tirzepatide

Mounjaro

Pharmaceutical company: Lilly

Pharmacologic classification: Glucose-dependent insulinotropic polypeptide receptor and glucagon-like peptide-1 receptor agonist

Therapeutic classification: Antidiabetics

AVAILABLE FORMS

Injection: 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/mL, 15 mg/mL single-dose pen

INDICATIONS AND DOSAGES

Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Adults: Initially, 2.5 mg subcut once weekly. After 4 weeks, increase to 5 mg subcut once weekly. If additional glycemic control is needed, increase in 2.5-mg increments after at least 4 weeks on the current dose, up to a maximum of 15 mg subcut once weekly.

CONTRAINDICATIONS AND CAUTIONS

- **Black Box Warning:** Contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) and in patients with multiple endocrine neoplasia syndrome type 2.
- **Black Box Warning:** Thyroid C-cell adenomas and carcinomas occurred in animal studies. It’s not known if tirzepatide causes thyroid C-cell tumors, including MTC, in humans.
- Contraindicated in patients with known serious hypersensitivity to tirzepatide or any of its components.
- Monitor renal function in patients with renal impairment reporting severe adverse GI reactions, especially if dehydration occurs.
- This drug is associated with GI adverse reactions, sometimes severe. Use in patients with severe GI disease isn’t recommended.
- Rapid improvement in glycemic control has been associated with temporary worsening of diabetic retinopathy. Monitor patients with a history of diabetic retinopathy for disease progression.
- Safety and effectiveness in children haven’t been established.

- **Dialyzable drug:** Unknown.

PREGNANCY-LACTATION-REPRODUCTION

- This drug may cause fetal harm based on animal reproduction studies. Use during pregnancy only if the potential benefit justifies the risk to the fetus.
- There are no data on the presence of this drug in animal or human milk, the effects on the breastfed infant, or the effects on milk production. Use cautiously during breastfeeding.

INTERACTIONS

**Drug-drug.** Insulin, insulin secretagogues (sulfonylureas): May increase the risk of hypoglycemia. Monitor blood glucose level and adjust the dose of insulin or insulin secretagogues accordingly.
Oral hormonal contraceptives: May reduce efficacy of oral contraceptive due to delayed gastric emptying. Switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after tirzepatide initiation and for 4 weeks after each dose escalation.

Oral medications: Tirzepatide delays gastric emptying and may affect absorption of concomitantly administered oral medications. Use cautiously together.

ADVERSE REACTIONS

CV: sinus tachycardia.

GI: nausea, diarrhea, vomiting, constipation, dyspepsia, abdominal pain, decreased appetite, eructation, flatulence, gastroesophageal reflux disease, abdominal distension.

Metabolic: increased amylase, increased lipase.

Skin: injection site reaction.

Other: hypersensitivity, anti-tirzepatide antibody development.

Reactions in bold italics are life-threatening.

Released: October 2022

Nursing Drug Handbook

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vonoprazan and amoxicillin

Voquenza Dual Pak

Pharmaceutical company: Phathom Pharmaceuticals

Pharmacologic classification: Potassium-competitive acid blocker and antibacterial

Therapeutic classification: Antacid and anti-infective

AVAILABLE FORMS

Copackage containing:

Capsules: amoxicillin 500 mg

Tablets: vonoprazan 20 mg

INDICATIONS AND DOSAGES

Helicobacter pylori infection

Adults: Vonoprazan 20 mg PO b.i.d. (morning and evening) plus amoxicillin 1,000 mg PO t.i.d. (morning, midday, and evening) for 14 days.
CONTRAINDICATIONS AND CAUTIONS

- Contraindicated in patients hypersensitive to vonoprazan, amoxicillin, or other beta-lactams (penicillins or cephalosporins).
- Avoid use in severe renal impairment (eGFR less than 30 mL/minute) or moderate-to-severe hepatic impairment (Child-Pugh B or C).
- Avoid use of this drug in patients with mononucleosis, because this drug may increase the risk of erythematous skin rash.
- Serious and occasionally fatal hypersensitivity reactions, including anaphylaxis, have been reported.
- Severe cutaneous adverse reactions (SCARs) have occurred. Discontinue at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.
- *Clostridioides difficile*-associated disease has been reported with use of acid-suppressing therapies and nearly all antibacterial agents, including amoxicillin.
- Safety and effectiveness in children haven’t been established.
- Use cautiously in older adults.
- **Dialyzable drug:** Vonoprazan, no; amoxicillin, yes.

