



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Xcopri® 12.5 mg, Tablets

Xcopri® 25, 50, 100, 150, 200 mg, Film-coated tablets

Each tablets contains Cenobamate 12.5, 25, 50, 100, 150 or 200 mg, respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

Xcopri is used in combination with other anti-epileptic medicines in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicines, to treat a type of epilepsy that has focal-onset seizures with or without secondary generalisation.

Focal-onset seizures are those caused by abnormal brain activity starting in a part of the brain on one side, and secondary generalisation means that the abnormal activity is spreading to both sides of the brain. The medicine is intended for use in adults only.

Therapeutic group: anti-epileptic medicines.

These medicines are used to treat epilepsy, a condition where someone has seizures or fits because of abnormal activity in the brain.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (cenobamate), or to any of the other ingredients this medicine contains (see section 6).
- You were born with heart problems, with changes in the electrical activity of the heart, related to a rare condition called familial short-QT syndrome.

Special warnings regarding the use of the medicine

Before the treatment with Xcopri, tell the doctor if:

- You have thoughts of harming or killing yourself. A few people being treated with anti-epileptic medicines such as **Xcopri** have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, contact the doctor immediately.
- You have a serious skin reaction which may include high temperature and other flu-like symptoms, rash on the face, rash spreading to other parts of the body, swollen glands (enlarged lymph nodes); and blood tests showing increased levels of liver enzymes and of a type of white blood cell (eosinophilia).

Children and adolescents

Xcopri is not intended for children and adolescents under 18 years, as it was not investigated in this group.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Taking **Xcopri** with certain other medicines may affect how the other medicines work or how **Xcopri** works. Do not start or stop other medicines without talking to the doctor or pharmacist.

Tell the doctor if you are taking any of the following medicines, as your dose may need to be adjusted:

- Medicines used to help you fall asleep such as barbiturates and benzodiazepines.
- Other medicines to treat epilepsy, such as clobazam, phenytoin, phenobarbital, lamotrigine.
- Birth control medicines (oral contraceptives) as these may be less effective when combined with **Xcopri**. Your doctor may prescribe alternative methods for preventing pregnancy while you take this medicine and up to 4 weeks after you stop taking this medicine.
- Medicines which are known to be transformed in the body by specific groups of enzymes, such as midazolam (a medicine used to stop prolonged, acute (sudden) convulsive seizures, for sedation and sleep problems), bupropion (a medicine used to help stop smoking), omeprazole (a medicine used to treat heartburn or stomach ulcer), baricitinib (a medicine used to treat painful inflammation of the joints or skin eczema), cefaclor (an antibiotic), empagliflozin (a medicine used to treat high blood glucose in diabetes), penicillin G (an antibiotic), ritobegron (a medicine used to treat overactive bladder), sitagliptin (a medicine used to control high blood glucose in diabetes).

Use of the medicine and food

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption

Do not take this medicine with alcohol. **Xcopri** can increase the effects of alcohol such as feeling tired or sleepy and you should not drink alcohol with this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Only take **Xcopri** during pregnancy if you and your doctor decide that it is absolutely necessary.

You must use effective contraception during use of cenobamate and until 4 weeks after you stop taking the medicine. Ask your doctor for advice regarding effective measures of birth control (see section "Drug interactions").

You should stop breastfeeding while taking **Xcopri**.

Driving and using machines

You may feel sleepy, dizzy or tired, and your vision may be reduced while taking **Xcopri**.

These effects are more likely at the start of the treatment or after the dose is increased.

Do not drive, cycle or use any tools or machines if your reactions are slowed down and until you know how the medicine affects you.

Important information about some of the ingredients of the medicine

Xcopri contains lactose. If you have been told by a doctor that you have an intolerance to some sugars, contact the doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

You will take **Xcopri** with other medicines to treat epilepsy.

Dosage

The dosage and manner of treatment will be determined by the doctor only.

You will start **Xcopri** with a daily dose of one 12.5 mg tablet for the first 2 weeks, followed by one 25 mg tablet once a day for the next 2 weeks. Then your dose will be gradually adjusted every 2 weeks until you reach the dose that works best. The doctor will work out the right daily dose for you and may need to adjust it over time.

The recommended daily dose is between 200 mg and 400 mg once daily.

Patients with impaired kidney function: the maximum recommended daily dose is 300 mg per day.

Patients with mild to moderate liver impairment: the maximum recommended daily dose is 200 mg per day.

Do not exceed the recommended dose.

Method of administration

Take the recommended dose once a day at around the same time. You can take **Xcopri** at any time, either during the day or in the evening, with food or between meals.

Swallow the tablets whole with a glass of water. Do not break the tablets in half because the tablets are not suitable for splitting into two equal halves.

There is no information about crushing or chewing the tablets.

If you have accidentally taken a higher dosage

Talk to your doctor. You may feel dizzy, tired and sleepy.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take medicine

If you forgot to take this medicine at the designated time and fewer than 12 hours have passed since you should have taken it, take the forgotten dose as soon as you remember. If more than 12 hours have passed, skip the forgotten dose and take the next dose at your regular time. Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor.

