cabotegravir

Apretude, Vocabria

Pharmaceutical company: ViiV Healthcare

Pharmacologic classification: HIV-1 integrase strand transfer inhibitor

Therapeutic classification: Antiretroviral

AVAILABLE FORMS

Injection (extended-release): 600 mg/3 mL single-dose vial

Tablets: 30 mg

INDICATIONS AND DOSAGES

Short-term treatment of HIV-1 infection in combination with rilpivirine in patients who are virologically suppressed (HIV 1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine

Adults (lead-in therapy): 30 mg PO daily in combination with oral rilpivirine for at least 28 days as oral lead-in therapy to assess tolerability of cabotegravir prior to starting cabotegravir and rilpivirine extended-release injections. Take last oral dose on the same day cabotegravir and rilpivirine injections are started.

Adults (bridging therapy): 30 mg PO daily in combination with oral rilpivirine for up to 2 months as oral bridging therapy for patients who plan to miss a scheduled injection visit by more than 7 days. The first dose of oral bridging therapy should begin about 1 month after the last cabotegravir and rilpivirine injection for patients on the monthly dosing schedule, and about 2 months after the last injections for patients on the every-2-month dosing schedule. Continue oral dosing until the day the injections are restarted.

Short-term preexposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk patients

Adults and adolescents age 12 and older weighing at least 35 kg (lead-in therapy): One tablet PO daily for 1 month (at least 28 days) as oral lead-in therapy prior to starting cabotegravir extended-release injections. Take last oral dose on the same day cabotegravir injections are started or within 3 days.

Adults and adolescents age 12 and older weighing at least 35 kg (bridging therapy): One tablet PO daily to replace one every 2-month injection as oral bridging therapy for patients who plan to miss cabotegravir injection by more than 7 days. The first dose of oral bridging therapy should begin about 2 months after the last cabotegravir injection and continued until injections are restarted or within 3 days. An alternate oral PrEP regimen is recommended for duration of more than 2 months.

PrEP to reduce the risk of sexually acquired HIV-1 infection in at-risk patients with or without an oral lead-in with oral cabotegravir

Adults and adolescents age 12 and older weighing at least 35 kg: Initially, 600 mg IM on the last day of or within 3 days after oral lead-in therapy, if used, followed by a second injection one month later. Continue with injections every 2 months thereafter.

CONTRAINDICATIONS AND CAUTIONS

- Contraindicated in patients hypersensitive to the drug or its components.
- Cabotegravir is contraindicated for PrEP in patients with unknown or positive HIV-1 status. Monotherapy with cabotegravir isn’t a complete regimen for HIV-1 treatment.
- **Black Box Warning:** There is a risk of drug resistance with use for HIV PrEP in patients with undiagnosed HIV-1 infection. Drug-resistant variants have been identified in patients with undiagnosed HIV-1 infections with use of cabotegravir injections.
- **Black Box Warning:** Prior to starting cabotegravir (oral or IM) for PrEP and prior to each subsequent injection, test for HIV-1 infections using an FDA approved or cleared test for the diagnosis of acute primary HIV-1 infections. Patients who become infected with HIV-1 while receiving injections for PrEP must transition to a complete HIV-w treatment regimen.
- **Black Box Warning:** Don’t initiate this drug for PrEP unless negative infections status in confirmed.
- The time from initiation of HIV-1 PrEP to maximal protection is unknown.
- Use of this drug for PrEP is part of a comprehensive prevention strategy, including adherence to the drug schedule and safer sex practices.
- Severe or life-threatening hypersensitivity reactions have occurred with other integrase inhibitors and may occur with cabotegravir. Treatment should be discontinued if signs or symptoms of hypersensitivity reactions develop.
- Use cautiously in patients with underlying liver disease or marked elevations in transaminases prior to treatment. Hepatotoxicity has been reported in patients with or without known preexisting hepatic disease or other risk factors.
- Residual extended-release formulation of this drug may remain in circulation for up to 12 months or longer.
- Use cautiously in older adults and patients with severe or end-stage renal disease. Use in severe hepatic impairment hasn’t been studied.
The safety and efficacy of cabotegravir for the treatment of HIV-1 infection in children, and for HIV-1 PrEP in children younger than age 12 or weighing less than 35 kg hasn’t been established.

