APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DULTA 30 mg delayed release capsules

DULTA 60 mg delayed release capsules

Duloxetine

DULTA 30 mg contains sugar (lactose monohydrate 62,54 mg)

DULTA 60 mg contains sugar (lactose monohydrate 125,08 mg)

Read all of this leaflet carefully before you start taking DULTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DULTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DULTA is and what it is used for
2. What you need to know before you take/use DULTA
3. How to take/use DULTA

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4. Possible side effects
5. How to store DULTA
6. Contents of the pack and other information

1. What DULTA is and what it is used for

DULTA contains duloxetine hydrochloride, one of a group of medicines called Psychoanaleptics (antidepressants).

DULTA is used:

- in the treatment of depression
- for neuropathic (nerve) pain associated with diabetic peripheral neuropathy (damaged nerves as a result of diabetes).

2. What you need to know before you take/use DULTA

Do not take DULTA:

- if you are hypersensitive (allergic) to duloxetine, or to any of the ingredients of DULTA (see section 6)
- if you are a child under the age of 18 years (see Warnings and Precautions)
- if you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility)
- if you have serious liver or kidney disease
- if you take other medicines called monoamine oxidase inhibitors (MAOIs) to treat depression and including the antibiotic for treating infections, linezolid (see Other

medicines and DULTA).

Warnings and precautions

Take special care with DULTA:

- DULTA should not be used by children under the age of 18 years (see Do not take DULTA)
- if you have major depression and generalised anxiety, as a child or adult, the use of DULTA may worsen your condition and result in suicidal thoughts and tendencies. Should you experience these thoughts or tendencies, inform your doctor or pharmacist or go to hospital immediately. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour
- If you have a history of mania or a diagnosis of bipolar disorder, and/or seizures
- if you suffer from an eye condition called glaucoma (high pressure in the eye)
- if you have been diagnosed with kidney problems
- if you have been diagnosed with a liver condition
- if you are currently being treated with another medicine which may cause liver damage
- if you have a heart condition such as high blood pressure or a rapid heart rate, as DULTA may affect this condition and your doctor may want to adjust your dose

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- if you are at risk of low sodium levels, e.g. elderly, treatment with diuretics, dehydrated
- if you have bleeding disorders or take any medicine to prevent your blood from clotting, as DULTA may interfere with the way it works
- if you experience side effects after starting treatment with DULTA such as agitation, restlessness, confusion, rapid heart rate, muscle twitching and incoordination, heavy sweating, diarrhoea, headache, shivering, goose bumps (see Possible side effects). You may have a serious condition called Serotonin syndrome
- if you are taking St John's Wort (natural medicine)
- if you feel restless and need to move most of the time after the first few weeks of starting treatment with DULTA
- if you are taking other medicines containing duloxetine (see Other medicines and DULTA
- DULTA may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment
- if you are a smoker, as a dosage adjustment may be needed
- Avoid alcohol intake whilst taking DULTA.

Do not suddenly stop taking DULTA as this may lead to headache, nausea, vomiting, dizziness, sleeplessness, anxiety and pins and needles.

Children

Safety and efficacy have not been established in patients younger than 18 years of age.

Other medicines and DULTA

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Monamine Oxidase inhibitors (MAOIs), such as moclobemide (another antidepressant medicine) and linezolid (an antibiotic). Taking an MAOI together with many prescription medicines, including DULTA, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking MAOI before you can take DULTA. Also you need to wait at least 5 days after taking DULTA before you can take MAOI
- fluvoxamine (to treat a mental disorder), ciprofloxacin and enoxacin (antibiotics), as these medicines may increase or decrease the levels of DULTA in your blood
- desipramine or paroxetine (antidepressants), as these medicines may affect the concentration of DULTA in your blood
- benzodiazepines (tranquiliser), phenobarbitone (treatment of epilepsy), strong painkillers, alcohol and antipsychotic medicines should be used with caution
- antihistamines that cause drowsiness should be used with caution
- St John's Wort (*Hypericum perforatum*) and tryptophan (natural medicines)
- tramadol and pethidine (for pain)
- medicines to prevent blood clotting, such as warfarin, should be used with caution as DULTA could increase the risk of bleeding.

