Package leaflet: Information for the patient

Duloxetine Sandoz 20 mg, maagsapresistente capsules, hard
Duloxetine Sandoz 40 mg, maagsapresistente capsules, hard

duloxetine

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 of the 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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance duloxetine. [Nationally completed name] increases the levels of serotonin and noradrenaline in the nervous system.

[Nationally completed name] is a medicine to be taken by mouth to treat Stress Urinary Incontinence (SUI) in women.

Stress urinary incontinence is a medical condition in which patients have accidental loss or leakage of urine during physical exertion or activities such as laughing, coughing, sneezing, lifting, or exercise.

[Nationally completed name] is believed to work by increasing the strength of the muscle that holds back urine when you laugh, sneeze, or perform physical activities.

The efficacy of [Nationally completed name] is reinforced when combined with a training program called Pelvic Floor Muscle Training (PFMT).

2. What you need to know before you take [Nationally completed name]

DO NOT take [Nationally completed name] if you:
- are allergic to duloxetine or any of the other ingredients of this medicine (listed in section 6)
- 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 'Other medicines and [Nationally completed name]')
- are taking fluvoxamine which is usually used to treat depression, ciprofloxacin or enoxacin which are used to treat some infections

Talk to your doctor if you have high blood pressure or heart disease. Your doctor will tell you if you should be taking [Nationally completed name].

Warnings and Precautions
The following are reasons why [Nationally completed name] may not be suitable for you. Talk to your doctor before you take [Nationally completed name] if you:
- are taking medicines to treat depression (see 'Other medicines and [Nationally completed name]')
- 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), especially if you are pregnant (see 'Pregnancy and breast-feeding')
- 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 'Other medicines and [Nationally completed name]')

[Nationally completed name] may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

You should also contact your doctor:
If you experience signs and symptoms of restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting, as you might be suffering a serotonin syndrome.

In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heart beat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Medicines like [Nationally completed name] (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of depression or anxiety disorder
Although [Nationally completed name] is not indicated for the treatment of depression, its active substance (duloxetine) is used as an antidepressant medicine. 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. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant

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

[Nationally completed name] should 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. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of [Nationally completed name] in this age group have not yet been demonstrated.

Other medicines and [Nationally completed name]

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.

The main ingredient of [Nationally completed name], 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 [Nationally completed name] 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:

Monoamine oxidase inhibitors (MAOIs): You should not take [Nationally completed name] if you are taking or have recently taken (within the last 14 days) an 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 [Nationally completed name], 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 [Nationally completed name]. Also, you need to wait at least 5 days after you stop taking [Nationally completed name] 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, buprenorphine, 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 [Nationally completed name], 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.

[Nationally completed name] with food, drink and alcohol
[Nationally completed name] may be taken with or without food. You should take extra care if you drink alcohol while taking [Nationally completed name].

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 [Nationally completed name]. You should use [Nationally completed name] only after discussing the potential benefits and any potential risks to your unborn child with your doctor.

Make sure your midwife and/or doctor knows you are on [Nationally completed name]. When taken during pregnancy, similar medicines (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 [Nationally completed name] 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.

If you take [Nationally completed name] near the end of your pregnancy, there is an increased risk of excessive vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking duloxetine so they can advise you.

Available data from the use of duloxetine during the first three months of pregnancy do not show an increased risk of overall birth defects in general in the child. If [Nationally completed name] is taken during the second half of pregnancy, there may be an increased risk that the infant will be born early (6 additional premature infants for every 100 women who take duloxetine in the second half of pregnancy), mostly between weeks 35 and 36 of pregnancy.

• Tell your doctor if you are breast-feeding. The use of [Nationally completed name] while breast-feeding is not recommended. You should ask your doctor or pharmacist for advice.

Driving and using machines
[Nationally completed name] may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how [Nationally completed name] affects you.

[Nationally completed name] contains sucrose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per hard gastro-resistant capsule, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

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

[Nationally completed name] is for oral use. You should swallow your capsule whole with a drink of water.

The recommended dose of [Nationally completed name] is 40 mg twice a day (in the morning and late afternoon/evening). Your doctor may decide to start your treatment with 20 mg twice a day for two weeks before increasing the dose to 40 mg twice a day.

