Package leaflet: Information for the patient

Celastymis 15 mg prolonged-release tablets
Celastymis 20 mg prolonged-release tablets
Celastymis 30 mg prolonged-release tablets
Celastymis 40 mg prolonged-release tablets
Celastymis 60 mg prolonged-release tablets
Celastymis 80 mg prolonged-release tablets

oxycodone hydrochloride

This medicine contains oxycodone which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

1. What Celastymis is and what it is used for

This medicine has been prescribed for you for the relief of moderate to severe pain over a period of 12 hours. Celastymis (oxycodone hydrochloride) is a centrally acting, strong painkiller from the group of opioids.This medicine has been prescribed for you and should not be given to anyone else.
Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly.
Celastymis is used to treat severe pain, which can be adequately managed only with opioid analgesics.
Celastymis is indicated in adults and adolescents aged 12 years and older.
Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Celastymis

Do not take Celastymis

- if you are allergic (hypersensitive) to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if you have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected,
- if you have a condition where the small bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen,
- if you have a heart problem after long-term lung disease (cor pulmonale),
- if you have a head injury that causes a severe headache or makes you feel sick. This is because the tablets may make these symptoms worse or hide the extent of the head injury,
- if you have severe kidney problems or moderate to severe liver problems. If you have other long-term kidney or liver problems you should only take these tablets if recommended by your doctor,
- if you have ongoing problems with constipation,
- if you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks,
- if you have increased carbon dioxide levels in the blood. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache,
- if you have a rare hereditary problem of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption.

Warnings and precautions

Talk to your doctor or pharmacist before taking Celastymis

- if you are elderly or weakened;
- if you have lung, liver or kidney function is severely impaired;
- if you suffer from myxoedema (a thyroid disorder with dryness, coldness and swelling [‘puffiness’] of the skin affecting the face and limbs);
- if you have an under-active thyroid gland (hypothyroidism), as you may need a lower dose;
- if you have poor adrenal gland function (your adrenal gland is not working properly), e.g. Addison’s disease;
- if you have an enlarged prostate gland, which causes difficulty in passing urine (in men);
- if you have breathing problems such as severe pulmonary disease. Your doctor will have told you if you have this condition. Symptoms may include breathlessness and coughing;
- if you have kidney or liver problems;
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, upon stopping taking alcohol or drugs;
- if you suffer from inflammatory bowel disorders;
- if you suffer from inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis);
- if you have problems with your gall bladder;
- if you are in conditions with increased brain pressure;
- if you suffer from colic of the bile duct and ureter;
- if you suffer from epilepsy or have a seizure tendency;
- if you take MAO inhibitors (a medicine for the treatment of depression);
- if you have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- if you have low blood pressure (hypotension);
- if you have low blood volume (hypovolaemia); this can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting;
- if you have a mental disorder as a result of an infection (toxic psychosis);
- if you have an increased sensitivity to pain;
- if you need to take increasingly higher doses of oxycodone to gain the same level of pain relief (tolerance);
- if you feel very lightheaded or faint;
- if you have long term pain unrelated to cancer;
- if you or anyone in your family are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;
- if you feel you need to take more tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking these tablets, Your doctor may adjust your dose.

Do not use these tablets for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Talk to your doctor if any of these apply to you or if any of these conditions applied to you in the past. If you are going to have an operation, please tell the doctor at the hospital that you are taking these tablets.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

<u>Tolerance, dependence and addiction</u>

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Celastymis may lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn’t help to relieve your pain.
Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Celastymis if:

- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”);
- you are a smoker;
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Celastymis, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’)

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Celastymis).

Celastymis has a primary dependence potential. When used for a long time tolerance to the effects and progressively higher doses may be required to maintain pain control.

Chronic use of Celastymis may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. When a patient no longer requires therapy with oxycodone hydrochloride, it may advisable to taper the dose gradually to prevent symptoms of withdrawal.

Celastymis are for oral use only. In case of abusive injection (injection in a vein) the tablet excipients (especially talc) may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially fatal events.

This medicine should be avoided in patients with a history of or present alcohol and drug abuse.

Withdrawal

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Celastymis tablets).
It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.
Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Do not inject Celastymis tablets. This can cause serious side effects including tissue death at the site of injection, infection, inflammation of the lungs and damage to the heart which may be fatal.

Anti-doping warning

Athletes should be aware that this medicine may cause a positive reaction to “anti-doping tests”. Use of Celastymis as a doping agent may become a health hazard.

Children and adolescents

Oxycodone has not been investigated in children under 12 years. Safety and efficacy have not been established therefore use in children under 12 years of age is not recommended.

