

XCOPRI® (cenobamate tablets) CV is indicated for the treatment of partial-onset seizures in adult patients¹

50% SEIZURE REDUCTION SHOULD NOT BE THE GOAL.

AIM FOR ZERO SEIZURES.

**READY. SET.
START WITH XCOPRI.**



In a study of adult patients with partial-onset seizures taking XCOPRI

Primary Outcome

Patients experienced **up to 2X greater seizure reduction** with XCOPRI compared with placebo (55% XCOPRI 400 mg, 55% XCOPRI 200 mg, 36% XCOPRI 100 mg vs 24% placebo)¹

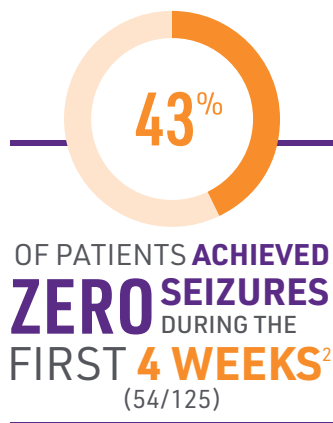
Secondary Outcome

As many as 1 in 5 patients experienced **zero seizures** with XCOPRI during the maintenance phase (21% XCOPRI 400 mg, 11% XCOPRI 200 mg, 4% XCOPRI 100 mg/day group, 1% placebo)¹

Please see Study Design information on page 4.*

Post hoc analysis of an open-label safety study

PERCENTAGE OF PATIENTS WITH 1-2 SEIZURES/28 DAYS AT BASELINE WHO ACHIEVED ZERO SEIZURES²



LIMITATIONS This post hoc analysis of an open-label 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.

Please see Study Design information on page 4.†

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

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.

Please see additional Important Safety Information on next page and full [Prescribing Information](#).

XCOPRI[®]
(cenobamate tablets) 
12.5 • 25 • 50 • 100 • 150 • 200 mg

YOU WANT TO PRESCRIBE XCOPRI

WE'VE GOT YOU COVERED.

LET US HELP YOU GET IT FILLED.

STARTING ON XCOPRI

Patients can receive **first month prescription for \$0** through the Trial Offer or Starter Sample Program⁵

SUPPORT FOR YOU AND YOUR PATIENTS

We have resources to help with **access to XCOPRI** and **prior authorization support**

STAYING ON XCOPRI

Most eligible commercial patients pay **as little as \$20 per month** on refills⁵

NATIONALLY

~97% of insured patients have access to XCOPRI⁴



FOR ADDITIONAL INFORMATION ON OUR SUPPORT SERVICES OR TO REQUEST SAMPLES

Scan the QR code.

⁵Eligibility requirements and terms and conditions will apply.

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

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.

References: 1. XCOPRI [package insert]. Paramus, NJ: SK Life Science, Inc. 2. Aboumatar S, Biton V, Wechsler R, Ferrari L, Rosenfeld WE. Post hoc analysis of a phase 3 study for treatment of uncontrolled focal seizures: adjunctive cenobamate dose and seizure reduction by baseline seizure frequency. *Epilepsy Res.* 2022. Doi: 10.1016/j.eplepsyres.2022.107014. 3. Data on file, IQVIA. SK Life Science, Inc. 4. Data on file. SK Life Science, Inc.

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.







INDICATION

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

XCOPRI® (cenobamate tablets) CV is indicated for the treatment of partial-onset seizures in adult patients¹

FLEXIBILITY FOR A PERSONAL APPROACH – FROM START TO MAINTENANCE

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

ONCE-DAILY STARTING DOSE					RECOMMENDED MAINTENANCE DOSAGE
Weeks 1-2	Weeks 3-4	Weeks 5-6	Weeks 7-8	Weeks 9-10	Week 11 & thereafter
12.5 mg once daily	25 mg once daily	50 mg once daily	100 mg once daily	150 mg once daily	200 mg once daily
					

Not actual sizes

XCOPRI may be taken any time, whole or crushed, with or without food.

Maximum dosage: Dosage may be increased above 200 mg/day by increments of 50 mg/day every 2 weeks to a maximum of 400 mg/day

Patients with mild or moderate hepatic impairment: 200 mg/day is the maximum dosage

TAKING PATIENTS THROUGH THEIR TREATMENT JOURNEY

 <p>Rx XCOPRI Titration pack 12.5 mg / 25 mg</p> <ul style="list-style-type: none"> Directions for Use: Take 12.5 mg tablet by mouth once daily for 2 weeks Take 25 mg tablet by mouth once daily for 2 weeks Quantity: 28 Refills: 0 	 <p>Rx XCOPRI Titration pack 50 mg / 100 mg</p> <ul style="list-style-type: none"> Directions for Use: Take 50 mg tablet by mouth once daily for 2 weeks Take 100 mg tablet by mouth once daily for 2 weeks Quantity: 28 Refills: 0 	 <p>Rx XCOPRI Titration pack 150 mg / 200 mg</p> <ul style="list-style-type: none"> Directions for Use: Take 150 mg tablet by mouth once daily for 2 weeks Take 200 mg tablet by mouth once daily for 2 weeks Quantity: 28 Refills: 0 	 <p>Rx XCOPRI 200 mg</p> <ul style="list-style-type: none"> Directions for Use: Take 200 mg tablet by mouth once daily Quantity: 30 Refills: (per HCP discretion)
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While 200 mg is the recommended maintenance dosage, dosing can vary based on clinical response and tolerability. Dosage may be increased above 200 mg/day by increments of 50 mg/day every 2 weeks to a maximum of 400 mg/day.



Titration blister packs

Designed to simplify the titration schedule of XCOPRI.

Titration blister packs available:

- 12.5 mg / 25 mg (28-day supply)
- 50 mg / 100 mg (28-day supply)
- 150 mg / 200 mg (28-day supply)



Maintenance blister packs and bottles

Designed to give you the flexibility to find the dosage that is right for your individual patients.¹

Maintenance blister packs available:

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

Maintenance bottles available:

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

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STUDY DESIGNS^{1,2}

*STUDIES OF ADULT PATIENTS WITH PARTIAL-ONSET SEIZURES TAKING XCOPRI

The efficacy of XCOPRI as adjunctive therapy in partial-onset seizures was established in 2 multicenter, randomized, double-blind, placebo-controlled studies in adult patients (Study 1 and Study 2). Patients had partial-onset seizures with or without secondary generalization and were not adequately controlled with 1 to 3 concomitant ASMs. Study 1 (N=221) compared XCOPRI 200 mg/day with placebo. Study 2 (N=434) compared XCOPRI 100 mg/day, 200 mg/day, and 400 mg/day with placebo. The double-blind treatment period consisted of a titration phase (6 weeks) and a maintenance phase (6 weeks for Study 1 and 12 weeks for Study 2). In both studies, patients were started on a higher starting dosage and/or faster titration than the Prescribing Information recommendation. The primary outcome was median percentage reduction in 28-day seizure frequency during the double-blind treatment period.

In Study 1, patients were started on a daily dosage of 50 mg (a higher starting dosage than currently recommended) and subsequently increased by 50 mg/day every 2 weeks, until the final daily target dosage of 200 mg/day was achieved. In Study 2, patients were started on a daily dosage of 50 mg (a higher starting dosage than currently recommended) and subsequently increased by 50 mg/day every week (a faster titration than currently recommended) until 100 mg/day or 200 mg/day was reached and then increased by 100 mg/day every week in patients randomized to 400 mg/day.

*POST-HOC ANALYSIS OF AN OPEN-LABEL, SAFETY STUDY

A multicenter, open-label safety study in patients 18 to 70 years old with uncontrolled focal seizures despite taking a stable dosage of 1 to 3 ASMs. The study included a screening period of up to 21 days was followed by an open-label treatment period consisting of a 12-week titration phase, followed by an open-label maintenance phase. The maintenance phase continued for the length of the study (total study duration up to 43 months). Patients initiated XCOPRI treatment using the FDA-approved titration schedule. After reaching 200 mg/day, further increases up to 400 mg/day using biweekly increments of 50 mg/day were allowed during the maintenance phase. Reductions below 200 mg were allowed at investigators' clinical judgment (minimum allowed dosage 50 mg/day). XCOPRI monotherapy was not allowed. Patient visits occurred every 2 weeks for 16 weeks and then every 1 to 3 months.

A post hoc analysis in a subset of patients (N=240) evaluated the impact of baseline seizure frequency (<3 seizures/28 days vs ≥3 seizures/28 days) on mean XCOPRI dosage required to achieve 100% seizure reduction, duration of this response, and responder rates. To be eligible for the post hoc analysis, the following criteria must have been met: patients must have had at least 1 focal aware motor, focal impaired awareness, or focal to bilateral tonic-clonic seizure per 13 weeks baseline prior to screening visit; seizure data while on treatment; and consistent documentation of good-quality, raw seizure data for ≥85% of the time spent in the study. Responder rates (≥50%, ≥75%, ≥90%, and 100%) were assessed during the entire treatment period, during the titration phase, and during the maintenance phase.

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

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