PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Front Top

340 mm

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XETSIA DR 30 / 60 mg

PM04342714

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

XETSIA DR 30 mg (Delayed release capsule)
Duloxetine 30 mg
Contains sugar (3,36 mg sucrose)

XETSIA DR 60 mg (Delayed release capsule)
Duloxetine 60 mg
Contains sugar (6,72 mg sucrose)

Read all of this leaflet carefully before you start taking XETSIA DR
- 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.
- **XETSIA DR** 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 **XETSIA DR** is and what it is used for
2. What you need to know before you take **XETSIA DR**
3. How to take **XETSIA DR**
4. Possible side effects
5. How to store **XETSIA DR**
6. Contents of the pack and other information

1. What XETSIA DR is and what it is used for
XETSIA DR is used in adults to treat:
- Depression.
- Diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock pain. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain).

2. What you need to know before you take XETSIA DR
Do not take XETSIA DR:
- If you are allergic to duloxetine or any of the other ingredients of **XETSIA DR**, listed in **section 6**.
- If you are pregnant or breastfeeding.
- If you have liver disease.
- If you have severe kidney disease.
- If you are taking or have taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI).
- If the patient is a child under the age of 18 years.

Warnings and precautions
Before treatment with XETSIA DR, tell your doctor:
- If you are taking other medicines to treat depression.
- If you are also taking or have taken any time within the last 14 days any medicines known as monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an MAOI together with **XETSIA DR**, can cause side effects such as nausea, vomiting, dizziness, tremor, flushing, muscle twitching, elevated body temperature, profuse sweating, seizures or even life-threatening side effects. Also, you must wait at least 5 days after you stop taking **XETSIA DR** before you take any MAOI.
- If you previously have had mental illness (mania).
- If you have had seizures (fits).
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have kidney or liver disease – your doctor may prescribe a lower starting dose.
- If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants or when your doctor makes changes to the dose. 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.
- If you have any pre-existing heart condition or disease which might affect your blood pressure. **XETSIA DR** may cause your blood pressure to increase and in some cases requiring immediate treatment to lower your blood pressure. Your doctor will test your blood pressure before start of treatment, after a dose increase and regularly thereafter.
- If you are taking St. John's Wort *(Hypericum perforatum)*, a herbal treatment for depression.
- If you suffer from bleeding tendencies or if you are taking medicines known as anti-coagulants (e.g. warfarin) or platelet inhibitors (e.g. aspirin) as the risk of skin and mucous membrane bleeding, including bleeding from the stomach wall, may be increased in patients taking **XETSIA DR**.
- There has been a relation between a group of medicine called SSRI and SNRI and heavy bleeding following birth. **XETSIA DR** belongs to the group of medicines called SSRIs. If you have any bleeding disorders or are pregnant, your doctor will have to change your treatment to an alternative group of medicines.

While taking XETSIA DR
- Serotonin syndrome, a potentially life-threatening condition may occur with **XETSIA DR** treatment. Inform your doctor or go to the nearest hospital if you notice a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, changes in blood pressure, overactive reflexes, diarrhoea, nausea, vomiting and coma.
- **XETSIA DR** may cause low levels of sodium in the blood and/or the syndrome of inappropriate antidiuretic hormone secretion (SIADH); a condition that causes your body to make too much antidiuretic hormone (ADH). ADH is a chemical that helps keep the right balance of fluids in your body. Increased ADH may cause too much water to remain inside your body and chemicals in your blood, such as salt, may decrease. This may prevent your organs from working properly. This side effect may occur especially if you are elderly, are taking diuretics (water pills) or are dehydrated.
- If your doctor thinks that you no longer need **XETSIA DR**, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using **XETSIA DR**, especially when **XETSIA DR** is stopped suddenly or the dose is reduced too quickly.
- **XETSIA DR** may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell your doctor if this happens to you.
- **XETSIA DR** may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

Children and adolescents
- **XETSIA DR** is not for use in children and adolescents as it has not been studied in patients under 18 years. Ask your doctor or pharmacist for advice before taking **XETSIA DR**.

Other medicines and XETSIA DR
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Only take other medicines while you are on **XETSIA DR** if your doctor tells you that you can.
You should tell your doctor if you are taking the following medicines:
- Monoamine oxidase inhibitors (MAOIs) such as moclobemide (an antidepressant) and linezolid (an antibiotic).
- Fluvoxamine (used to treat anxiety).
- Quinolone antibiotics.
- Desipramine (used to treat depression).
- Medicines that cause sleepiness: These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbitone and 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 (herbal medicine for depression) and MAOIs (such as moclobemide and linezolid). These medicines increase the risk of side effects; if you experience any unusual symptoms taking any of these medicines together with **XETSIA DR**, you should see your doctor.
- Oral anticoagulants or antiplatelet medicines: Medicines which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

XETSIA DR with food, drink and alcohol
XETSIA DR should be taken with or without food.
Alcohol should be avoided.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **XETSIA DR**.
- Tell your doctor if you become pregnant, or you are trying to become pregnant, while you are taking **XETSIA DR**. You should use **XETSIA DR** 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 **XETSIA DR**. 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 **XETSIA DR** 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 **XETSIA DR** 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 **XETSIA DR** so they can advise you.
- Tell your doctor if you are breastfeeding. The use of **XETSIA DR** while breastfeeding is not recommended. You should ask your doctor or pharmacist for advice.