**Dialyzable drug:** Unlikely.

**PREGNANCY-LACTATION-REPRODUCTION**

- Use of cabotegravir during pregnancy hasn’t been evaluated. Use of cabotegravir injections isn’t recommended for use in patients planning to become pregnant. Risks and benefits of treatment should be discussed with individuals of childbearing potential or who are pregnant.
- Enroll pregnant women exposed to this drug during pregnancy in the Antiretroviral Pregnancy Registry (1-800-258-4263).
- Women with HIV-1 infection shouldn’t breastfeed due to the potential risk of HIV-1 transmission to the infant.
- For uninfected women taking cabotegravir for PrEP, assess the risks and benefits of treatment while breastfeeding. Extended-release formulation may be found in human milk 12 months or more after discontinuing the drug.

**INTERACTIONS**

**Drug-drug.** Antacids containing aluminum, magnesium, or calcium carbonate: Concomitant use may decrease the absorption of oral cabotegravir. Administer antacid products at least 2 hours before or 4 hours after taking cabotegravir.

**Methadone:** May decrease methadone level. Monitor patient and adjust methadone dose as needed.

**Other antiretroviral drugs:** Other antiretrovirals shouldn’t be used with cabotegravir when used as monotherapy for PrEP or in combination with rilpivirine for treatment of HIV-1.

**Rifabutin:** May decrease cabotegravir level when given with extended-release injection. When used together, the second injection of extended-release cabotegravir should be given 2 weeks after the initial dose, and maintenance doses given monthly while on rifabutin.

**Strong inducers of UGT1A1 or 1A9 (carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine):** May significantly decrease cabotegravir levels and cause loss of virologic response. Use together is contraindicated.

**ADVERSE REACTIONS**

**CNS:** asthenia, depression, depressed mood, mood swings, headache, fever, sleep disorders, dizziness, somnolence, fatigue, abnormal dreams.

**GI:** diarrhea, nausea, abdominal pain, flatulence, vomiting, decreased appetite.

**Hepatic:** hepatoxicity.

**Musculoskeletal:** myalgia, back pain.

**Respiratory:** upper respiratory infection.

**Other:** suicidality, injection site reactions.

Reactions in bold italics are life-threatening.

Released: April 2022

**Nursing Drug Handbook**

© 2022 Wolters Kluwer

**daridorexant**

Quiviviq

**Pharmaceutical company:** Idorsia Pharmaceuticals

**Pharmacologic classification:** Orexin receptor antagonist

**Therapeutic classification:** Hypnotic

**Controlled substance schedule:** Pending

**AVAILABLE FORMS**

**Tablets:** 25 mg, 50 mg
INDICATIONS AND DOSAGES

Insomnia characterized by difficulties with sleep onset or sleep maintenance

*Adults:* 25 to 50 mg PO no more than once per night 30 minutes before going to bed and at least 7 hours until planned awakening.

*Adjust-a-dose:* For moderate hepatic impairment (Child Pugh 7 to 9) or coadministered with moderate CYP3A4 inhibitor, maximum dosage is 25 mg once per night.

CONTRAINDICATIONS AND CAUTIONS

- Contraindicated in patients with narcolepsy.
- Use in severe hepatic impairment isn’t recommended.
- Use cautiously in patients with psychiatric disorders; hypnotics may worsen depression, or suicidal ideation or behavior.
- Use cautiously in patients with a history of abuse or addiction to alcohol or other drugs.
- Use cautiously in patients with compromised respiratory function.
- Evaluate patients for comorbid diseases as cause of insomnia prior to starting daridorexant or if insomnia persists after 7 to 10 days.
- Use cautiously in older adults as they are more prone to CNS effects and falls.
- Safety and effectiveness haven’t been established in children.
- Sleep paralysis, hallucinations, and cataplexy-like symptoms (periods of leg weakness lasting from seconds to a few minutes and may not be associated with an identified triggering event [laughter or surprise]) may occur.
- Complex sleep behaviors (sleepwalking, sleep-driving, engaging in activities while not fully awake, including preparing and eating food, making phone calls, or having sex) may occur. If these occur, discontinue daridorexant immediately.

