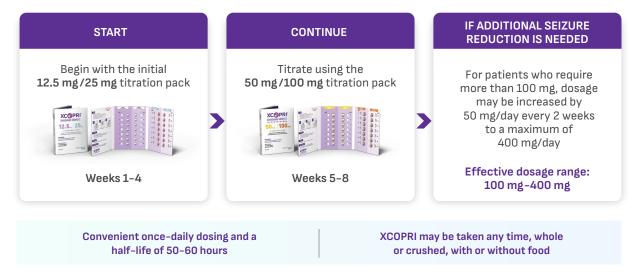
SWITCHING ON XCOPRI

Dosing guide to get patients started

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

PERSONALIZE YOUR APPROACH WITH ONCE-DAILY XCOPRI¹

XCOPRI is titrated at 2-week intervals and can be used as monotherapy or adjunctive therapy.



XCOPRI makes the concentration of some drugs increase. Consider decreasing the dosage of clobazam, phenytoin, and phenobarbital early in XCOPRI titration.

Liver function tests should be conducted prior to starting XCOPRI to establish baseline liver function if results are not available from the past 3 months.

200 mg is the maximum dosage for patients with mild or moderate hepatic impairment. XCOPRI is not recommended for use in patients with severe hepatic impairment.

IMPORTANT SAFETY INFORMATION for XCOPRI® (cenobamate tablets) CV

CONTRAINDICATIONS

XCOPRI is contraindicated in patients with hypersensitivity to cenobamate or any of the ingredients in the 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 openlabel 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.

Please see additional Important Safety Information throughout and full <u>Prescribing Information</u>.



FLEXIBILITY TO MEET YOUR PATIENTS' UNIQUE NEEDS1

Blister packs can simplify the titration schedule when starting XCOPRI.







12.5 mg/25 mg (28-day supply)

50 mg/100 mg (28-day supply)

150 mg/200 mg (28-day supply)

Bottles and maintenance blister packs allow for adjustments to find the right dosage for each patient.



- · 25 mg (30-count bottle)
- 50 mg (30-count bottle)
- · 100 mg (30-count bottle)
- 150 mg (30-count bottle)
- · 200 mg (30-count bottle)



- 250 mg (28-day supply)
- 350 mg (28-day supply)

REDUCING CONCOMITANT ASM DRUG LOAD WITH XCOPRI

Results from a post hoc analysis of a phase 3 study:



of patients on XCOPRI discontinued and/or reduced

1 or more anti-seizure medications (ASMs) across all drug classes (110/177)²

In this group of patients there was no increase or addition of concomitant ASMs.^{2*} The most common concomitant ASMs used at baseline included lacosamide, levetiracetam, lamotrigine, zonisamide, and clobazam.³

Limitations: This post hoc analysis of an open-label phase 3 study of XCOPRI did not include a control arm. These data are descriptive and representative of an enriched population with a relatively small number of patients. Appropriate multiplicity adjustments were not applied.



Scan here or visit
XCOPRIhcp.com/efficacy/
to explore the power of XCOPRI.

IMPORTANT SAFETY INFORMATION for XCOPRI® (cenobamate tablets) CV (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Please see additional Important Safety Information throughout and full <u>Prescribing Information</u>.



^{*}Sodium channel blockers, synaptic vesicle protein 2A ligands, benzodiazepines, and others.





Scan here or visit

XCOPRIhcp.com/rep-visit/
to reach out to your local
sales representative.



For any medical questions or to report an adverse event, please contact Medical Information at 1-866-657-5574.

IMPORTANT SAFETY INFORMATION for XCOPRI® (cenobamate tablets) CV (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

Liver Injury: Clinically significant liver injury has occurred in patients taking XCOPRI. Obtain serum transaminases (ALT and AST) and total bilirubin, if not recently available (i.e., within 3 months) before initiating XCOPRI, and during treatment if clinically indicated. Monitor patients for signs and symptoms of any hepatic injury during treatment. Discontinue XCOPRI in patients with evidence of liver injury in the absence of an alternative etiology.

Neurological Adverse Reactions: XCOPRI can cause 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. 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 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 is not recommended in patients with severe hepatic impairment.

DRUG ABUSE

XCOPRI is a Schedule V controlled substance.

Please see additional Important Safety Information throughout and full Prescribing Information.

REFERENCES: 1. XCOPRI [package insert]. Paramus, NJ: SK Life Science, Inc. **2.** Data on file. SK Life Science, Inc. **3.** Rosenfeld WE, Abou–Khalil B, Aboumatar S, et al. Post hoc analysis of a phase 3, multicenter, open–label study of cenobamate for treatment of uncontrolled focal seizures: effects of dose adjustments of concomitant antiseizure medications. *Epilepsia*. 2021;62(12):3016–3028.