Driving and using machines
It is not always possible to predict to what extent **XETSIA DR** may interfere with the daily activities of a patient. **XETSIA DR** can cause dizziness. If you feel dizzy while taking **XETSIA DR** do not drive and do not use any tools or machines.

XETSIA DR contains sugar (sucrose)
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **XETSIA DR**. **XETSIA DR** contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take XETSIA DR
- Do not share medicines prescribed for you with any other person.
- Always take **XETSIA DR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your treatment with **XETSIA DR** will last. Do not stop treatment early.
- If you have the impression that the effect of **XETSIA DR** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **XETSIA DR**. Do not change your treatment or stop treatment without first talking with your healthcare provider.

Recommended dose of XETSIA DR
- **XETSIA DR** capsules are for oral use.
- Your doctor will tell you how to take **XETSIA DR** and how long you should continue to take them.
- The usual recommended dose for treatment of depression and diabetic peripheral neuropathic pain is 60 mg per day.

Take **XETSIA DR** at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved. **XETSIA DR** can be taken with or without food.

If you take more XETSIA DR than you should
Seek emergency medical attention if you think you have taken too much of **XETSIA DR**.
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take XETSIA DR
If you forget to take a dose, take it as soon as you remember, and then continue as before.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking XETSIA DR
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 **XETSIA DR** he or she will ask you to reduce your dose over at least 2 weeks before stopping treatment altogether.
Some patients who stop taking **XETSIA DR** suddenly 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.

4 Possible side effects
XETSIA DR can have side effects.
Not all side effects reported for **XETSIA DR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **XETSIA DR**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking XETSIA DR and tell your doctor immediately or go to the casualty department at your nearest hospital:
Get emergency medical help if you have any of these signs of an allergic reaction:
- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Feeling dehydrated, having 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), retention of water by the body (syndrome of inappropriate secretion of anti-diuretic hormone (SIADH).
- Having convulsions (fits).
- Suicidal thoughts.
- Serotonin syndrome, a potentially life-threatening condition may occur with **XETSIA DR** treatment. Inform your doctor or go to the nearest hospital if you notice a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, changes in blood pressure, overactive reflexes, diarrhoea, nausea, vomiting and coma.
- Fast and/or irregular heartbeat.
- Hypertensive crisis - a severe increase in blood pressure that can lead to a stroke. Symptoms include headache and dizziness.
- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature.
- Vomiting blood, or black tarry stools (faeces), passing bright red blood in your stools.
- Inflammation of the liver or liver failure that may cause abdominal pain and yellowing of the skin or whites of the eyes (jaundice).
- Stevens-Johnson syndrome (serious illness with blistering of the skin, mouth, eyes and genitals).
- Contraction of the jaw muscle (lockjaw).
- Abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, excessive vaginal bleeding shortly after birth (postpartum haemorrhage).

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
- Lack of appetite.
- Trouble sleeping, feeling agitated, less sex drive, anxiety, difficulty or failure to experience orgasm, unusual dreams.
- Headache, feeling sleepy, dizziness, feeling sluggish, tremor, numbness, including numbness, pricking or tingling of the skin.
- Blurred eyesight.
- Tinnitus (hearing sound in the ear when there is no external sound).
- Feeling the heart pumping in the chest.
- Increased blood pressure, flushing.
- Increased yawning.
- Feeling sick (nausea), dry mouth, constipation, diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion, breaking wind.
- Increased sweating, (itchy) rash.
- Muscle pain, muscle spasm.
- Painful urination, frequent urination.
- Problems getting an erection, changes in ejaculation.
- Falls, fatigue.
- Weight loss.

