

YOUR ONTOZRY® TREATMENT GUIDE

You have been given this brochure because you have been prescribed ONTOZRY® (cenobamate) for the treatment of epilepsy.

Read the package leaflet carefully and follow the instructions you have been given by your doctor.

Epilepsy is a disease that more than **81,000 people in Sweden** live with¹ and that affects up to 2% of the world's population, which makes it one of the most common neurological diseases.² **Focal seizures account for more than 60% of the cases of epilepsy** and these seizures often respond worse to treatment than generalised seizures.^{3,4}

Most seizures can be controlled with the treatments that are available. However, **around a third of all people with epilepsy do not achieve seizure relief** due to therapy resistance.⁵⁻⁷

Definition of treatment-resistant epilepsy: Continued epileptic seizures despite treatment with at least two correctly selected antiepileptic medicines, in adequate doses, individually or in combination.¹

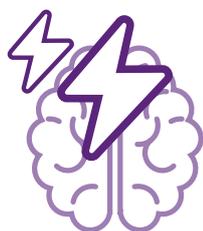
Ontozry is used in combination with other antiepileptics in adult patients with epilepsy, who have not achieved adequate seizure control despite previous treatment with at least two antiepileptic medicines. Ontozry is used for the treatment of focal seizures, with or without secondary generalisation.⁸



2%
OF THE WORLD'S
POPULATION



81,000
PEOPLE
IN SWEDEN



60%
HAVE FOCAL
SEIZURES



1/3
DO NOT ACHIEVE
SEIZURE CONTROL

1

HOW TO TAKE ONTOZRY

The recommended dose should be taken once daily at about the same time.



STARTING DOSE

The recommended starting dose is 12.5 mg a day.

Your dose will then **be adjusted gradually every two weeks** until you achieve the dose that works best for you.



ADMINISTRATION

Swallow the tablets **whole** with a glass of water, **with or without food**.

Do not break the tablets in half because the tablets are not suitable for splitting into two equal halves.



MISSED DOSES

If less than **12 hours have passed** since you should have taken the dose, **take the dose as soon as you can**.

If more than **12 hours have passed**, **skip the forgotten dose** and take the next dose at your usual time. **Do not take a double dose** to make up for the dose you missed.

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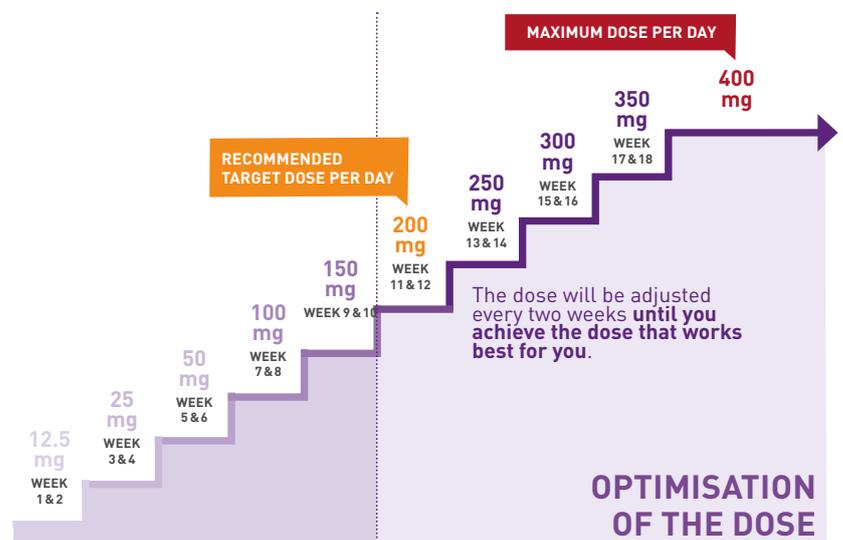
RECOMMENDED DOSE

The recommended starting dose is 12.5 mg during the first 2 weeks. The dose is then increased gradually until you achieve the dose that works best for you. The recommended dose is between 200 mg and 400 mg once daily.¹

If you stop taking Ontozry

You must not reduce the dose or stop taking Ontozry without checking with your doctor. Your doctor will explain how to stop treatment with Ontozry by reducing the dose gradually.