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DULTA with food and drink

Avoid drinking alcohol. DULTA can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

You should not take DULTA:

- if you are pregnant, planning to become pregnant or if you suspect you are pregnant
- if you are breastfeeding your baby.

If you become pregnant whilst taking DULTA, please consult your doctor immediately (see Do not take DULTA).

Taking DULTA while you are pregnant may result in:

- your baby being born with some symptoms. 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
- a risk of excessive bleeding after childbirth, if you are pregnant and your doctor has prescribed DULTA for you in the month before your baby is due, 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
- an increased risk that the infant will be born early
- an increased 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.

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Driving and using machines

You may feel dizzy or sleepy while taking DULTA.

It is not always possible to predict to what extent DULTA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DULTA affects them.

DULTA contains lactose

DULTA contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take DULTA.

DULTA contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take/use DULTA

Do not share medicines prescribed for you with any other person. Always use DULTA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults

Depression:

DULTA should be started and maintained at a dose of 60 mg once daily with or without meals.

Diabetic nerve pain:

The usual dose is 60 mg once daily with or without meals.

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Children

Safety and efficacy have not been established in patients younger than 18 years of age (see Do not take DULTA and Take special care with DULTA).

Your doctor will tell you how long your treatment with DULTA will last. Do not stop treatment early because you may experience unwanted side effects.
If you have the impression that the effect of DULTA is too strong or too weak, tell your doctor or pharmacist.

If you take/use more DULTA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- sleepiness, coma, serotonin syndrome (a 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/use to take DULTA

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It is important to take DULTA every day. If you forget to take DULTA, take a dose as soon as you remember and then go on as prescribed on a normal daily dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking/using DULTA

It is important that you continue the course of treatment. Do not stop taking DULTA as this may lead to withdrawal symptoms such as headache, nausea, vomiting, dizziness, sleeplessness or a feeling of “pins and needles”. Your doctor will gradually reduce the dose to minimise these side effects.

If your doctor thinks that you no longer need DULTA, he will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether, this in order to prevent or reduce unwanted withdrawal symptoms.

4. Possible side effects

DULTA can have side effects.

Not all side effects reported for DULTA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DULTA, please consult your healthcare provider for advice.

If any of the following happens, stop using DULTA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DULTA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- jaundice (yellow discolouration of the skin and eyes)
- rapid heartbeat, increased blood pressure, feeling dizzy when standing up
- Stevens-Johnson syndrome (a serious skin disorder, with purple rash)
- suicidal thoughts and tendencies
- mania (mental condition where you feel very excited or disorientated)
- convulsions (fits)
- liver disorders, liver failure with symptoms such as nausea, vomiting, loss of appetite, generally feeling unwell, fever, itching, dark urine
- glaucoma (high eye pressure).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decreased appetite, weight decrease
- headache, yawning, drowsiness or sleepiness, difficulty falling asleep, feeling agitated or anxious, abnormal dreams, dizziness, tremor, physical weakness or

lack of energy, abnormal sensation (usually “pins and needles”), tendency to fall (in the elderly 65 years and older)

- blurred vision
- ringing, buzzing or throbbing sound in the ears
- hot flushes
- nausea, vomiting, constipation, diarrhoea, dry mouth, indigestion, abdominal pain, flatulence (passing wind)
- increased sweating, rash
- musculoskeletal pain, muscle spasm
- urinary problems such as abnormal or frequent urination, painful or difficult urination
- male sexual dysfunction, decreased sexual desire (libido decreased).