Less frequent side effects
- Throat inflammation that causes a hoarse voice.
- Decreased thyroid gland activity which can cause tiredness or weight gain.
- Difficulty sleeping, grinding or clenching the teeth, feeling disorientated, lack of motivation.
- Sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, feeling nervous, difficulty concentrating, changes in sense of taste, difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, restless legs syndrome, poor sleep quality.
- Large pupils (the dark center of the eye), problems with eyesight, increased pressure in the eyes (glaucoma).
- Feeling of dizziness or "spinning" (vertigo), ear pain.
- Fainting, high blood pressure, dizziness, light headedness or fainting on standing up, cold fingers and/or toes.
- Throat tightness, nose bleeds.
- Inflammation of the large intestine (leading to diarrhoea), burping, difficulty swallowing, inflammation of the mouth, bad breath.
- Night sweats, hives, skin rash, cold sweats, sensitivity to sunlight, increased tendency to bruise, inflammation of the blood vessels in the skin (cutaneous vasculitis).
- Muscle tightness, muscle twitching.
- Difficulty or inability to pass urine, difficulty to start urinating, needing to pass urine during the night, needing to pass more urine than normal, having a decreased urine flow, abnormal urine odour.
- Unusually light or missed periods, less sex drive, pain in the testicles or scrotum, menopausal symptoms, abnormal production of breast milk in men or women.
- Haemorrhage (heavy bleeding) after giving birth.
- Chest pain, feeling cold or hot, thirst, shivering, feeling unwell, abnormal gait
- Weight gain.
- Laboratory tests may show increases in liver enzymes or blood levels of potassium, creatine phosphokinase, sugar, or cholesterol.

Frequency unknown
- Stress cardiomyopathy – this is a condition where stress may trigger an onset of chest pain, breathlessness and other symptoms that mimic a heart attack.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **XETSIA DR**.

5. How to store XETSIA DR
Store at or below 25 °C.
Protect from light and moisture.
Keep the blisters in the carton until required for use.
Keep HDPE containers tightly closed.
KEEP OUT OF REACH OF CHILDREN
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information
What XETSIA DR contains
- The active substance is duloxetine hydrochloride 30/60 mg.
- The other ingredients are hypromellose, hypromellose phthalate, polyethylene glycol, sucrose, sodium lauryl sulphate, sugar spheres (consisting of maize starch and sucrose), triethyl citrate, talc, hard gelatin capsules consisting of FD & C Blue 2 colour, titanium dioxide, gelatin, water and sodium lauryl sulfate. In addition **XETSIA DR 60 mg** contains iron oxide yellow.

What XETSIA DR looks like and contents of the pack
XETSIA DR 30 mg (Capsules)
Opaque blue cap/ opaque white body, size "3" capsules containing white to off-white coloured pellets with "WI" on cap and "D30" on body imprinted with green ink.

XETSIA DR 60 mg (Capsules)
Opaque blue cap/ opaque yellowish green body, size "1" capsules containing white to off - white coloured pellets with "WI" on cap and "D60" on body imprinted with white ink.

Blister pack
Silver coloured 25 µ aluminium foil/ 6-8 gsm HSL as the lidding material and silver coloured cold form laminate (25 µ OPA/45 µ aluminum foil/60 µ PVC) as the forming material, packed in a pre-printed unit carton containing 28 or 30 capsules.

HDPE container pack
Round, white HDPE container with screw neck with white child-resistant polypropylene closure with pulp and heat seal liner containing 28 or 30 capsules packed in a pre-printed unit carton.
Not all packs and pack sizes are necessarily marketed.

7. Holder of certificate of registration
Macleods Pharmaceuticals SA (Pty) Ltd
Ground Floor, Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock Ext 12,
Alberton, South Africa

This leaflet was last revised on
09 October 2023

Registration numbers
XETSIA DR 30 mg: 51/1.2/0933
XETSIA DR 60 mg: 51/1.2/0934

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

Marketed by:
United Pharma Marketing (Pty) Ltd

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PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

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340 mm

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S5

XETSIA DR 30 mg (Vertraagde vrystelling kapsules)
Duloksetien 30 mg
Bevat suiker (3,36 mg sukrose)

XETSIA DR 60 mg (Vertraagde vrystelling kapsules)
Duloksetien 60 mg
Bevat suiker (6,72 mg sukrose)

Lees hierdie hele inligtingstuk noukeurig deur, voordat u begin om XETSIA DR te gebruik
- Hou hierdie inligtingstuk. U mag dit dalk weer moet lees.
- Indien u nog vrae het, vra asseblief vir u dokter of u apteker.
- **XETSIA DR** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hul skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat is in hierdie inligtingstuk
1. Wat **XETSIA DR** is en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **XETSIA DR** neem
3. Hoe om **XETSIA DR** te neem
4. Moontlike newe effekte
5. Hoe om **XETSIA DR** te berg
6. Inhoud van die pak en ander inligting

1. Wat XETSIA DR is en waarvoor dit gebruik word
XETSIA DR word gebruik in volwassenes om die volgende te behandel:
- Depressie.
- Diabetiese perifere neuropatiese pyn (dikwels beskryf as 'n brandende, kloppende steekpyn,wat skiet of pyn soos 'n elektriese skok tipe pyn. Verlies aan gevoel in die area, of sensasies soos aanraking, hitte, koue of druk mag pyn veroorsaak).

2. Wat u behoort te weet voordat u XETSIA DR neem
Moet nie XETSIA DR neem:
- Indien u hipersensitief (allergies) vir duloksetien of enige van die ander bestanddele van **XETSIA DR** is nie.
- Indien u swanger is of u baba borsvoed nie.
- Indien u 'n lewersiekte het nie.
- As u 'n ernstige niersiekte het nie.
- Indien u medisyne bekend as monoamienoksidase-inhibeerders (MAOI) gebruik of die afgelope twee weke gebruik het nie.
- Indien u, die pasiënt 'n kind jonger as 18 jaar oud is nie.

Waarskuwings en voorsorgmaatreëls
Voordat u met XETSIA DR behandeling begin, vertel u dokter:
- Indien u enige ander middels neem om depressie te behandel.
- Indien u medisyne bekend as monoamienoksidase-inhibeerders (MAOI) gebruik of die afgelope twee weke gebruik het. Hierdie middels kan gebruik word vir die behandeling van depressie of Parkinson siekte. Indien u **XETSIA DR** saam met 'n MAOI neem, kan dit newe-effekte veroorsaak soos naarheid, braking, duiseligheid, bewing, blosing, spiertrekkings, verhoogde liggaamstemperatuur, profuse sweet, stuiptrekkings of selfs lewensbedreigende newe-effekte. Let asseblief daarop dat u vir ten minste 5 dae moet wag, nadat u die behandeling met **XETSIA DR** gestop het, voordat u enige MAOI kan neem.
- Indien u voorheen gelei het aan 'n geestesiekte (manie).
- As u al stuiptrekkings gehad het.
- Indien u oogprobleme het, soos sekere tipe gloukoom (verhoogde druk in die oog).
- Indien u lewerprobleme of nierprobleme het – u dokter mag dalk u behandeling op 'n laer dosis begin.
- As u depressief is en/of angsafwykings het en soms gedagtes koester om u self skade aan te rig of om selfmoord te pleeg, dit mag vererger wanneer u begin om antidepressante te gebruik, of wanneer u dokter veranderinge aan die dosis maak. Kontak u dokter onmiddellik of gaan na die hospitaal, indien u gedagtes van selfskade of selfmoord het. U kan dit nuttig vind om 'n familielid of 'n hegte vriend te vertel dat u depressief is of 'n angsversteuring het en hulle vra om hierdie inligtingstuk te lees. U kan hulle moontlik vra om u te vertel of hulle dink dat u depressie of angs erger word, of as hulle bekommerd is oor veranderinge in u gedrag.
- As u 'n bestaande hartkwaal of siektetoestand het wat u bloeddruk kan beïnvloed. **XETSIA DR** kan veroorsaak dat u bloeddruk toeneem en in sommige gevalle sal onmiddellike behandeling benodig word om u bloeddruk te verlaag. U dokter sal u bloeddruk toets voor die aanvang van die behandeling, na 'n dosisverhoging en gereeld daarna.
- Indien u St. Janskruid *(Hypericum perforatum)* 'n kruiemiddel vir die behandeling van depressie neem.
- As u ly aan geneigheid tot bloeding, of as u medisyne neem wat bekend staan as anti-stollingsmiddels (bv. warfarien) of bloedplaatjie-remmers (bv. aspirien), kan die risiko van bloeding van die vel en slymvlies, insluitend bloeding vanaf die maagwand verhoog in pasiënte wat **XETSIA DR** gebruik.
- Daar bestaan 'n verband tussen 'n groep medisyne bekend as SSHI en SNHI en swaar bloeding na geboorte. **XETSIA DR** behoort tot die groep medisyne wat SSRI's genoem word. Indien jy enige bloedingsversteurings het of swanger is, sal jou dokter jou behandeling moet verander na 'n alternatiewe groep van medisyne.

Terwyl u XETSIA DR neem
- 'n Potensiële lewensbedreigende toestand, serotoniensindroom, mag voorkom wanneer u met **XETSIA DR** behandel word. Stel u dokter in kennis, of gaan na die naaste hospitaal indien u 'n kombinasie van die volgende simptome ondervind: rustelooosheid, hallusinasies, verlies aan koordinasie, vinnige harttempo, verhoogde liggaamstemperatuur, veranderinge in u bloeddruk, ooraktiewe reflekse, diaree, naarheid, braking en koma.
- **XETSIA DR** kan lae vlakke van natrium in die bloed en/of die sindroom van onvanpaste antidiuretiese hormoonafskeiding (SOADH) veroorsaak; 'n toestand wat veroorsaak dat u liggaam te veel antidiuretiese hormoon (ADH) maak. ADH is 'n chemiese middel wat help om die regte balans van vloeistowwe in u liggaam te hou. Verhoogde ADH kan te veel water in u liggaam laat bly en chemikalieë in u bloed, soos sout, kan afneem. Dit kan voorkom dat u organe nie goed werk nie. Hierdie newe-effek kan veral voorkom as u bejaard is, diuretika neem (waterpille) of ontwater is.
- As u dokter dink dat u nie meer **XETSIA DR** benodig nie, kan hy/sy u versoek om u dosis stadig te verminder voordat u die behandeling heeltemal stop. Dit is bekend dat newe-effekte voorkom wanneer mense ophou om **XETSIA DR** te gebruik, veral as **XETSIA DR** skielik gestaak word of die dosis te vinnig verminder word.
- **XETSIA DR** kan gedurende die eerste paar weke van behandeling 'n gevoel van rustelooosheid of die onvermoë om stil te sit of staan veroorsaak. U moet u dokter vertel indien dit met u gebeur.
- **XETSIA DR** kan simptome van seksuele disfunksie veroorsaak, en in sommige gevalle het hierdie simptome voortgeduur nadat die behandeling gestaak is.