- **Dialyzable drug:** Unlikely.
- **Overdose S&S:** Somnolence, muscle weakness, cataplexy-like symptoms, sleep paralysis, disturbance in attention, fatigue, headache, constipation.

PREGNANCY-LACTATION-REPRODUCTION

- There are no data available on safety of use during pregnancy. Health care providers are encouraged to register patients who are pregnant in a pregnancy exposure registry at 1-833-400-9611.
- There are no data on the presence of this drug in human milk, or its effects on breastfed infants or on milk production. This drug was present in animal milk and is likely to be present in human milk. Consider the mother’s need against the risk to the breastfed infant. Monitor breastfed infants for excessive sedation.

INTERACTIONS

**Drug-drug.** *CNS depressants:* May increase risk of CNS depression. Use with caution and consider dose decrease of daridorexant or CNS depressant.

- **Strong and moderate CYP3A4 inducers:** May reduce efficacy level of daridorexant. Avoid concomitant use together.
- **Strong or moderate CYP3A4 inhibitors:** May increase daridorexant level and risk of adverse reactions. Avoid concomitant use with strong CYP3A4 inhibitors. Decrease daridorexant dose to 25 mg once nightly with moderate CYP3A4 inhibitors.

**Drug-food.** *High-fat and high-calorie meal:* May delay sleep onset if meal is consumed 30 minutes prior to taking daridorexant.

**Drug-lifestyle.** *Alcohol:* May increase risk of CNS depression. Discourage use together.

ADVERSE REACTIONS

*CNS:* headache, somnolence or fatigue, dizziness.

*GI:* nausea.

Reactions in bold italics are *life-threatening.*

Released: April 2022

Nursing Drug Handbook

© 2022 Wolters Kluwer

inclisiran

Leqvio

*Pharmaceutical company:* Novartis
Pharmacologic classification: Proprotein convertase subtilisin kexin type 9 mRNA inhibitor

Therapeutic classification: Antilipemic

AVAILABLE FORMS

Injection: 284 mg/1.5 mL (189 mg/mL) prefilled syringe

INDICATIONS AND DOSAGES

Adjunct to diet and maximally tolerated statin therapy for the treatment of heterozygous familial hypercholesterolemia or clinical atherosclerotic CV disease, in patients who require additional lowering of LDL cholesterol

Adults: 284 mg subcut for one dose. Repeat dose at 3 months, then every 6 months thereafter.

CONTRAINDICATIONS AND CAUTIONS

- Use of this drug hasn’t been studied in those with end-stage renal disease or severe hepatic impairment.
- The effect of this drug on CV morbidity and mortality hasn’t been determined.
- Safety and effectiveness in children haven’t been established.

- Dialyzable drug: Unknown.

PREGNANCY-LACTATION-REPRODUCTION

- There are no adequate and well-controlled studies in women who are pregnant. This drug may cause fetal harm based on the mechanism of action.
- Discontinue the drug when pregnancy is recognized; consideration may be given to the therapeutic needs of the individual patient. Treatment of hyperlipidemia isn’t generally necessary during pregnancy.
- There are no data on the safety of this drug while breastfeeding. Consider the benefits of breastfeeding, the clinical need of the drug to the mother, and potential adverse effects on the infant.

INTERACTIONS

None reported.

ADVERSE REACTIONS

GI: diarrhea.

GU: UTI.

Musculoskeletal: arthralgia, extremity pain.

Respiratory: bronchitis, dyspnea.

Skin: injection site reaction (pain, erythema, rash).

Reactions in bold italics are life-threatening.

Released: April 2022

Nursing Drug Handbook

© 2022 Wolters Kluwer