PREGNANCY-LACTATION-REPRODUCTION

- There are no adequate and well-controlled studies during pregnancy. Use with caution.
- There are no data regarding the presence of vonoprazan or amoxicillin in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential risk of adverse liver effects, patients who are breastfeed should pump and discard milk for the duration of therapy and for 2 days after therapy ends, and feed the infant stored human milk (collected prior to therapy) or formula.
- A pregnancy exposure registry is available at Phathom Pharmaceuticals, Inc. at 1-800-775-PHAT (7428).

INTERACTIONS

**Drug-drug.** *Allopurinol:* May increase incidence of rash. Discontinue allopurinol at first sign of skin rash.

*Atazanavir:* May alter absorption of atazanavir. Avoid use together.

*Clopidogrel:* May reduce clopidogrel level and platelet inhibition. Carefully monitor efficacy of clopidogrel or use alternative antiplatelet therapy.

*CYP2C19 substrates (citalopram, cilostazol):* May increase substrate level. Monitor for adverse reactions.

*CYP3A4 substrates (tacrolimus, cyclosporine):* May increase risk of adverse reactions of substrate. Frequent monitoring of substrate drug level or for adverse effects may be required.

*Drugs dependent on gastric pH for absorption (antiretrovirals, iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole, itraconazole):* Vonoprazan reduces intragastric acidity which may decrease the absorption of these drugs and their effectiveness. Refer to prescribing information for the individual drugs for dosing information if used together.

*Nelfinavir:* May alter absorption of nelfinavir. Avoid concomitant use.

*Oral anticoagulants:* May increase PT and INR. Monitor closely and adjust dose of oral anticoagulants as necessary.

*Probenecid:* May increase amoxicillin exposure resulting in adverse reactions. Monitor for adverse reactions.

*Rilpivirine:* May alter absorption of rilpivirine. Concomitant use is contraindicated.

*Strong or moderate CYP3A inducers:* May decrease vonoprazan effectiveness. Avoid use together.
ADVERSE REACTIONS

CNS: dysgeusia, headache.
CV: hypertension.
EENT: nasopharyngitis.
GI: diarrhea, abdominal pain.
GU: vulvovaginal candidiasis.
Other: hypersensitivity reaction.

Reactions in bold italics are life-threatening.

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vonoprazan–amoxicillin–clarithromycin
Voquenza Triple Pak

Pharmaceutical company: Phathom Pharmaceuticals

Pharmacologic classification: Potassium-competitive acid blocker, antibacterial, and antimicrobial

Therapeutic classification: Antacid and antibiotic

AVAILABLE FORMS

Copackage containing:

Capsules: amoxicillin 500 mg

Tablets: vonoprazan 20 mg and clarithromycin 500 mg

INDICATIONS AND DOSAGES

Helicobacter pylori infection

Adults: Vonoprazan 20 mg PO plus amoxicillin 1,000 mg PO plus clarithromycin 500 mg PO b.i.d. for 14 days.