Kinders en adolessente
XETSIA DR word nie aangedui vir die gebruik in kinders en adolessente nie, aangesien dit nie by pasiënte jonger as 18 jaar bestudeer is nie. Vra u dokter of apteker voordat u **XETSIA DR** gebruik.

Neem van ander medisyne saam met XETSIA DR
Vertel altyd vir u gesondheidsorgdeskundige indien u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).
Neem slegs ander medisyne wanneer u op **XETSIA DR** is, indien u dokter vir u sê dat u dit kan gebruik.
Vertel u dokter indien u enige van die volgende medisyne neem:
- Monoamien-oksidase-inhibeerders (MAOI's) soos moklobemied ('n antidepressant) en linesolied ('n antibiotikum).
- Fluvoksamien (gebruik om depressie te behandel).
- Kinoloon antibiotikum.
- Desimipramien (om depressie te behandel).
- Medisyne wat slaperigheid veroorsaak: dit sluit medisyne in wat deur u dokter voorgeskryf is, insluitend bensodiasepiene, sterk pynstillers, antipsigotika, fenobarbitoon en antihistamiene.
- Medisyne wat die serotonienvlak verhoog: Triptane, tramadol, triptofaan, SSHI's (soos paroksetien en fluoksetien), SNHI's (soos venlafaksien), trisikliese antidepressante (soos klomipramien, amitriptillien), petidien, St. Janskruid (kruidemedisyne vir depressie) en MAOI's (soos moklobemied en linesolied). Hierdie medisyne verhoog die risiko van newe-effekte; indien u enige ongewone simptome ervaar wanneer u enige van hierdie medisyne neem saam met **XETSIA DR**, moet u u dokter raadpleeg.
- Orale antikoagulante of medisyne teen plaatjievorming: medisyne wat die bloed verdun of voorkom dat die bloed stol; hierdie medisyne kan die risiko van bloeding verhoog.

Neem van XETSIA DR saam met voedsel, vloeistof en alkohol
XETSIA DR behoort met of sonder kos geneem te word.
Alkohol behoort vermy te word.

Swangerskap, borsvoeding en voortplanting
Indien u swanger is of u baba borsvoed, vra asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies voordat u **XETSIA DR** neem.
- Vertel u dokter as u swanger raak, of u probeer om swanger te raak, terwyl u **XETSIA DR** gebruik. U moet **XETSIA DR** slegs gebruik nadat u die moontlike voordele en moontlike risiko's vir u ongebore kind met u dokter bespreek het.
- Maak seker dat u vroedvrou en/of dokter weet dat u **XETSIA DR** gebruik. Indien dit tydens u swangerskap geneem word, kan soortgelyke medisyne (SSHI's) die risiko verhoog vir 'n ernstige toestand by babas, wat aanhoudende pulmonale hipertensie van die pasgeborene genoem word (APHN), wat die baba vinniger laat asemhaal en blouerig laat lyk. Hierdie simptome begin gewoonlik gedurende die eerste 24 uur nadat die baba gebore is. As dit met u baba gebeur, moet u u vroedvrou en/of dokter onmiddellik kontak.
- U baba kan simptome hê tydens die geboorte, indien u **XETSIA DR** naby die einde van u swangerskap neem. Dit begin gewoonlik by geboorte of binne 'n paar dae nadat u baba gebore is. Hierdie simptome kan insluit slap spiere, bewing, jitterigheid, voed nie behoorlik nie, probleme met asemhaling en stuipe. As u baba enige van hierdie simptome tydens die geboorte het, of as u bekommerd is oor die gesondheid van u baba, kontak u dokter of vroedvrou wat u kan adviseer.
- As u **XETSIA DR** neem aan die einde van u swangerskap, is daar 'n verhoogde risiko van oormatige vaginale bloeding kort na geboorte, veral as u 'n geskiedenis van bloeding het. U dokter of vroedvrou moet daarvan bewus wees dat u **XETSIA DR** neem, sodat hulle u kan adviseer.
- Vertel u dokter as u borsvoed. Die gebruik van **XETSIA DR** tydens borsvoeding word nie aanbeveel nie. Raadpleeg u dokter of apteker vir advies.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate **XETSIA DR** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. **XETSIA DR** kan duiseligheid veroorsaak, indien u duiselig voel tydens die neem van **XETSIA DR**, moet nie bestuur nie en gebruik geen gereedskap of masjiene nie.