If you stop taking the medicine

Do not reduce the dose or stop taking **Xcopri** without consulting the doctor. The doctor will explain how to stop taking **Xcopri** by reducing the dose gradually.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Xcopri** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if you have any of the following serious side effects:

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) – a serious skin reaction which may include fever and other flu-like symptoms, a rash on the face, rash spreading to other areas of the body, and swollen glands (enlarged lymph nodes). Blood tests may show increased levels of liver enzymes and of a type of white blood cell (eosinophilia).

Additional side effects

Very common side effects (effects that occur in more than 1 in 10 users):

- Feeling sleepy (somnolence), sedated or very tired (fatigue)
- Dizziness
- Spinning sensation (vertigo)
- Problems with coordination of movements, problems walking or keeping your balance (ataxia, gait disturbance, abnormal coordination)
- Headache

Common side effects (effects that occur in 1-10 out of 100 users):

- Reduced memory, confusion
- Excitability
- Having difficulty in saying words or difficulty speaking
- Rapid and uncontrollable movements of the eyes (nystagmus), blurred vision, double vision
- Nausea, vomiting, constipation or diarrhoea
- Dry mouth
- Rash, itching
- Swollen eyelids, swollen limbs
- Blood tests showing increases in levels of certain liver enzymes

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Allergic reactions
- Thoughts of harming or killing yourself

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects:

Side effects can be reported to the Ministry of Health by clicking the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** No special storage conditions. It is recommended to store at room temperature.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide

25 mg and 100 mg film-coated tablets also contain:

Polyvinyl alcohol-part. hydrolyzed, macrogol, titanium dioxide (E171), talc, iron oxide red (E172), iron oxide yellow (E172), indigo carmine aluminum lake (E132)

50 mg film-coated tablets also contain:

Polyvinyl alcohol-part. hydrolyzed, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172)

150 mg and 200 mg film-coated tablets also contain:

Polyvinyl alcohol-part. hydrolyzed, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172), iron oxide red (E172)

What the medicine looks like and what the package contains:

Xcopri 12.5 mg: round, white to off-white tablets, debossed "SK" on one side and "12" on the other side.

Xcopri 25 mg: round, brown film-coated tablets, debossed "SK" on one side and "25" on the other side.

Xcopri 50 mg: round, yellow film-coated tablets, debossed "SK" on one side and "50" on the other side.

Xcopri 100 mg: round, brown film-coated tablets, debossed "SK" on one side and "100" on the other side.

Xcopri 150 mg: round, light orange film-coated tablets, debossed "SK" on one side and "150" on the other side.

Xcopri 200 mg: oval, light orange film-coated tablets, debossed "SK" on one side and "200" on the other side.

Approved package sizes:

Xcopri 12.5 mg and 25 mg:

Blister: 7, 14 tablets. Titration pack (Treatment Initiation pack): 14 tablets of 12.5 mg and 14 film-coated tablets of 25 mg.

Xcopri 50 mg:

Blister: 7, 14, 30 film coated tablets. Titration pack: 14 film-coated tablets of 50 mg and 14 film-coated tablets of 100 mg. Maintenance pack (daily dose of 250 mg): 28 film-coated tablets of 50 mg and 28 film-coated tablets of 200 mg.

Bottle: 30 film-coated tablets.

Xcopri 100 mg:

Blister: 14, 30 film-coated tablets. Titration pack: 14 film-coated tablets of 50 mg and 14 film-coated tablets of 100 mg.

Bottle: 30 film-coated tablets.

Xcopri 150 mg:

Blister: 14, 30 film-coated tablets. Titration pack: 14 film-coated tablets of 150 mg and 14 film-coated tablets of 200 mg. Maintenance pack (daily dose of 350 mg): 28 film-coated tablets of 150 mg and 28 film-coated tablets of 200 mg.

Bottle: 30 film-coated tablets.

Xcopri 200 mg:

Blister: 14, 30 film-coated tablets. Titration pack: 14 film-coated tablets of 150 mg and 14 film-coated tablets of 200 mg. Maintenance pack (daily dose of 250 mg): 28 film-coated tablets of 50 mg and 28 film-coated tablets of 200 mg. Maintenance pack (daily dose of 350 mg): 28 film-coated tablets of 150 mg and 28 film-coated tablets of 200 mg.
Bottle: 30 film-coated tablets.

Not all package sizes may be marketed.

Manufacturer and address: SK Life Science, Inc. (a subsidiary of SK Biopharmaceuticals Co., Ltd.), New Jersey, USA

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Drug registration number at the national drug registry of the Ministry of Health:

Xcopri 12.5 mg: 172-86-37490-99

Xcopri 25 mg: 172-87-37491-99

Xcopri 50 mg: 172-88-37492-99

Xcopri 100 mg: 172-89-37493-99

Xcopri 150 mg: 172-90-37494-99

Xcopri 200 mg: 172-91-37495-99

Registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel