fills per calendar year. Savings card activation is required. Participation in the Program requires a valid patient HIPAA authorization. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Zepbound Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at https://zepbound.lilly.com/coverage-savings. Card benefits void where prohibited by law.

Select Important Safety Information

Acute Gallbladder Disease: Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

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TO THE PHARMACIST

- This Card must be accompanied by a valid prescription for Zepbound and can only be used by one Patient. By accepting this offer, you certify that you understand and agree to comply with the offer terms set forth herein.
- If you are required to do so under the terms of your third-party payer contracts or as otherwise required by law, you should notify the affected third-party payer of your redemption of this offer.
- This offer is valid for commercially insured Patients only. **Offer is not valid for Patients who are eligible to have their prescriptions reimbursed in whole or part by any governmental program.**
- Please return Card to Patient after claim is processed.
- Transmit claim online to RxBIN 018844. Processor requires valid Prescriber ID #, PCN, Patient Name, and DOB for claim adjudication.
- Card expires and savings end on 12/31/2024.
- For Insured/Covered Patients – Submit the co-pay authorized by the Patient's primary insurance as a secondary claim to Eversana using BIN 018844 and using the Coordination of Benefits fields with Coverage Code type 08. This will reduce the eligible Patient's out-of-pocket costs to as little as $25, subject to a maximum monthly savings of $150 and a separate maximum annual savings of $1,800 for the Program. Card may be used for a maximum of up to 13 prescription fills per calendar year
- For Insured/Not Covered Patients – If Zepbound is Not Covered by the Patient's insurance, continue to process the Card along with the Patient's insurance card using the Coordination of Benefits fields with Coverage Code type 03. This will reduce the eligible Patient's out-of-pocket costs by up to $563 off their monthly fill for 4 pens of Zepbound, subject to a maximum monthly savings of up to $563 and a separate maximum annual savings of up to $7,319. Card may be used for a maximum of up to 13 prescription fills per calendar year.
- Pharmacy must submit claim within 90 days from date of service to be reimbursed.
- Pharmacists with questions, please call the Pharmacy Benefit Manager 1-855-282-4888.

Eligible patients can pay as little as $25 for a 1-month, 2-month, or 3-month prescription if commercially insured with coverage for Zepbound. For eligible patients with commercial insurance without coverage, save up to $563 for a 1-month supply of Zepbound*

*One month is defined as 28 days and 4 pens. Two months is defined as 56 days and 8 pens. Three months is defined as 84 days and up to 12 pens.

Governmental beneficiaries excluded, terms and conditions apply.

Select Important Safety Information

Acute Pancreatitis: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists or tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Zepbound. Observe patients for signs and symptoms of pancreatitis, including persistent severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting. If pancreatitis is suspected, discontinue Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

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Zepbound™ Savings Card

General instructions for processing a non-covered (OCC3) Savings Card claim

Submit the claim to the primary Third-Party Payer first. Confirm the details of the primary claim submissions if it has a managed care restriction (e.g., a step-edit, prior authorization, or NDC block). **If the primary claim restriction shows a prior authorization is required, please initiate the appropriate prior authorization process before proceeding with next steps.** After that, continue the claim adjudication process and submit the balance to CHANGE HEALTHCARE as a Secondary Payer (Coordination of Benefits claim) with patient responsibility amount and a valid Other Coverage Code (OCC) of 03. The Savings Card must be adjudicated as a Secondary Payer. Each pharmacy may have its own set of practice management systems and procedures, so these instructions may not apply.

WALGREENS

The Savings Card must be adjudicated as a Secondary Payer. If the Primary Insurance rejects the claim due to a plan restriction (e.g., drug not covered or prior authorization required), and the prescription meets the terms and conditions of the saving card program, the pharmacy team member should refer to Coordination of Benefits (COB) guide on StoreNet on how to process the prescription claim.

If the claim still rejects after following the steps in the COB guide, please open a ticket through the following pathway:

- Store Net
- 3rd Party
- Third Party Reference
- Billing and Collections
- Third Party Rejects (TPR's)
- COB Third Party Rejects
- Yes-Proceed to troubleshooting
- Yes-Open a ticket

CVS

The Zepbound™ Savings Card must be adjudicated as a Secondary Payer. Pharmacist should enter both the Primary and Secondary Insurance coordination of benefits. Bill the Primary Insurance first in order to get to the Secondary Insurance. If the Primary Insurance returns a Managed Care Restriction (e.g., step-edit, prior authorization, or NDC block, etc.), then:

- Click Bypass (Target/CVS has it as "BP" in their systems) and Submit
- Take the necessary steps to resolve the primary issue. If unable to resolve issue, contact the CVS help desk/ insurance company and the Secondary Insurance can be applied

RITE AID

The Zepbound™ Savings Card must be adjudicated as a Secondary Payer. Pharmacist should enter both the Primary Insurance and Secondary Insurance.

- If Primary Insurance rejects for a Prior Authorization, the pharmacist will need to contact Rite Aid's Support Desk for an override to process the COB claim with OCC 03
- If Primary Insurance rejects for "70 NDC not covered," click the "Continue Bill" button and submit to the Secondary Card text provided in the savings card

WALMART

Submit Primary Insurance and Zepbound™ Savings Card (first submission). If Primary Insurance rejects due to NDC not covered or PA required:

- Highlight the primary in the payment section of the resolution screen
- Delete the primary insurer
- Press F10
- Select OCC 03 for "Other Coverage Exists, This Claim Not Covered"
- Hit accept from the F10 screen
- Submit from the resolution screen

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

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Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

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Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound-treated patients had severe hypersensitivity reactions compared to no placebo-treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown if such patients will be predisposed to these reactions with Zepbound.

Please see accompanying Prescribing Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

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Important Safety Information (continued)

Hypoglycemia: Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2, hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). Hypoglycemia has also been associated with Zepbound and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Suicidal Behavior and Ideation: Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

The most common adverse reactions, reported in ≥5% of patients treated with Zepbound are: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, and gastroesophageal reflux disease.

Drug Interactions: Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

Pregnancy: Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Zepbound when a pregnancy is recognized. Available data with tirzepatide in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Zepbound (tirzepatide) during pregnancy. Pregnant patients exposed to Zepbound and healthcare providers are encouraged to contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Lactation: There are no data on the presence of tirzepatide or its metabolites in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zepbound and any potential adverse effects on the breastfed infant from Zepbound or from the underlying maternal condition.

Females and Males of Reproductive Potential: Use of Zepbound may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation.

Pediatric Use: The safety and effectiveness of Zepbound have not been established in pediatric patients less than 18 years of age.

Please see accompanying Prescribing Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

ZP HCP ISI 08NOV2023

Reference: 1. Zepbound. Prescribing Information. Lilly USA, LLC.

once weekly zepbound™ (tirzepatide) injection 0.5 mL
2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg