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

GETTING YOUR PATIENTS STARTED ON XCOPRI

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

ONCE-DAILY XCOPRI IS TITRATED AT 2-WEEK INTERVALS[1]

XCOPRI® (cenobamate tablets) CV is indicated for the treatment of partial-onset seizures in adult patients. It can be prescribed as monotherapy or adjunctive therapy.[1]

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 (recommended maintenance dosage)

Not actual sizes.

Maximum dosage: If needed 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.

XCOPRI may be taken any time with or without food. Swallow tablets whole with liquid. Do not crush or chew.

For patients with mild or moderate hepatic impairment, the maximum recommended dosage is 200 mg once daily.

PRESCRIBING XCOPRI

Below is an example* for a titration schedule of prescribing **XCOPRI**. After you have titrated up to find the right maintenance dose, maintenance blister packs and bottles are available.

Example Month 1

PRESCRIPTION

℞

XCOPRI Titration Pack
12.5 mg/25 mg

- 12.5 mg once daily by mouth for 2 weeks
- 25 mg once daily by mouth for 2 weeks
- Quantity: one 28-day pack. No refills

Example Month 2

PRESCRIPTION

℞

XCOPRI Titration Pack
50 mg/100 mg

- 50 mg once daily by mouth for 2 weeks
- 100 mg once daily by mouth for 2 weeks
- Quantity: one 28-day pack. No refills

Example Month 3

PRESCRIPTION

℞

XCOPRI Titration Pack
150 mg/200 mg

- 150 mg once daily by mouth for 2 weeks
- 200 mg once daily by mouth for 2 weeks
- Quantity: one 28-day pack. No refills

Example Maintenance Dose

PRESCRIPTION

℞

XCOPRI
200 mg

- XCOPRI 200 mg; 1 tab PO QD
- Quantity: 30

*While 200 mg is the recommended maintenance dose, dosing can vary based on clinical response and tolerability.

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.

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.

Please see additional Important Safety Information on the reverse side.

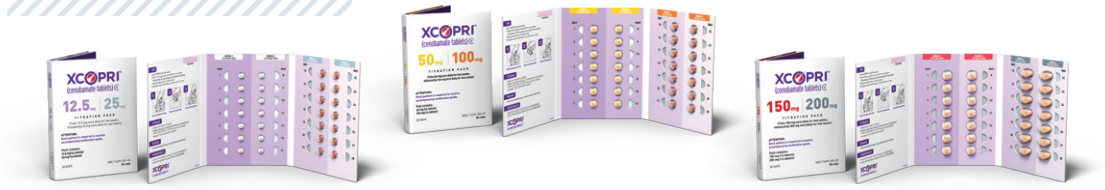
IMPORTANT PHARMACOKINETIC DRUG-DRUG INTERACTIONS

When prescribing **XCOPRI**, dosage adjustments to certain concomitant medications may be needed.

Looking for more XCOPRI tools and resources?
Visit XCOPRI.COM

Drug or Substrate Type	Clinical Recommendation
Phenytoin	↓ Gradually reduce dosage by up to 50%
Phenobarbital and clobazam	↓ Dosage as needed
Lamotrigine and carbamazepine	↑ Dosage as needed
CYP2B6 (eg, bupropion) and CYP3A (eg, midazolam, alprazolam[2]) substrates	↑ Dosage as needed
CYP2C19 substrates (eg, omeprazole, escitalopram[3])	↓ Dosage as needed
Oral contraceptives	Effectiveness of hormonal oral contraceptives may be reduced when administered concomitantly with **XCOPRI**. Women should use additional or alternative non-hormonal birth control.
Pharmacokinetic drug interactions do not necessarily translate into pharmacodynamic observations and clinical responses[4]	
No clinically significant differences in the pharmacokinetics of the following drugs were observed when prescribed concomitantly with XCOPRI: valproic acid, levetiracetam, or lacosamide[1]	
Please see Section 7 of the Prescribing Information for additional details on drug-drug interactions	

XCOPRI PACKAGING



Titration blister packs are designed to reinforce the start low, go slow titration schedule of **XCOPRI**. At-a-glance instructions have been included to assist you and your patients as XCOPRI doses are slowly increased over time.

Maintenance blister packs and bottles are designed to give you the flexibility to find the dose of **XCOPRI** that is right for your individual patients.

Maintenance blister packs available:

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

Bottles available:

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

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

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.

INDICATION

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

Please see full Prescribing Information.

References: 1. XCOPRI [package insert]. Paramus, NJ: SK Life Science, Inc. **2.** Alprazolam [package insert]. Parsippany, NJ: Actavis Pharma; Inc; 2017. **3.** Escitalopram [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; 2019. **4.** Data on file. SK Life Science, Inc.

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

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