PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

DENLAZYD 50 extended-release tablets

DENLAZYD 100 extended-release tablets

Desvenlafaxine

Sugar free.

Read all of this leaflet carefully before you start taking DENLAZYD.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DENLAZYD 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 DENLAZYD is and what it is used for

DENLAZYD contains the active ingredient desvenlafaxine and belongs to a group of medicines called selective serotonin and norepinephrine reuptake inhibitors (SNRI) used to treat depression.

DENLAZYD is indicated for the treatment of major depressive disorder (MDD).

2. What you need to know before you take DENLAZYD

Do not take DENLAZYD

- If you are hypersensitive (allergic) to desvenlafaxine succinate, venlafaxine hydrochloride or any of the other ingredients of DENLAZYD (listed in section 6).
- If you are taking, or you have taken within the last 14 days, other medicines known as monoamine oxidase inhibitors (MAOI), used to treat depression or Parkinson's disease. If you stop taking DENLAZYD you should wait at least 7 days before taking an MAOI. Taking an MAOI together with DENLAZYD can cause serious or even life-threatening reactions, which include tremor, muscle twitching, sweating, nausea, vomiting, flushing (redness in the face), dizziness, elevated body temperature or seizures.
- If you are younger than 18 years of age.
- If you are pregnant or breastfeeding (see section 2).

Warnings and precautions

Take special care with DENLAZYD

- If you suffer from depression, you may experience worsening of your symptoms. This can happen especially at the start of treatment and when the dose is altered. Consult your doctor if you feel anxious, agitated, experience irritability, aggressiveness, impulsivity, sleeplessness or experience any thoughts of harming or killing yourself. Your doctor might change your dose or tell you to stop taking DENLAZYD.
- If you have a history of or if someone in your family has had mania (extremely elevated and excitable mood).
- If you are taking other medicines that together with DENLAZYD could increase the risk of developing serotonin syndrome (a potentially life-threatening medicine reaction that causes the body to have too much serotonin). Symptoms may include agitation, hallucinations, coma, fast heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, loss of coordination, nausea, vomiting, diarrhoea. Examples of medicines that cause this reaction when used together with DENLAZYD are: triptans (migraine medicines) and antidepressant medicines

such as selective serotonin reuptake inhibitors (SSRIs), selective serotonin/norepinephrine reuptake inhibitors (SSNRIs) and MAOIs. Tell your doctor if you think you are using any of these medicines or of you experience any of these symptoms while taking DENLAZYD.

- If you have eye problems, such as narrow angle glaucoma (increased pressure in your eye).
- If you have recently suffered a heart attack or suffer from a heart disease which has not been stabilised.
- If treatment is stopped suddenly, because withdrawal symptoms can occur after treatment with DENLAZYD depending on the dose which has been taken and the duration of treatment. It is recommended to end treatment by reducing the dose in steps (see section 3).
- If you are taking other medicines containing venlafaxine hydrochloride or other medicines containing desvenlafaxine.
- If you have a history of high blood pressure. Your doctor may check your blood pressure at regular intervals.
- If you have been diagnosed with cerebrovascular disease, a condition which affects the blood flow to your brain.
- If you suffer from seizures (fits).
- If you have a history of bleeding disorders (tendency to develop bruises or a tendency to bleed easily).
- If you have a history of low sodium levels in our blood (hyponatraemia), if you are dehydrated or if you are taking any diuretic medicines (used to remove excessive water from your body).
- If you have lung problems including difficulty breathing, cough or chest discomfort.
- If you are elderly. You may experience greater sensitivity to the effects of DENLAZYD.

High cholesterol (high levels of fat in your blood) may occur while you are taking DENLAZYD, especially during long-term treatment with DENLAZYD. Your doctor may check your cholesterol (fat) levels in your body.

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

Do not give DENLAZYD to children less than 18 years of age as safety and efficacy have not been established. Patients under the age of 18 years have an increased tendency to develop side effects, including hostile behaviour, suicidal tendencies and self-harm.

Other medicines and DENLAZYD

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

The use of DENLAZYD with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care provider for advice.

Monoamine oxidase inhibitors (MAOIs)

MAOIs, which are used to treat depression or Parkinson's disease, must not be taken with DENLAZYD. Tell your doctor if you have taken these medicines within the last 14 days. If you stop taking DENLAZYD you should wait at least 7 days before taking an MAOI (see section 2).