XETSIA DR bevat suiker (sukrose)
As u dokter u meegedeel het dat u nie verdraagsaam is teenoor sommige suikers nie, kontak u dokter voordat u **XETSIA DR** gebruik. **XETSIA DR** bevat sukrose wat 'n invloed kan hê op die beheer van u bloedsuiker as u diabetes mellitus het.

3. Hoe om XETSIA DR te neem
- Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
- Neem altyd u **XETSIA DR** presies soos wat u dokter of apteker u aanbeveel het. Raadpleeg u dokter of apteker indien u twyfel.
- U dokter sal u vertel hoe lank u behandeling met **XETSIA DR** sal duur. Moet nie die behandeling vroeër stop nie.
- As u onder die indruk is dat die effek van **XETSIA DR** te sterk of te swak is, vertel u dokter of apteker.
- Bly onder die sorg van 'n gesondheidsorgverskaffer wanneer u **XETSIA DR** gebruik. Moet nie u behandeling verander of stop voordat u nie eers met u gesondheidsorgverskaffer gepraat het nie.

Aanbevole dosis van XETSIA DR
- **XETSIA DR** kapsules is vir orale gebruik.
- U dokter sal u vertel hoe om **XETSIA DR** te neem en vir hoe lank u moet aanhou om die te neem.
- Die gewone aanbevole dosis vir die behandeling van depressie en diabetiese perifere neuropatiese pyn is 60 mg per dag.

Neem **XETSIA DR** ongeveer dieselfde tyd elke dag, hetsy soggens of saans. Kapsules moet heel met vloeistof ingesluk word en nie oopgemaak, gekneus, gekou of opgelos word nie. **XETSIA DR** kan met of sonder voedsel geneem word.

Indien u meer XETSIA DR geneem het as wat u moes
Soek dadelik mediese hulp indien u vermoed dat u te veel **XETSIA DR** geneem het.
In die geval van 'n oordosis, kontak u dokter of apteker onmiddellik. Indien nie een beskikbaar is nie, soek hulp of kontak die naaste hospitaal of vergiftigingsbeheersentrum.

Indien u vergeet om XETSIA DR te neem
Indien u vergeet om 'n dosis te neem, neem dit sodra u onthou, en gaan dan voort met die behandeling soos voorheen. Moet nie 'n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

Indien u stop om XETSIA DR te neem
Moet nie ophou om u kapsules te neem sonder die advies van u dokter nie, selfs al voel u beter. As u dokter dink dat u nie meer **XETSIA DR** nodig het nie, sal hy/sy u vra om u dosis oor minstens 'n periode van twee weke te verminder voordat u die behandeling heeltemal stop.
Sommige pasiënte wat skielik ophou om **XETSIA DR** te neem, het simptome gehad soos: duiseligheid, tintelende gevoelens soos spelde en naalde of elektriese skokagtige gevoelens (veral in die kop), slaapsteurnisse (aanskoulike drome, nagmerries, slaap onvermoë), moegheid, slaperigheid, onrustigheid, angstigheid, siek gevoel (naarheid)) of siek wees (braak), bewe (bewing), hoofpyne, spierpyne, prikkelbaar, diaree, oormatige sweet of vertigo.
Hierdie simptome is gewoonlik nie ernstig nie en verdwyn binne enkele dae, maar as u simptome het wat kommerwekkend is, moet u u dokter raad vra.

4. Moontlike newe-effekte
XETSIA DR kan newe-effekte hê.
Nie alle newe-effekte wat vir **XETSIA DR** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheidstoestand vererger of indien u enige ongewenste effekte ervaar terwyl u **XETSIA DR** gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, staak die inname van XETSIA DR en vertel dadelik vir u dokter of gaan na die naaste hospitaal se ongevalle-afdeling:
- Skielike tekens van allergie – insluitend veluitslag, jeuk of netelroos; swelling van die gesig, lippe of tong, kortasem of moeilike asemhaling.

