

ONELAR

Duloxetine (as hydrochloride) 30mg, 60mg

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What ONELAR is used for

ONELAR is used in adults to treat:

- depression
- generalised anxiety disorder (chronic feeling of anxiety or nervousness)
- diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain)

How ONELAR works

ONELAR contains the active substance duloxetine. ONELAR increases the levels of serotonin and noradrenaline in the nervous system.

ONELAR starts to work in most people with depression or anxiety within two weeks of starting treatment, but it may take 2-4 weeks before you feel better. Tell your doctor if you do not start to feel better after this time. Your doctor may continue to give you ONELAR when you are feeling better to prevent your depression or anxiety from returning.

In people with diabetic neuropathic pain it can take some weeks before you feel better. Talk to your doctor if you do not feel better after 2 months.

Before you use ONELAR

- When you must not use it

Do not take ONELAR if you:

- are allergic to duloxetine or any of the other ingredients of this medicine (listed in Product Description)
- have liver disease
- have severe kidney disease
- are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI) (see 'Taking other medicines')
- are taking fluvoxamine which is usually used to treat depression,

ciprofloxacin or enoxacin which are used to treat some infections

- are taking other medicines containing duloxetine (see 'Taking other medicines')

Talk to your doctor if you have high blood pressure or heart disease. Your doctor will tell you if you should be taking ONELAR.

- Before you start to use it

Talk to your doctor before taking ONELAR if you:

- are taking medicines to treat depression (see 'Taking other medicines')
- are taking St. John's Wort, a herbal treatment (*Hypericum perforatum*)
- have kidney disease
- have had seizures (fits)
- have had mania
- suffer from bipolar disorder
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- have a history of bleeding disorders (tendency to develop bruises)
- are at risk of low sodium levels (for example if you are taking diuretics, especially if you are elderly)
- are currently being treated with another medicine which may cause liver damage
- are taking other medicines containing duloxetine (see 'Taking other medicines')

ONELAR may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

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.

Tell your doctor if you become pregnant, or you are trying to become pregnant, while you are taking ONELAR. You should use ONELAR only after discussing the potential benefits and any potential risks to your unborn child with your doctor.

If you take Onelar near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking Onelar so they can advise you.

Make sure your midwife and/or doctor knows you are on ONELAR. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you take ONELAR near the end of your pregnancy, your baby might have some symptoms when it is born. These usually begin at birth or within a few days of your baby being born. These symptoms may include floppy muscles, trembling, jitteriness, not feeding properly, trouble with breathing and fits. If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

Tell your doctor if you are breast-feeding. The use of ONELAR while breast-feeding is not recommended. You should ask your doctor or pharmacist for advice.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The main ingredient of ONELAR 30mg capsules, duloxetine, is used in other medicines for other conditions:

- diabetic neuropathic pain, depression, anxiety and urinary incontinence

Using more than one of these medicines at the same time should be avoided. Check with your doctor if you are already taking other medicines containing duloxetine.

Your doctor should decide whether you can take ONELAR with other medicines. **Do not start or stop taking any medicines, including those bought without a prescription and herbal remedies, before checking with your doctor.**

You should also tell your doctor if you are taking any of the following:

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Monoamine oxidase inhibitors (MAOIs):

You should not take ONELAR if you are taking, or have recently taken (within the last 14 days) another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic). Taking a MAOI together with many prescription medicines, including ONELAR, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking an MAOI before you can take ONELAR. Also, you need to wait at least 5 days after you stop taking ONELAR before you take a MAOI.

Medicines that cause sleepiness:

These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbital and sedative antihistamines.

Medicines that increase the level of serotonin:

Triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort and MAOIs (such as moclobemide and linezolid). These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with ONELAR, you should see your doctor.

Oral anticoagulants or antiplatelet agents:

Medicines which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

How to use ONELAR

- How much to use

For depression and diabetic neuropathic pain:

The usual dose of ONELAR is 60 mg once a day, but your doctor will prescribe the dose that is right for you.

For generalised anxiety disorder:

The usual starting dose of ONELAR is 30 mg once a day after which most patients will receive 60 mg once a day, but your doctor will prescribe the dose that is right for you.

The dose may be adjusted up to 120 mg a day based on your response to

ONELAR.

- When to use it

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

ONELAR is for oral use. You should swallow your capsule whole with a drink of water.

To help you remember to take ONELAR, you may find it easier to take it at the same time every day.

- How long to use it

Do not stop taking ONELAR, or change your dose, without talking to your doctor. Treating your disorder properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and difficult to treat.

- If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of ONELAR that has been prescribed for you in one day.

- If you use too much (overdose)

Call your doctor or pharmacist immediately if you take more than the amount of ONELAR prescribed by your doctor. Symptoms of overdose include sleepiness, coma, serotonin syndrome (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits, vomiting and fast heart rate.

While you are using it

- Things you must do

Tell all doctors, dentists and pharmacists treating you that you are taking ONELAR.

- Things you must not do

DO NOT stop taking your capsules without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need ONELAR he or she will ask you to reduce your dose over 2 weeks.

Some patients, who stop taking

ONELAR after more than 1 week of therapy have had symptoms such as:

- dizziness, tingling feelings like pins and needles or electric shock-like feelings (particularly in the head), sleep disturbances (vivid dreams, nightmares, inability to sleep), fatigue, sleepiness, feeling restless or agitated, feeling anxious, feeling sick (nausea) or being sick (vomiting), shaking (tremor), headaches, muscle pain, feeling irritable, diarrhoea, excessive sweating or vertigo.