To help you remember to take [Nationally completed name], you may find it easier to take it at the same times every day.

Do not stop taking [Nationally completed name], 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 take more [Nationally completed name] than you should
Call your doctor or pharmacist immediately if you take more than the amount of [Nationally completed name] 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.

If you forget to take [Nationally completed name]
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 [Nationally completed name] that has been prescribed for you in one day.

If you stop taking [Nationally completed name]
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 [Nationally completed name] he or she will ask you to reduce your dose over 2 weeks.

Some patients, who suddenly stop taking [Nationally completed name] 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.

If you have 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. 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
• trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty sleeping
• headache, dizziness, feeling sluggish, feeling sleepy, tremor, numbness, including numbness, pricking 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)
• feeling abnnormal, generally felling unwell
• throat inflammation that causes a hoarse voice
• allergic reactions
• falls (mostly in elderly people),
• 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
- [Nationally completed name] 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 1,000 people)
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- 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, inflammation of the large intestine (leading to diarrhoea)
- 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
- abnormal gait
- excessive vaginal bleeding shortly after birth (postpartum haemorrhage)

Very rare side effects (may affect up to 1 in 10,000 people)
- inflammation of the blood vessels in the skin (cutaneous vasculitis)

Frequency not known (cannot be estimated from the available data)
- signs and symptoms of a condition called "stress cardiomyopathy" which may include chest pain, shortness of breath, dizziness, fainting, irregular heart beat.

Reporting of side effects

If you get any side effects, talk to your doctor of pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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 blister and carton after "EXP". The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.
Do not store above 30°C.

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

6. Contents of the pack and other information

What [Nationally completed name] contains

- The active substance is duloxetine.
  Each hard gastro-resistant capsule contains 20 mg of duloxetine (as hydrochloride).
  Each hard gastro-resistant capsule contains 40 mg of duloxetine (as hydrochloride).

- The other excipients are:

Capsule content: sugar spheres (contain maize starch), hypromellose, talc, sucrose, hypromellose phthalate, triethyl citrate.
Capsule shell (20 mg): gelatin, sodium lauryl sulphate, titanium di oxide (E 171), indigo carmine (E 132) (contains sodium).
Capsule shell (40 mg): gelatin, sodium lauryl sulphate, titanium dioxide (E 171), indigo carmine (E 132) (contains sodium), yellow iron oxide (E 172), red iron oxide (E 172).
Black ink: Black iron oxide (E 172), Propylene glycol, Shellac, Potassium hydroxide.

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is a hard gastro-resistant capsule. Each capsule of Duloxetine Sandoz contains pellets of duloxetine hydrochloride with a covering to protect them from stomach acid.

The 20 mg hard gastro-resistant capsules are blue printed with '163' and the letter 'A'.
The 40 mg hard gastro-resistant capsules are blue and orange and are printed with '162' and the letter 'A'.

The hard gastro-resistant capsules are packed in aluminium-aluminium blisters or in transparent PVC/Aclar blisters sealed with aluminium foil and inserted in a carton.

NL/H/3304/001-002
Pack sizes:

Blister: 28, 30, 98 hard gastro-resistent capsules
Blister (unit dose): 28 hard gastro-resistent capsules

NL/H/3322/001-002
Blister: 28, 98 hard gastro-resistent capsules
Blister (unit dose): 28 hard gastro-resistent capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
Sachsen-Anhalt, 39179 Barleben
Duitsland

In het register ingeschreven onder:
RVG 116083
RVG 116084

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Duloxetine Sandoz 20 mg, maagsapresistente capsules, hard
	Duloxetine Sandoz 40 mg, maagsapresistente capsules, hard
Duitsland	Duloxetin - 1 A Pharma 20 mg magensaftresistente Hartkapseln
	Duloxetin – 1 A Pharma 40 mg magensaftresistente Hartkapseln
Malta	Duloxetin - 1 A Pharma 20 mg gastroresistant capsule, hard
	Duloxetin – 1 A Pharma 40 mg gastroresistant capsule, hard

Deze bijsluiter is voor het laatst goedgekeurd in september 2024.