Hierdie is ernstige newe-effekte en indien u dit het, kan u 'n ernstige allergiese reaksie op **XETSIA DR** hê. U kan dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die naaste hospitaal se ongevalle-afdeling indien u enige van die volgende waarneem:
- U voel gedehidreerd, het 'n lae hoeveelheid natrium in die bloed (meestal by bejaardes; die simptome kan die volgende insluit; voel duiselig, swak, verward, slaperigheid of, baie moeg, voel siek. Meer ernstige simptome is floutes, val, of stuipe), retensie van water deur die liggaam (sindroom van onvanpaste afskeiding van anti-diuretiese hormoon (SOADH).
- Stuipe of aanvalle.
- Selfmoord gedagtes.
- Serotoniensindroom, 'n potensieel lewensbedreigende toestand wat mag voorkom met **XETSIA DR** behandeling. Vertel jou dokter,of gaan na die naaste hospitaal indien u 'n kombinasie van die volgende simptome ervaar, of opmerk: rustelooosheid, hallusinasies, verlies aan koördinasie, vinnige harttempo, verhoogde liggaamstemperatuur, verandering in u bloeddruk, ooraktiewe reflekse, diaree, naarheid, braking en 'n koma.
- Vinnige – en/of onreëlmatige hartklop.
- Hipertensiewe krisis – 'n erge verhoging in die bloeddruk wat kan lei tot 'n beroerte. Simptome kan hoofpyn en duiseligheid insluit.
- Hoes, vluitende asemhaling en kortasem wat gepaard kan gaan met 'n hoë koors.
- Opbraak van bloed, of swart teeragtige stoelgang (ontlasting), helderrooi bloed in u stoelgang.
- Inflammasie van die lewer of lewerversaking wat buikpyn en vergeling van die vel of wit van die oë (geelsug) kan veroorsaak.
- Stevens-Johnson-sindroom (ernstige siekte met blase op die vel, mond, oë en geslagsdele).
- Sametrekking van die kaakspier (kaakklem).
- Abnormale vaginale bloeding, abnormale siklusse, insluitend swaar, pynlike, onreëlmatige of lang periodes, oormatige vaginale bloeding kort na geboorte (postpartum bloeding).

Hierdie is almal ernstige newe-effekte en u kan dringende mediese aandag benodig.

Vertel ook vir u dokter indien u enige van die volgende opmerk:
Dikwelse newe-effekte
- Gebrek aan eetlus.
- Moeite om te slaap, voel ontsteld, verminderde seksdrang, angstig, probleme of onmoontlik om orgasme te ervaar, ongewone drome.
- Hoofpyn, slaperigheid, duiseligheid, traagheid, bewing, gevoelloosheid, tinteling van die vel.
- Dowwe visie.
- Tinnitus (suising/gehoorklank in die oor as daar geen eksterne geluid is nie).
- Voel hoe die hart in die bors pomp.
- Verhoogde bloeddruk, spoeling.
- Gaap meer.
- Voel siek (naarheid), droë mond, hardlywigheid, diaree, maagpyn, word siek (braking), sooibrand of slegte spysvertering, breek winde op.
- Sweet meer, (jeukerige) uitslag.
- Seer spiere, spierspasmas.
- Pynlike urinering, gereelde urinering.
- Probleme met 'n ereksie, veranderinge in ejakulasie.
- Val maklik, vermoeidheid.
- Gewigsverlies.

Minder dikwelse newe-effekte
- Hees stem veroorsaak deur 'n keelontsteking.
- Verminderde aktiwiteit in die skildklier wat moegheid of gewigstoename kan veroorsaak.
- Moeite om te slaap, tande te kners of te slyp, gedisoriënteerd te voel, 'n gebrek aan motivering.
- Skielike onwillekeurige ruk of trek van die spiere, gevoel van rusteloosheid of 'n onvermoë om stil te sit of stil te staan, senuweeagtig te voel, konsentrasieprobleme, verandering in smaaksensasie, probleme om beweging te beheer, bv. gebrek aan koördinasie of onwillekeurige bewegings van die spiere, rustelose bene-sindroom, swak slaapkwaliteit.
- Vergrote pupille (die donker middelpunt van die oog), probleme met sig, verhoogde druk in die oë (gloukoom).
- Gevoel van duiseligheid of 'asof die kamer draai' (vertigo), oorpyn.
- Word flou, hoë bloeddruk, duiseligheid, lighoofdig of word flou wanneer u opstaan, koue vingers en/of tone.
- Toegetrekte keel, neus wat bloei.
- Ontsteking van die dikderm (wat lei tot diaree), winde opbreek, probleme met sluk, ontsteking in die mond, slegte asem.
- Nagsweet, netelroos, veluitslag, koue sweet, sensitiwiteit vir sonlig, verhoogde neiging tot kneusplekke, ontsteking van die bloedvate in die vel (kutane vaskulitis).
- Spierstyfheid, spiertrekking.
- Probleme of onvermoë om uriene te passeer, moeite om te urineer, behoefte om gedurende die nag te urineer, behoefte om meer te urineer as normaal, 'n verminderde urienvloei, uriene se reuk is abnormal.
- Ongewone ligte of oorgeslane siklusse, verminderde seksdrif, pyn in die testikels of skrotum, menoposale simptome, abnormale produksie van borsmelk in mans en vroue.
- Hemoragie (swaar bloeding) nadat geboorte geskenk is.
- Borskaspyn, gevoel van koud of warm, dors, bewing, voel sleg, abnormale gang.
- Gewig optel.
- Laboratoriumtoetse kan verhoging in die lewerensieme of die bloedvlakke van kalium, kreatienfosfokinase, suiker of cholesterol toon.