Sleep-related breathing disorders

Celastymis can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Celastymis

Concomitant use of Celastymis and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Celastymis together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor’s dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The risk of side effects increases, if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Please follow your doctor’s dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

Please tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking or if the dose needs to be adjusted for:

- a type of medicine known as a monoamine oxidase inhibitor (such as tranylcypromine, phenelzine and isocarboxazid). You should not take Celastymis tablets if you are currently taking this type of medicine, or have taken this medicine in the last two weeks;
- medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines);
- medicines to treat depression (such as paroxetine);
- a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline;
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- other strong analgesics (‘painkillers’);
- muscle relaxants;
- medicines to treat high blood pressure;
- quinidine (a medicine to treat a fast heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole);
- antibiotics (such as clarithromycin, erythromycin or telithromycin);
- medicines known as ‘protease inhibitors’ to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
- rifampicin (to treat tuberculosis);
- carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions);
- phenytoin (a medicine to treat seizures, fits or convulsions);
- a herbal remedy called St. John’s Wort (also known as Hypericum perforatum);
- antihistamines;
- medicines to treat Parkinson’s disease;
- medicines used to treat allergies,such as cetirizine, fexofenadine or chlorphenamine; other medicines used to treat pain known as opioids (such as codeine or morphine);
- anaesthetics;
- medicines used to treat epilepsy (gabapentinoids) such as pregabalin.

Because of this, your doctor will only prescribe Celastymis tablets where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor **immediately**.
Taking Celastymis tablets with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity.
The symptoms of this include agitation, seeing or hearing things that aren’t real (hallucinations), loss of consciousness, a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, stiffness, feeling or being sick, or diarrhoea.
If you are taking SSRI or SNRI medicines such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine your doctor may reduce your dose of Celastymis tablets.
Also tell your doctor if you have recently been given an anaesthetic.

Celastymis with food, drink and alcohol

Drinking alcohol whilst taking Celastymis may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking Celastymis. You should avoid drinking grapefruit juice during your treatment with Celastymis.

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 taking this medicine.

Pregnancy

Celastymis should not be taken in pregnancy unless clearly necessary. There are only limited data from the use of oxycodone in pregnant women. Oxycodone crosses the placenta into the blood circulation of the baby.
Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. Use of oxycodone during delivery can cause respiratory depression in the newborn.

Breast-feeding

You should not take Celastymis when you are breastfeeding as oxycodone passes into breast milk.

Driving and using machines

Celastymis may impair your ability to drive or use machines. These tablets may cause a number of side effects such as drowsiness or dizziness. This is particularly likely at the start of treatment with Celastymis, after a dose increase or changes in your medicinal product therapy and if Celastymis is combined with medicines which may affect brain function.

General driving restrictions may not apply during stable treatment. Your doctor makes this decision based upon your individual situation. Please discuss with your doctor whether or not, or under which conditions you may drive or use machines.
Do not drive while taking this medicine until you know how it affects you. It is an offence to drive if this medicine affects your ability to drive. However you would not be committing an offence if:

- The medicine has been prescribed to treat a medical or dental problem and;
- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and;
- It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Celastymis contains lactose

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Celastymis

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Celastymis, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking Celastymis).

Your doctor should have discussed with you how long the course of Celastymis tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults and adolescents (12 years of age and older)

The usual initial dose is 10 mg oxycodone hydrochloride every 12 hours. However, your doctor will prescribe the dose required to treat pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor.
Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with water. **Do not crush, dissolve or chew them.**

Pharma code / Artwork Number may be added

novumgen	
Product : Celastymis 15/20/30/40/ 60/80 mg prolonged-release tablets	**Dimension (mm) :** 200 mm x 690 mm **Font :** Times New Roman - 8 pt
Version : V3	**Date :** Feb 2025
Sequence Number : 0009	**Colors** (number & pantone codes) **:** Pantone 100% black

Celastymis tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed, dissolved or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

You must only take the tablets by mouth. The tablets should never be crushed or injected as this may lead to serious side effects, which may be fatal (see section 2 'Warnings and precautions').

Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.

For the treatment of non-cancer pain a daily dose of 40 mg of oxycodone hydrochloride is generally sufficient, but higher dosages may be necessary.

Patients with cancer pain usually require dosages from 80 to 120 mg of oxycodone hydrochloride which may be increased up to 400 mg in individual cases.

For those doses where this particular strength is not suitable for you, other strengths of this medicinal product are available.

Special populations

If you have impaired kidney and/or liver function or if you have a low body weight your doctor may prescribe a lower starting dose.

If you take more *Celastymis* tablets than you should or if someone accidentally swallows your tablets:

Call your doctor or hospital **immediately**. People who have taken an overdose may feel very sleepy, sick or dizzy, or have hallucinations.

They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. An overdose may result in a brain disorder (known as toxic leukoencephalopathy). When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show to the doctor.