These symptoms are usually not serious and disappear within a few days, but if you have symptoms that are troublesome you should ask your doctor for advice.

- Things to be careful of

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself
- are a young adult.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents under 18 years of age

ONELAR should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe ONELAR for patients under 18

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because he/she decides that this is in their best interests. If your doctor has prescribed ONELAR for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking ONELAR. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of ONELAR in this age group have not yet been demonstrated.

ONELAR contains sucrose and carmoisine

ONELAR contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Carmoisine may cause allergic reactions.

Driving and using machines

ONELAR can make you dizzy and have other side effects that make you less alert. Don't drive or use machines if you do not feel well.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild to moderate and often disappear after a short time.

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

- feeling sick (nausea), dry mouth, constipation
- fatigue

Common side effects (may affect up to 1 in 10 people)

- lack of appetite
- difficulty sleeping, feeling agitated, less sex drive, anxiety
- headache, dizziness, feeling sluggish, feeling sleepy, tremor, numbness, including numbness, prickling or tingling of the skin
- blurred eyesight
- feeling of dizziness or "spinning" (vertigo)
- increased blood pressure, flushing
- diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion
- increased sweating
- weakness, shivering

Uncommon side effects (may affect up to 1 in 100 people)

- throat inflammation that causes a hoarse voice
- allergic reactions
- decreased thyroid gland activity which can cause tiredness or weight gain
- dehydration
- grinding or clenching the teeth, feeling disorientated, lack of motivation, difficulty or failure to experience orgasm, unusual dreams
- feeling nervous, difficulty concentrating, changes in sense of taste, poor sleep quality
- large pupils (the dark centre of the eye), problems with eyesight, eyes feel dry
- tinnitus (hearing sound in the ear when there is no external sound), ear pain
- feeling the heart pumping in the chest, fast and/or irregular heart beat
- fainting
- increased yawning
- vomiting blood, or black tarry stools (faeces), gastroenteritis, inflammation of the mouth, burping, difficulty swallowing, breaking wind, bad breath
- inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes
- (itchy) rash, night sweats, hives, cold sweats, increased tendency to bruise
- muscle pain, muscle tightness, muscle spasm, contraction of the jaw muscle
- difficulty to start urinating, painful urination, needing to pass urine during the night, frequent urination, abnormal urine odour
- abnormal vaginal bleeding, menopausal symptoms
- chest pain, feeling cold, thirst, feeling hot
- weight loss, weight gain
- ONELAR may cause effects that you may not be aware of, such as increases in liver enzymes or blood levels of potassium, creatine phosphokinase, sugar, or cholesterol

Rare side effects (may affect up to 1 in 1000 people)

- serious allergic reaction which causes difficulty in breathing or dizziness with swollen tongue or

lips

- low levels of sodium in the blood (mostly in elderly people; the symptoms may include feeling dizzy, weak, confused, sleepy or very tired, or feeling or being sick, more serious symptoms are fainting, fits or falls), syndrome of inappropriate secretion of anti-diuretic hormone (SIADH)
- suicidal behaviour, suicidal thoughts, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger
- "Serotonin syndrome" (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles), fits, sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, restless legs syndrome
- increased pressure in the eye (glaucoma)
- dizziness, lightheadedness or fainting on standing up, cold fingers and/or toes
- throat tightness, nose bleeds
- passing bright red blood in your stools
- liver failure, yellowing of the skin or whites of the eyes (jaundice)
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals), serious allergic reaction which causes swelling of the face or throat (angioedema), sensitivity to sunlight
- muscle twitching
- difficulty or inability to pass urine, needing to pass more urine than normal, having a decreased urine flow
- abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, abnormal production of breast milk
- falls (mostly in elderly people), abnormal gait

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers

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→ Reporting Side Effects to Medicines (ConSERF) of Vaccines (AEFI)]

Storage and Disposal of ONELAR

- Storage

Keep this medicine out of sight and reach of children.

Store below 30°C in the original package.

- Disposal

Do not use this medicine after the expiry date stated on the carton and blister after "EXP".

The expiry date refers to the last day of that month

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

Product description

- What it looks like

ONELAR 30mg is a blue/white hard gastro-resistant capsule.

ONELAR 60mg is a light grey/pink hard gastro-resistant capsule.

Each capsule of ONELAR contains pellets of duloxetine hydrochloride with a covering to protect them from stomach acid.

ONELAR hard gastro-resistant capsules are available in carton boxes with PA/Al/PVC-Alu blisters (for ONELAR 30mg) and transparent PVC/PE/PVDC-Alu blister(s) (for ONELAR 60mg hard gastro-resistant capsules) strips containing 28 and 100 capsules

Not all pack sizes may be marketed.

- Ingredients

- Active ingredient

The active substance is duloxetine.

- Inactive ingredients

The other ingredients are:

Pellet Core: Sugar spheres (sucrose, maize starch)

Pellet Coating: Hypromellose 2910/5mPa.s, Crospovidone type A, Sucrose, Hypromellose Acetate Succinate, Triethyl Citrate (E1505), Talc, Macrogol 8000, Titanium Dioxide (E171).

Capsule shell: Titanium dioxide (E171), Gelatin ([The source of gelatin is bovine.](#)), Patent blue V (E131).

- MAL number:

ONELAR 30mg hard gastro-resistant capsules: MALxxxxxxxAZ

ONELAR 60mg hard gastro-resistant capsules: MALxxxxxxxAZ

Manufacturer

Medochemie Ltd (Factory AZ), 2, Michael Erakleous Street, Agios Athanassios Industrial Area, Agios Athanassios, Limassol, 4101 Cyprus

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Product registration holder

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