TITRATION OF THE DOSE



1. Ontozry package leaflet.

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POSSIBLE SIDE EFFECTS*



Like all medicines, Ontozry can cause side effects, although not everybody gets them.



If you get any side effects, **talk to your doctor, nurse or pharmacist.**



Very common side effects (may affect more than 1 in 10 people):¹

- Sleepiness (somnolence), tiredness or severe tiredness (fatigue)
- Dizziness, feeling of unsteadiness (vertigo)
- Problems co-ordinating movements, difficulty walking or difficulties balancing (ataxia, gait disorders, abnormal co-ordination)
- Headache



Tell your doctor immediately if you have any of the following uncommon side effects:

- Serious skin reaction, which may include fever and other flu-like symptoms
- Skin rash, rash that spreads 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).

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APPEARANCE AND PACK SIZES

HOW ONTOZRY IS SUPPLIED¹

Starter and titration packs for easy dose titration every two weeks.

Starter packs (28 days)

- 14 x tablets of cenobamate 12.5 mg
- 14 x film-coated tablets of cenobamate 25 mg

Titration pack (to be used until the optimal dose is achieved)

- 14 x film-coated tablets of cenobamate 50 mg
- 14 x film-coated tablets of cenobamate 100 mg
- 14 x film-coated tablets of cenobamate 150 mg
- 14 x film-coated tablets of cenobamate 200 mg
- Your dose will then be adjusted gradually every two weeks until you achieve the dose that works best for you. Your doctor will give you the correct daily dose, and it may need to be adjusted over time.

Packs for maintenance treatment

- The recommended target dose of Ontozry is 200 mg
- Depending on the clinical response, the dose of Ontozry can be increased to a maximum of 400 mg per day

Available packs

- 28 x film-coated tablets of cenobamate 50 mg
- 28 x film-coated tablets of cenobamate 100 mg
- 28 x film-coated tablets of cenobamate 150 mg
- 28 x film-coated tablets of cenobamate 200 mg



The tablets are shown in their actual size

* Read the package leaflet for a list of all side effects.

1. Ontozry package leaflet.

ONTOZRY®

cenobamat

Important product information. See the Ontozry package leaflet for complete information.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the package leaflet for how to report side effects.

Ontozry (cenobamate) 12.5 mg uncoated tablets and 25 mg, 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets. Ontozry contains the active substance cenobamate. It belongs to a group of medicines called 'antiepileptics'. These medicines are used to treat epilepsy, a condition where someone has seizures because of abnormal brain activity. Ontozry is used in combination with other antiepileptics in adult patients with epilepsy who have not achieved adequate seizure control despite treatment with at least two antiepileptic medicines. Ontozry is used to treat focal seizures, with or without secondary generalisation. Focal seizures are caused by abnormal brain activity starting in a specific part of the brain on one side, and secondary generalisation means that the abnormal activity spreads to both sides of the brain. The medicine should only be used in adults. **Warnings and precautions:** Do not take Ontozry if you are allergic to cenobamate or any of the other ingredients in this medicine. If you have congenital heart problems, with changes in the electrical activity in the heart related to a rare condition called familial short-QT syndrome. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking Ontozry with certain other medicines may affect how the other medicines work or how Ontozry works. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before you take this medicine. Do not drive, cycle or use any tools or machines if your reaction is impaired and until you know how the medicine affects you. Ontozry contains lactose. 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. **Read the package leaflet carefully before you start taking Ontozry. It contains important information for you. If you have any further questions, ask your doctor or pharmacist and always follow their instructions.** For further information, see the package leaflet and www.fass.se. **Contact:** Angelini Pharma Nordics, nordics.angelinipharma.com. Abbreviated information based on the package leaflet dated: 10/2021.