Method of administration

Swallow the prolonged-release tablet whole with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

The tablets must be swallowed whole, not chewed, divided or crushed as this leads to rapid oxycodone release due to the damage of the prolonged release properties. The administration of chewed, divided or crushed prolonged release tablets leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section "If you take more Celastymis than you should"). The prolonged-release tablets may be taken with or independent of meals with a sufficient amount of liquid.

Celastymis should not be taken with alcoholic beverages.

Opening instructions:

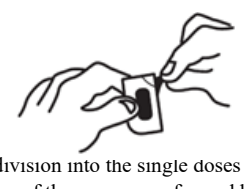
This medicinal product is in child resistant packaging.

The prolonged-release tablets cannot be pressed out of the blister. Please observe the following instructions when opening the blister.

1.Pull off a single dose by tearing along the perforated line on the blister.

2.An unsealed area is exposed/can be reached by this; this area is at the point where the perforated lines intersect with each other.

3.At the unsealed flap, peel away the cover foil from the bottom foil.



Further determination of the daily dose, the division into the single doses and any dose adjustments during the further course of therapy are performed by the treating physician and depend on the previous dosage.

Some patients who receive Celastymis according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Celastymis is not intended for the treatment of breakthrough pain.

The treatment needs to be controlled regularly with regard to pain relief and other effects in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects in good time and to decide whether treatment should be continued.

If you take more Celastymis than you should

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy, sick or dizzy, or have hallucinations. They may also have a brain disorder (known as toxic leukoencephalopathy), breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show to the doctor. In no case you should expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Celastymis

If you use a smaller dose of Celastymis than directed or you miss a dose, pain relief will consequently be insufficient or cease altogether.

If you remember within 4 hours of the time your tablet was due, take your tablet straight away. Take your next tablet at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten tablet. Do not take a double dose to make up for a forgotten dose.

If you stop taking Celastymis

You should not suddenly stop taking these tablets unless your doctor tells you to. If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking or sweating may occur if you suddenly stop taking these tablets. If you have any further questions on how to take 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. As with other strong analgesics or painkillers, there is a risk that you may become reliant (physically dependent) or addicted on these tablets.

Significant side effects or signs which you should be aware of and the measures to take if you are affected:

If you are affected by any of the following significant side effects, call the next available doctor immediately:

- Sudden difficulties in breathing, wheeziness, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body – these are signs of severe allergic reactions
- Shallow and slowed down breathing – this occurs most commonly if you are elderly and debilitated, or if you have taken too much medicine
- A severe in blood pressure – you may feel dizzy and faint if this happens
- Reduction in the size of the pupils in the eye, cramping of the bronchial muscles (causing shortness of breath), reduced ability to cough when you need to
- The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and Celastymis tablets'). **Tell your doctor immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

Drug withdrawal

When you stop taking Celastymis tablets you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

Other possible side effects

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

- Constipation - this may be countered by preventative measures such as drinking plenty of fluids, eating foods rich in fibre
- Feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem)
- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days)
- Vomiting, nausea – especially at the beginning of therapy, if you experience nausea or vomiting, your doctor may prescribe medicine to prevent this
- Feel more sleepy than normal (up to sedation), dizziness, headache
- Itchy skin

Common (may affect up to 1 in 10 people):

- Abdominal pain or discomfort, diarrhoea, dry mouth, hiccups, indigestion,
- Decreased appetite up to loss of appetite
- Anxiety, confusion, depression, decreased activity, restlessness, increased activity, nervousness, difficulty in sleeping, abnormal thinking
- Shaking (tremors), feeling lethargic
- Difficulty in breathing, wheezing, shortness of breath, decreased cough reflex
- Skin reactions/rash, sweating
- Pain whilst urinating, increased urge to urinate
- A feeling of unusual weakness, fatigue

Uncommon (may affect up to 1 in 100 people):

- Withdrawal symptoms, a need to take increasing doses of Celastymis to achieve the same level of pain relief (tolerance)
- Injuries from accidents
- Allergic reactions
- Dehydration
- A feeling of dizziness or spinning (vertigo), hallucinations, Agitation, mood swings, a feeling of extreme happiness, disorientation, perception disturbances (e.g. hallucinations, derealisation)
- Decreased sexual drive
- Epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures)
- Loss of memory, concentration impaired, migraine
- Unusual muscle stiffness, involuntary muscle contractions, reduced sensitivity to pain or touch, abnormal coordination
- Difficulty in speaking, tingling (pins and needles), changes in taste
- Impaired vision
- Hearing impaired, a feeling of dizziness or 'spinning'
- A fast heart beat, palpitations
- Flushing of the skin
- Vocal changes (dysphonia), cough
- Mouth ulcers, sore mouth, difficulty in swallowing belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste or unpleasant taste
- Flatulance (wind), belching, a condition where the bowel stops working properly (ileus)
- A worsening in liver function tests (seen in a blood test)
- Dry skin, severe flaking or peeling of the skin
- Inability to fully empty the bladder
- Redness of the face, reduction in size of the pupils in the eye, high temperature
- Difficulty or pain in passing urine, Impotence, decreased sexual drive, reduced level of sex hormones (hypogonadism, seen in a blood test)
- Chills
- Pain (e.g. chest pain), generally feeling unwell
- Swelling of the hands, ankles or feet, thirst
- Colicky abdominal pain or discomfort;

A worsening of liver function tests (seen in a blood test).