CONTRAINDICATIONS AND CAUTIONS

- Known hypersensitivity to vonoprazan, amoxicillin or other beta-lactams, (penicillins or cephalosporins), or clarithromycin or other macrolide antibacterials.
• Use in patients with a history of cholestatic jaundice or hepatic dysfunction associated with clarithromycin is contraindicated.
• Serious and occasionally fatal reactions, including anaphylaxis, have been reported. If hypersensitivity reactions occur, discontinue therapy and institute immediate supportive care.
• Severe cutaneous adverse reactions (SCARs) have occurred. Discontinue at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.
• Clostridiodes difficile-associated disease has been reported with use of acid-suppressing therapies and nearly all antibacterial agents.
• Clarithromycin may increase the risk of QT prolongation and arrhythmias, including torsades de pointes. Avoid use in patients with known QT prolongation, ventricular cardiac arrhythmia, patients on drugs known to prolong the QT interval, patients with proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, or significant bradycardia.
• Avoid use in patients with mononucleosis due to amoxicillin content since many of these patients develop an erythematous skin rash.
• Avoid use in patients with severe renal impairment (eGFR less than 30 mL/min) or moderate-to-severe hepatic impairment (Child-Pugh B or C).
• Exacerbation of symptoms of myasthenia gravis and new onset of symptoms of myasthenic syndrome related to clarithromycin may occur.
• Safety and effectiveness in children haven’t been established.
• Use cautiously in older adults.
• Dialyzable drug: Vonoprazan, no; amoxicillin, yes; clarithromycin, no.
• Overdose S&S: Amoxicillin: interstitial nephritis, crystalluria, reversible renal impairment; clarithromycin: GI symptoms.

PREGNANCY-LACTATION-REPRODUCTION

• There are no adequate and well-controlled studies in pregnant women to evaluate for vonoprazan-associated risks. Clarithromycin may cause adverse fetal and pregnancy effects, including miscarriage. Use isn’t recommended in women who are pregnant unless there are no appropriate alternative therapies.
• There are no data regarding the presence of vonoprazan in human milk, the effects on the breastfed infant or the effects on milk production. Because of the potential for adverse liver effects, women who are breastfeeding should pump and discard milk for the duration of therapy and for 2 days after therapy ends, and feed the infant stored human milk (collected prior to therapy) or formula.
• Advise patients who are exposed to vonoprazan–amoxicillin–clarithromycin during pregnancy to contact Phathom Pharmaceuticals, Inc. at 1-800-775-PHAT (7428).
• Based on animal fertility study findings, clarithromycin may impair fertility in males of reproductive potential.

INTERACTIONS


Antiarrhythmics: (amiodarone, dofetilide, procainamide, sotalol, quinidine): May increase risk of adverse reactions, including QT prolongation and cardiac arrhythmias. Avoid concomitant use. If concomitant use is unavoidable, monitor patients for QTc prolongation.

Atazanavir, nelfinavir: May alter absorption of these drugs. Avoid concomitant use.

Atorvastatin: May increase level of statin. Avoid use together. If use can’t be avoided, limit atorvastatin dose to 20 mg daily.

Benzodiazepines (alprazolam, midazolam, triazolam): May increase benzodiazepine level. Closely monitor patients for increased or prolonged central nervous system effects, and refer to the benzodiazepine prescribing information for dosage recommendations.
Calcium channel blockers (amlodipine, diltiazem, nifedipine, verapamil): May increase calcium channel blocker level and risk of adverse reactions. Use cautiously together.

Clopidogrel: May reduce the clopidogrel level and platelet inhibition. Carefully monitor efficacy of clopidogrel or use alternative antiplatelet therapy.

Colchicine: May increase colchicine level and risk of adverse reactions. Concomitant use is contraindicated in patients with renal or hepatic impairment. If coadministration is necessary in patients with normal renal or hepatic function, carefully monitor patients for colchicine toxicity.

CYP2C19 substrates (citalopram, cilostazol): May increase substrate level. Carefully monitor patients for adverse reactions associated with substrate. See the prescribing information of substrate for dosage adjustments if used together.

CYP3A substrates (alfentanil, bromocriptine, cilostazol, methylprednisolone, phenobarbital, vinblastine): Clarithromycin may increase substrate level. Use cautiously together.

CYP3A4 substrates (tacrolimus, cyclosporine): May increase level of these substrates. Monitor substrate level frequently, monitor for adverse effects and decrease substrate level if needed.

CYP450 substrates (hexobarbital, phenytoin, valproate): May increase substrate level and risk of adverse reactions. Use together with caution.