Frekwensie onbekend
- Stress-kardiomiopatie - dit is 'n toestand waar stress die aanvang van borskaspyn, uitasemheid en ander simptome wat soo 'n hartaanval voel, mag veroorsaak.

Indien u enige newe-effek opmerk of ervaar wat nie in hierdie inligtingstuk aangemeld is nie, stel asseblief u dokter of apteker in kennis.

Rapportering van newe effekte
Indien u enige newe effekte waarneem of ervaar, praat asseblief met u dokter of apteker of verpleegster. Dit sluit enige moontlike newe-effekte wat nie in hierdie inligtingstuk gelys is nie, in. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com.
Indien jy newe effekte rapporteer, kan jy bydrae om meer inligting oor die veiligheid van **XETSIA DR** te verskaf.

5. Hoe om XETSIA DR te bewaar
Berg by of benede 25°C.
Beskerm teen lig en vogtigheid.
Hou die stulpverpakking in die buitenste karton, totdat u dit benodig om te gebruik.
Hou HDPE houers dig toe.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Moet nie hierdie medisyne in 'n badkamer bêre nie.
Moet nie na die vervaldatum, aangedui op die etiket/karton/bottel, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting
Wat XETSIA DR bevat
- Die aktiewe bestanddeel is duloksetienhidrochloried 30/60 mg.
- Die ander onaktiewe bestanddele is: hipromellose, hipromelloseftalaat, poliëtileenglikol, sukrose, natriumlourielsulfaat, suiker sfere (bestaande uit mieliestysel en sukrose), triëtielsitraat, talk. Die harde gelatien kapsules bestaan uit FD & C blou 2 kleur, titaandioksied, gelatien, water en natriumlaurielsulfaat. Boonop bevat **XETSIA DR 60 mg** ysteroksiedgeel.

Hoe lyk XETSIA DR en die inhoud van die verpakking
XETSIA DR 30 mg (Kapsules)
Ondeursigtige blou dop/ ondeursigtige wit lyf, grootte "3" kapsules wat wit tot naaswit gekleurde korrels bevat met "WI" op dop en "D30" op lyf wat met groen ink bedruk is.

XETSIA DR 60 mg (Kapsules)
Ondeursigtige blou dop / ondeursigtige geelgroen lyf, grootte "1" kapsules wat wit tot naaswit gekleurde korrels bevat met "WI" op dop en "D60" op lyf wat met wit ink bedruk is.

Stulp- of strookverpakking
Silwergekleurde 25 µ aluminiumfoelie/6-8 gsm HSL as die dekmateriaal en silwer gekleurde koue vorm laminaat (25 µ OPA/45 µ aluminiumfoelie/60 µ PVC) as die vormings materiaal, verpak in 'n voorafgedrukte buitenste karton eenheid, met 28 of 30 kapsules.

HDPE houer
Ronde, wit HDPE houers,wat 28 of 30 kapsules bevat, met 'n skroefnek en wit kinderbestande polipropileen deksel met pulp en hitte seëlvoering, verpak in voorafgedrukte karton.
Nie alle pakke en pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en vervaardiger
Macleods Pharmaceuticals SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoor Park (Oos),
1 Cussonia Weg, Bassonia Rock, Uitbreiding 12,
Alberton, Suid-Afrika

Hierdie inligtingstuk is laas hersien op
09 Oktober 2023

Registrasienommer
XETSIA DR 30 mg: 51/1.2/0933
XETSIA DR 60 mg: 51/1.2/0934

Toegang tot die ooreenstemmende professionele inligting
Die toepaslike professionele inligting kan verkry word by https://www.macleodssaproducts.co.za / of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

Bemark deur:
United Pharma Marketing (Edms) Bpk

2602A341

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product : XETSIA DR 30/60 (Duloxetine DR Capsules 30/60 mg)						
2. Country: South Africa - UNICORN			**3. Packaging component: Patient Information Leaflet**			
4. No. of Colours: 1 colours			**5. Pantone Shade No.: Black**			
6. Specification : 40 GSM Bible paper						
7. Machine Layout No.: NA			**8. Dimensions: 340 (L) x 320 (W) mm**			
9. Design / Style: Booklet			**10. Item code No.: PM04342714**			
11. Artwork has been made: Actual			**12. Pharma code No.: 41254 mini**			
13. Barcode/NDC No: NA			**14. Supersedes Item code No: NA**			
15. Revision no: 00			**16. A/W File name: G:\Regulated_Artwork\SOUTH AFRICA\Duloxetine\UNICORN\Xetsia DR 30-60 mg PIL - PM04342714.ai**			
Approved By:			**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**RAD**	**QC**	**PRODN**	**QA**	**UNICORN**
	11/05/2026					Jeanine Janse van Rensburg | Head of Technical Affairs | Responsible Pharmacist 2026.05.11 16:39:42 +02'00'

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - UNICORN	PM04342714		