Less frequent side effects:

- hypothyroidism (thyroid condition, some of the symptoms include feeling tired and increase in weight, feeling cold, constipation, dry skin, puffy face, hoarse voice)
- increased tendency to bruise
- dehydration
- high blood sugar level (especially in diabetics)
- disorientation, hallucinations, anger, nervousness, restlessness, problems concentrating, aggression, lack of interest or enthusiasm
- uncontrollable muscle movements, muscle twitching compulsion to constantly move about, tension, change in sense of taste, excessive grinding of teeth, restless

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leg syndrome, disturbance in attention

- dilation of pupil of the eye, visual disturbances, vertigo (sensation of spinning around), ear pain
- feeling of coldness (hands, feet, arms, lower legs)
- throat infections, throat tightness, nose bleeds
- burping, inflammation of mouth and lips, gastrointestinal bleeding, stomach irritation, difficulty swallowing, mouth sores or inflammation, passing fresh blood through the anus, breath odour
- abnormal liver test results
- night sweats, urticaria (skin rash with red raised bumps), skin sensitivity to light, pruritus (severe itching of skin), contact dermatitis (skin rash), cold sweats, cutaneous vasculitis (inflamed blood vessels on the surface of the skin)
- muscle pain, muscle tightness, muscle cramps, lock jaw
- difficulty urinating, nocturia (waking at night one or more times to urinate), polyuria (abnormally large amount of urine), decreased urine flow, abnormal urine odour
- excessive menstrual blood flow, testicle pain, milky secretions from the breasts, abnormal orgasm, problems getting an erection, changes in ejaculation, menopausal symptoms, postpartum haemorrhage (excessive vaginal bleeding shortly after birth)
- feeling hot or cold, chills, thirst, generally feeling unwell, gait disturbance (abnormal walk)
- increase in weight
- laryngitis

- interstitial lung disease
- lung disease with symptoms such as dry cough, and shortness of breath
- chest pain
- increased potassium and cholesterol levels in the blood, abnormal blood test results.

Frequency unknown side effects

problems with your heart muscle (stress cardiomyopathy also known as takotsubo syndrome) that present with signs such as chest pain and shortness of breath.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of DULTA.

You can also send an email can directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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5. How to store DULTA

Store all medicines out of reach of children.

Store at or below 25 °C in original container.

Do not remove capsule from blister until required for use.

Keep the blister in the outer container until required for use.

Keep the HDPE container tightly closed.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DULTA contains

The active ingredient is duloxetine.

DULTA 30 mg: Each delayed release capsule contains duloxetine hydrochloride, equivalent to 30 mg duloxetine.

DULTA 60 mg: Each delayed release capsule contains duloxetine hydrochloride, equivalent to 60 mg duloxetine.

The other ingredients are:

Croscarmellose sodium, hypromellose, hypromellose phthalate, lactose monohydrate, magnesium stearate, polysorbate 80, pregelatinised starch, talc, triethyl citrate and gelatine capsule shells.

DULTA contains sugar in the form of lactose monohydrate.

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What DULTA looks like and contents of the pack

DULTA 30 mg: Size ’3’ capsules with dark blue cap and white body imprinted with ‘LU’ in white ink on cap and ‘Q02’ in black ink on the body, containing six white to off-white mini tablets.

DULTA 60 mg: Size ’1’ capsules with dark blue cap and a green body imprinted with ‘LU’ in white ink on cap and ‘Q03’ in black ink on the body, containing twelve white to off-white mini tablets.

DULTA: Blisters are packed in a PVC/PE/ACLAR aluminium strip pack containing 7, 10,14 or 15 capsules per strip, each packed in an outer carton containing 28, 30, 56, 60, 84, 90 or 100 capsules.

DULTA 30 mg: White, round HDPE bottle with a white child resistant cap containing 28, 30, 56, 60, 84, 90 or 100 capsules.

DULTA 60 mg: White, round HDPE bottle with a white child resistant cap containing 28, 30, 56, 60, 84, 90 or 100 capsules.

*Not all presentations are marketed

Holder of Certificate of Registration

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