

XCOPRI[®] (cenobamate tablets) CV FACT SHEET FOR REDSAIL

XCOPRI[®] (cenobamate tablets) CV is a prescription medicine used to treat partial-onset seizures in adults. For epilepsy patients, it is critical that patients are adherent to their medication and do not lapse in therapy.

What is the copay assistance offered by SK Life Science?

- Copay Assistance allows eligible, commercially insured patients to pay no more than \$20/Rx for up to \$3,500/year
 - \$10/Rx up to \$3,500/year maximum in Alabama, Georgia, Massachusetts, and Delaware
 - \$20/Rx up to \$4,000/year maximum in South Carolina and Oregon
- The copay assistance resets for all eligible patients on January 1 of every calendar year

Who can use copay assistance?

- Only available for commercially insured patients who are over the age of 18
- Not available to patients with Government insurance (even secondary) i.e., Medicare, Medicaid, Tricare, etc.
- Available for cash patients

How to use the copay assistance:

- The copay assistance is applied automatically at the pharmacy, if the patient is eligible based on their insurance type
- No enrollment is needed for patients to be eligible for copay assistance
- There is no physical copay card; there is no ID, BIN, PCN to enter on the pharmacist's end
- Copay assistance is applied at "Point of Sale," so the transaction must occur at the pharmacy for the benefit to be applied

Other Common Questions:

- What is XCOPRI's coverage?
 - 97% patients are covered with some type of pharmacy insurance
- How often are Prior Authorizations required?
 - PAs are required 30% of the time
- How often are Prior Authorizations approved?
 - PAs are approved 90% of the time
- Will copay assistance work if a PA is not approved?
 - If a Prior Authorization (PA) is needed, copay assistance will not work unless that PA or appeal is approved

- What is XCOPRI's efficacy?
 - Please visit www.xcoprihcp.com/efficacy for more information about efficacy
- Will copay assistance be applied if a patient's copay is less than \$20?
 - Copay assistance is not applied if a patient's copay is less than \$20; it will not be bought down to \$0
 - If a patient is located in a state in which the copay is \$10 (AL, GA, MA, DE), copay assistance will not be applied if the patient's copay is less than \$10
- Does copay assistance apply for a patient's deductible?
 - The \$3,500/\$4,000 copay allowance will apply to a patient's deductible

SK Life Science Navigator Patient Assistance Program

- If a patient utilizes the \$3,500/\$4,000 copay allowance and cannot afford the copay, they may apply for the SK Life Science Navigator Patient Assistance Program (PAP)
- More information is available at www.sklsnavigator.com or patients can call 866-756-2844

INDICATION and IMPORTANT SAFETY INFORMATION and INDICATION for XCOPRI® (cenobamate tablets) CV

INDICATION

XCOPRI is indicated for the treatment of partial-onset seizures in adult patients.

CONTRAINDICATIONS

XCOPRI® is contraindicated in any patients with known hypersensitivity to the compound or any of the components of the drug product.

XCOPRI is contraindicated in patients with Familial Short QT syndrome.

WARNINGS AND PRECAUTIONS

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Also known as Multiorgan hypersensitivity, has been reported in patients taking antiepileptic drugs, including XCOPRI. DRESS has been reported, including one fatality, when XCOPRI is titrated rapidly (weekly or faster titration). No cases of DRESS were reported in an open-label safety study of 1339 partial-onset seizure patients when XCOPRI was initiated at 12.5 mg/day and titrated every two weeks. This finding does not establish that the risk of DRESS is prevented by a slower titration; however, XCOPRI should be initiated at 12.5 mg once daily and titrated every two weeks. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement. Eosinophilia is often present. If such signs or symptoms are present, the patient should be evaluated immediately. XCOPRI should be discontinued immediately and not restarted if an alternative etiology for the signs or symptoms cannot be established.

QT Shortening: XCOPRI can cause shortening of the QT interval. Caution should be used when administering XCOPRI and other drugs that shorten the QT interval as there may be a synergistic effect on the QT interval that would increase the QT shortening risk.

Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including XCOPRI, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Advise patients, their caregivers, and/or families to be alert for these behavioral changes and report

them immediately to a healthcare provider.

Neurological Adverse Reactions: XCOPRI causes dose-dependent increases in the neurologic adverse reactions including, dizziness, diplopia, disturbance in gait and coordination, somnolence, and fatigue.

Prescribers should advise patients against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of XCOPRI is known.

Withdrawal of AEDs: As with all antiepileptic drugs, XCOPRI should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. But if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

MOST COMMON ADVERSE REACTIONS

In adult adjunctive therapy placebo-controlled clinical studies, the most common adverse reactions that occurred in XCOPRI-treated patients (incidence at least 10% and greater than placebo) were somnolence, dizziness, fatigue, diplopia, headache.

DOSING CONSIDERATIONS

Dosage adjustment of XCOPRI or other concomitant medications may be necessary.

Consider gradually reducing phenytoin dosages by up to 50% during initial titration.

Consider reducing dosages of phenobarbital and clobazam as needed when used concomitantly with XCOPRI. When XCOPRI and carbamazepine or lamotrigine are taken concomitantly, consider increasing dosages as needed of carbamazepine or lamotrigine.

Consider increasing dosages as needed of drugs which are CYP2B6 and CYP3A substrates and decreasing dosages as needed of drugs which are CYP2C19 substrates.

Effectiveness of hormonal oral contraceptives may be reduced when administered concomitantly with XCOPRI. Women should use additional or alternative non-hormonal birth control.

Dosage reduction of XCOPRI may be considered in patients with mild to moderate and severe renal impairment. XCOPRI use is not recommended in end-stage renal disease.

The maximum recommended daily dose is 200 mg for patients with mild or moderate hepatic impairment. XCOPRI use is not recommended in patients with severe hepatic impairment

DRUG ABUSE

XCOPRI is a Schedule V controlled substance.

Please see [Full Prescribing Information](#)