Rare (may affect up to 1 in 1,000 people):

- Low blood pressure, A feeling of faintness, especially on standing up
- Dark coloured tarry stools, dental changes, bleeding gums
- Infections such as cold sores or herpes (which may cause blisters around the mouth or genital area)
- Increased appetite
- Hives (urticaria)
- Weight increase, weight decrease

Not known (frequency cannot be estimated from the available data):

- Aggression
- An increase in sensibility to pain
- Tooth decay
- Colicky abdominal pain, problems with bile flow
- Absence of menstrual periods
- A problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- Long term use of Celastymis during pregnancy may cause life threatening withdrawal symptoms in the new-born. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight
- You may see the remains of the tablets in your faeces. This should not affect how the tablets work
- Sleep apnoea (breathing pauses during sleep)
- A need to take increasingly higher doses of the tablets to obtain the same level of pain relief (tolerance)
- A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools.Dependence and addiction (see 'How do I know if I am addicted?' in section 2 of the leaflet)
- Withdrawal symptoms (see 'Drug withdrawal' in section 2 of the leaflet).

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 the 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 Celastymis

Keep this medicine out of the sight and reach of children. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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

This medicinal product does not require any special storage conditions.

Do not take your tablets if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

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. Content of the pack and other information

What Celastymis contains

- The active substance is oxycodone hydrochloride.

[15 mg]:

Each prolonged-release tablet contains 15 mg oxycodone hydrochloride corresponding to 13.5 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate

Tablet coating:

Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Iron oxide black (E172)

[20 mg]:

Each prolonged-release tablet contains 20 mg oxycodone hydrochloride corresponding to 17.9 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate,

Tablet coating:

Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Iron oxide red (E172),

[30 mg]:

Each prolonged-release tablet contains 30 mg oxycodone hydrochloride corresponding to 26.9 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate

Tablet coating:

Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Iron oxide brown (E172), Iron oxide black (E172)

[40 mg]:

Each prolonged-release tablet contains 40 mg oxycodone hydrochloride corresponding to 35.9 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate

Tablet coating:

Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Iron oxide red (E172), Iron oxide yellow (E172)

[60 mg]:

Each prolonged-release tablet contains 60 mg oxycodone hydrochloride corresponding to 53.8 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate

Tablet coating:

Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Iron oxide red (E172), Erythrosine (E127)

[80 mg]:

Each prolonged-release tablet contains 80 mg oxycodone hydrochloride corresponding to 71.7 mg oxycodone.

The other ingredients are:

Tablet core:

Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B dispersion 30%, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate

Tablet coating:

Hypromellose, Macrogol 400, Titanium dioxide (E171), Indigo carmine aluminium lake (E132), Iron oxide yellow (E172)

What Celastymis looks like and contents of the pack

[Celastymis 15 mg prolonged-release tablets:]
Grey, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.
[Celastymis 20 mg prolonged-release tablets:]
Light pink, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.
[Celastymis 30 mg prolonged-release tablets:]
Brown, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.
[Celastymis 40 mg prolonged-release tablets:]
Light orange to ochre, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.
[Celastymis 60 mg prolonged-release tablets:]
Pink-red, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 4.6 – 5.3 mm.
[Celastymis 80 mg prolonged-release tablets:]
Green, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 5.0 – 5.6 mm.
Celastymis is available for 10, 14, 20, 25, 28, 30, 40, 50, 56, 60, 98 and 100 prolonged-release tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Novumgen Limited
20-22 Wenlock Road,
London, N1 7GU,
United Kingdom

Manufacturer:
Cubic Pharmaceuticals Limited
Unit 3, Sextant Park,
Neptune Close,
Medway city estate,
Rochester, ME2 4LU,
United Kingdom

This leaflet was last revised in Feb 2025.

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Pharma code / Artwork Number may be added

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Product : Celastymis 15/20/30/40/ 60/80 mg prolonged-release tablets	**Dimension (mm) :** 200 mm x 690 mm **Font :** Times New Roman - 8 pt
Version : V3	**Date :** Feb 2025
Sequence Number : 0009	**Colors** (number & pantone codes) **:** Pantone 100% black