Digoxin: Clarithromycin may increase digoxin level and risk of adverse reactions. Monitor digoxin level.

Disopyramide: May increase risk of adverse reactions, including cardiac arrhythmias and hypoglycemia. Avoid concomitant use. If unavoidable, monitor for QTc prolongation and changes in blood glucose level.

Drugs dependent on gastric pH for absorption (antiretrovirals, iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole, itraconazole): Vonoprazan reduces intragastric acidity which may decrease the absorption of these drugs and their effectiveness. See the prescribing information for other drugs dependent on gastric pH for absorption.

Ergot alkaloids (ergotamine, dihydroergotamine): May increase ergot alkaloid level. Concomitant use is contraindicated.

Etravirine: Clarithromycin may increase risk of adverse reactions or loss of effectiveness of both agents. Avoid use together.

Fluvastatin: May increase fluvastatin level. Avoid use together. If use together can’t be avoided, give at the lowest dose.

Hypoglycemic agents (insulin, nateglinide, pioglitazone, repaglinide, rosiglitazone): May increase hypoglycemic agent level and risk of hypoglycemia.

Itraconazole: Clarithromycin may increase risk of adverse effect of both agents. Monitor for adverse effects.

Lovastatin, simvastatin: May increase statin level. Use with these statins is contraindicated.

Maraviroc: Clarithromycin may increase maraviroc level. Use together with caution. See maraviroc prescribing information for coadministration with clarithromycin.

Omeprazole: May increase clarithromycin level. Avoid concomitant use.

Oral anticoagulants: May increase PT and INR. Monitor closely and adjust dose of oral anticoagulants as necessary.
**Phosphodiesterase inhibitors (sildenafil, tadalafil, vardenafil):** Clarithromycin may increase phosphodiesterase inhibitor level and risk of adverse reactions. Avoid concomitant use. If use can’t be avoided, refer to inhibitor prescribing information for dosage adjustment when given with strong CYP3A inhibitor.

**Pimozide:** May increase pimozide level, somnolence, neuroleptic malignant syndrome, and risk of QT prolongation and arrhythmias. Concomitant use is contraindicated.

**Pravastatin:** May increase statin level. Avoid use together. If use can’t be avoided, limit pravastatin dose to 40 mg daily.

**Probenecid:** May increase amoxicillin exposure resulting in adverse reactions. Monitor for adverse reactions associated with amoxicillin.

**Quetiapine:** May increase quetiapine level and risk of adverse reactions. Refer to quetiapine prescribing information for recommendations on coadministration with clarithromycin.

**Rilpivirine-containing products:** May alter absorption of rilpivirine. Concomitant use is contraindicated.

**Ritonavir:** Clarithromycin may increase risk of adverse reactions or loss of effectiveness of both agents. Concomitant administration is not recommended in patients with decreased renal function.

**Saquinavir:** May increase risk of adverse reactions or loss of effectiveness of saquinavir and clarithromycin. See saquinavir prescribing information for instructions on coadministration.

**Strong or moderate CYP3A inducers (rifampicin, efavirenz):** May decrease vonoprazan and clarithromycin effectiveness. Avoid concomitant use.

**Theophylline:** Clarithromycin may increase theophylline level. Closely monitor serum theophylline level in patients receiving high dosages of theophylline or with baseline concentrations in the upper therapeutic range.

**Tolterodine:** May increase tolterodine level and risk of adverse reactions. Tolterodine 1 mg b.i.d. is recommended in patients deficient in CYP2D6 poor metabolizers activity when coadministered with clarithromycin.

**Zidovudine:** May increase level of zidovudine and clarithromycin. Separate drug administration by at least 2 hours.

**Drug-herb. St. John’s wort:** May decrease clarithromycin level. Use together with caution.

**ADVERSE REACTIONS**

**CNS:** dysgeusia, headache.

**CV:** hypertension.

**EENT:** nasopharyngitis.

**GI:** diarrhea, abdominal pain.

**GU:** vulvovaginal candidiasis.

**Other:** hypersensitivity reaction.

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