Package leaflet: Information for the patient

Ontozry 12.5 mg tablets
Ontozry 25 mg film-coated tablets
Ontozry 50 mg film-coated tablets
Ontozry 100 mg film-coated tablets
Ontozry 150 mg film-coated tablets
Ontozry 200 mg film-coated tablets
cenobamate

▼This medicine 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 end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ontozry is and what it is used for
2. What you need to know before you take Ontozry
3. How to take Ontozry
4. Possible side effects
5. How to store Ontozry
6. Contents of the pack and other information

1. What Ontozry is and what it is used for

Ontozry contains the active substance cenobamate. It belongs to a group of medicines called 'anti-epileptics'. These medicines are used to treat epilepsy, a condition where someone has seizures or fits because of abnormal activity in the brain.

Ontozry is used in combination with other antiepileptic medicines in adult patients with epilepsy who have not been adequately controlled despite treatment with at least 2 anti-epileptic products, 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 that the abnormal activity is spreading to both sides of the brain. The medicine can be used only in adults.

2. What you need to know before you take Ontozry

Do not take Ontozry

- **if you are allergic** to cenobamate or any of the other ingredients of this medicine (listed in 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ontozry or during treatment if:
- you have thoughts of harming or killing yourself. A few people being treated with anti-epileptic medicines such as Ontozry have had thoughts of harming or killing themselves. If you have any of these thoughts at any time, contact your 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).

Liver disorders

• Your doctor should do blood tests to check your liver function prior to your starting treatment with Ontozry and during your treatment with Ontozry. Contact your doctor or pharmacist immediately if you develop a sudden illness and particularly if it includes one, or some of the signs and symptoms described in Section 4 – *Liver disorders*.

Children and adolescents

Ontozry is not recommended in children and adolescents under 18 years, as it was not investigated in this group.

Other medicines and Ontozry

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. Do not start or stop other medicines without talking to your doctor or pharmacist.

Tell your 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 and phenobarbital, lamotrigine.
- birth control medicines (oral contraceptives) as these may be less effective when combined with Ontozry. 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 problem), 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).

Ontozry with alcohol

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

Pregnancy and breast-feeding

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.
Only take Ontozry 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 this medicine. Ask your doctor for advice regarding effective measures of birth control.
You should stop breast-feeding while taking Ontozry.

Driving and using machines

- You may feel sleepy, dizzy or tired, and your vision may be reduced while taking Ontozry.
- These effects are more likely at the start of the treatment or after your dose is increased.
- Do not drive, cycle or use any tools or machines if your reaction are slowed down and until you know how the medicine affects you.

Ontozry contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, speak with your doctor before taking this medicine.

3. How to take Ontozry

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will take Ontozry with other medicines to treat epilepsy.

The recommended dose is
You will start Ontozry 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. Your 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.

Method of use
Take the recommended dose once a day at around the same time. You can take Ontozry 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.

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

Administration of Crushed Tablets via Nasogastric (NG) tube

Ontozry crushed tablet can be mixed with water and administered also through a nasogastric feeding tube (NG tube) as follows:

1. Crush the appropriate number of tablet(s) for the prescribed dose.
2. In an appropriate container, combine the crushed tablet(s) and 25 mL of water.
3. Shake to suspend the crushed tablet(s).
4. Ensuring no particles are left in the container, instill the suspension with a syringe into the NG tube.
5. Refill the catheter-tip syringe again with 10 mL of water, swirl gently, and administer.
6. Visually confirm that no particles are left in the syringe. If particles remain, repeat step 5.

If you have any further questions, ask your doctor.

If you take more Ontozry than you should

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

If you forget to take Ontozry

Take the forgotten dose as soon as you remember, if fewer than 12 hours have passed since you should have taken it. 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.

If you stop taking Ontozry

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

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

4. Possible side effects

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

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

Rare side effects (may affect up to 1 in 1,000 people):
- 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).

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 (see Section 2).

You may get the following other side effects with this medicine. Tell the doctor if you have any of the following:

Very common side effects (may affect more than 1 in 10 people):
- feeling sleepy (somnolence), sedated or very tired (fatigue)
- feeling dizzy
- spinning sensation (vertigo)
- having problems with coordination of movements, having problems walking or keeping your balance (ataxia, gait disturbance, abnormal coordination)
- headache

Common side effects (may affect up to 1 in 10 people):
- 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 (feeling sick), 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 (may affect up to 1 in 100 people):
- allergic reactions
- thoughts of harming or killing yourself.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ontozry

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ontozry contains

- The active substance is cenobamate.
  One Ontozry 12.5 mg tablet contains 12.5 mg cenobamate.
  One Ontozry 25 mg film-coated tablet contains 25 mg cenobamate.
  One 50 mg film-coated tablet contains 50 mg cenobamate.
  One 100 mg film-coated tablet contains 100 mg cenobamate.
  One 150 mg film-coated tablet contains 150 mg cenobamate.
  One 200 mg film-coated tablet contains 200 mg cenobamate.
- The other ingredients are microcrystalline cellulose (E460), lactose monohydrate, sodium starch glycolate, silica colloidal anhydrous (E551), magnesium stearate (E470b)

  25 mg and 100 mg film-coated tablets: indigo carmine aluminium lake (E132), iron oxide red (E172), iron oxide yellow (E172), -macrogol, partially hydrolysed poly(vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171)

  50 mg film-coated tablets: iron oxide yellow (E172), macrogol, partially hydrolysed poly(vinyl alcohol) (E1203), talc, titanium dioxide (E171)

150 mg and 200 mg film-coated tablets: iron oxide red (E172), iron oxide yellow (E172), macrogol, partially hydrolysed poly(vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171)

What Ontozry looks like and contents of the pack

Ontozry 12.5 mg are uncoated round white to off-white tablets with AV on one side and '12' on the other side.
Ontozry 25 mg are round brown film-coated tablets with AV on one side and '25' on the other side.
Ontozry 50 mg are round yellow film-coated tablets with AV on one side and '50' on the other side.
Ontozry 100 mg are round brown film-coated tablets with AV on one side and '100' on the other side.
Ontozry 150 mg are round light orange film-coated tablets with AV on one side and '150' on the other side.
Ontozry 200 mg are oval light orange film-coated tablets with AV on one side and '200' on the other side.

Ontozry Treatment Initiation pack contains 14 tablets of 12.5 mg and 14 film-coated tablets of 25 mg.

Ontozry 50 mg, 100 mg, 150 mg and 200 mg film-coated tablets are available in packs of 14, 28 or 84.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in 06/2026.