

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 antiseizure medications, 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



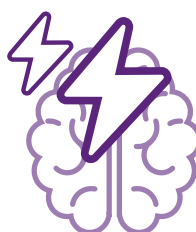
2%

OF THE WORLD'S
POPULATION



81,000

PEOPLE
IN SWEDEN



60%

HAVE FOCAL
SEIZURES



1/3

DO NOT ACHIEVE
SEIZURE CONTROL

Why have you been prescribed Ontozry?

When your doctor or nurse assesses your condition, they will carefully consider:

- How well your current medicines are working to control your epilepsy
- How intense your seizures are
- If it takes a long time for you to recover after a seizure
- What side effects you may be getting with your current medicine
- Whether the healthcare team can improve your current condition

As you can see, there are a lot of factors for your doctor or nurse to consider. It's understandable that treatment changes may make you feel anxious or confused – but you won't be given ONTOZRY® unless your doctor or nurse feels that you could benefit from it.

1. The Swedish National Board of Health and Welfare; National guidelines for epilepsy care, article number 2019-2-8. 2. Chung S, et al. *Seizure*. 2007;16(4):296-304. 3. Schmitz B, et al. *Epilepsia*. 2010;51(11):2231-40. 4. Cockerell OC, et al. *Epilepsia*. 1997;38(1):31-46. 5. Chen Z, et al. *JAMA Neurol*. 2018;75(3):279-86. 6. Kwan P and Brodie MJ. *N Engl J Med*. 2000;342(5):314-9. 7. Kwan P et al. *Epilepsia*. 2010;51(6):1069-77. 8. Ontozry package leaflet.

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. The tablet can be crushed, mixed with water and administered orally or via nasogastric tube.

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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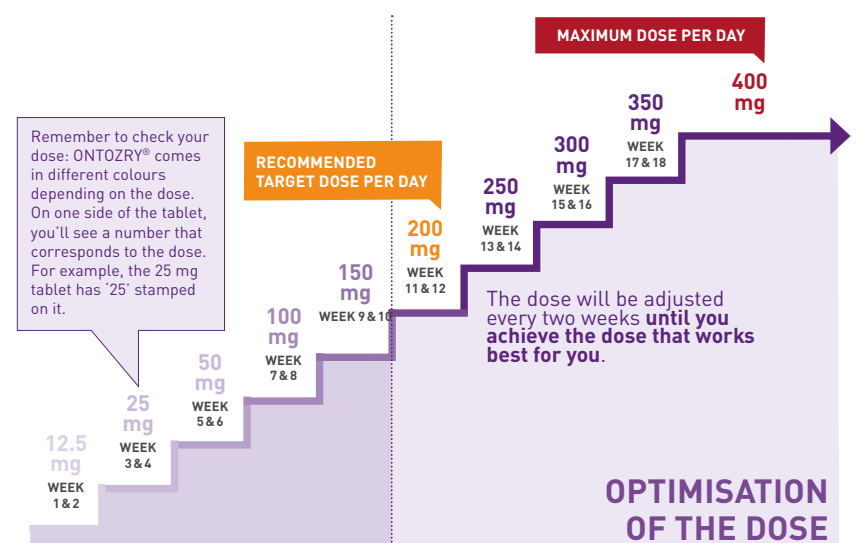
RECOMMENDED DOSE

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.

Your doctor should do blood tests to check your liver function prior to your starting treatment with Ontozry and during your treatment with Ontozry¹. See further information on the next page.

3 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).

Liver disorders - If you develop a sudden illness particularly if it includes nausea, repeated vomiting, extreme tiredness, abdominal pain, drowsiness, weakness, loss of appetite, upper stomach pain, jaundice (yellowing of the skin or whites of the eyes), unusually dark urine, pale or clay-coloured stools, or bruising more easily than normal. These may be signs of severe liver disorders.¹

4 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

1. Ontozry package leaflet.

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

ONT[®]OZRY[®]

cenobamat



Visit brainpower.se for more information about epilepsy.

BrainPower is a website for everyone who is looking for community, understanding, and information about a rarely discussed condition. The website is in Swedish.