Serotonin syndrome

Using DENLAZYD with certain medicines may cause a serious and potentially life-threatening reaction called serotonin syndrome (see section 2). These medicines include: triptans (migraine medicines); other medicines to treat depression such as SSRIs and SSNRIs, MAOIs, lithium (used to treat mood disorders), St John's wort (a herbal medicine used to treat depression and mood disorders), tryptophan supplements; and sibutramine (used for weight loss), tramadol or pethidine (used to treat pain), linezolid (an antibiotic used to treat bacterial infection).

Care needs to be taken when DENLAZYD is used together with the following:

- Medicines acting on your central nervous system (e.g. midazolam).
- Alcohol.
- Tricyclic antidepressants (used to treat depression).
- Medicines containing codeine since the effect of codeine may be enhanced.
- Ketoconazole (used to treat fungal infections).
- Medicines used for schizophrenia, such as aripiprazole.
- Medicines used for treating breast cancer, such as tamoxifen.

False-positive laboratory test results may occur for phencyclidine (PCP) and amphetamines when using DENLAZYD.

DENLAZYD with food and alcohol

You should avoid drinking alcohol while you are using DENLAZYD (see section 3).

Pregnancy, breastfeeding and fertility

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

Do not take DENLAZYD if you are pregnant or breastfeeding.
Safety during pregnancy and breastfeeding has not been established. If you take DENLAZYD 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.
DENLAZYD passes into breast milk in humans. Ask your doctor for advice before breastfeeding your baby.

No data on the influence on fertility is available.

Driving and using machines

DENLAZYD may lower your ability to react quickly and appropriately to unexpected or sudden events. Do not drive a vehicle or operate any dangerous electrical tools or machines until you know how DENLAZYD affects you. Especially bear in mind that alcohol and other sedatives can additionally impair your reaction capacity.

3. How to take DENLAZYD

Do not share medicines prescribed for you with any other person.
Always take DENLAZYD exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DENLAZYD should be taken at approximately the same time each day. Tablets must be swallowed whole with fluid and not divided, crushed, chewed or dissolved.

The recommended dose for DENLAZYD is 50 mg once daily, with or without food. Your doctor may increase the dose slowly at an interval of not less than 7 days, up to a maximum daily dose of 100 mg.

Children

Not recommended for children under the age of 18 years.

Patients with kidney problems

Care should be taken when treating patients with severe kidney problems. You should inform your doctor if you have or have had renal disease. Depending on the condition of your kidneys, your doctor may reduce the dose to avoid potential side effects.

Patients with impaired liver function

No dosage adjustment is necessary for patients with liver problems.

Your doctor will tell you how long your treatment with DENLAZYD will last. If you have the impression that the effect of DENLAZYD is too strong or too weak, tell your doctor or pharmacist.

If you receive more DENLAZYD than you should

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

If you forget to use DENLAZYD

If you are concerned that you may have missed a dose, talk to your doctor or health care provider. Do not take a double dose to make up for forgotten individual doses. Take your next dose at the regularly scheduled time.

If you stop taking DENLAZYD

If your doctor decides treatment with DENLAZYD should be stopped, it will be done by gradually reducing the dose rather than abruptly stopping treatment so that the occurrence of withdrawal symptoms is minimised.

Withdrawal symptoms that have been reported include the following: dysphoric mood (e.g. being in a depressive, disapproving state), irritability, agitation, dizziness, sensory disturbances (e.g. paraesthesia such as electric shock sensations), anxiety, confusion, headache, tiredness, experiencing strong and uncontrollable emotions and feelings, sleeplessness, feeling overexcited, euphoric or overly irritable, tinnitus (ringing or buzzing in your ears) and seizures (convulsions/fits). Careful attention and monitoring should be considered in case any intolerable symptoms occur (see section 3).

Switching from other antidepressants

If you are already using an antidepressant medicine prescribed by your doctor, you may experience side effects when discontinuing it in order to switch to DENLAZYD. Your doctor may gradually reduce

the dose of your current antidepressant medicine to help to reduce these side effects.

4. Possible side effects

DENLAZYD can have side effects.

Not all side effects reported for DENLAZYD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DENLAZYD, please consult your doctor, pharmacist or other health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips and 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 reaction to DENLAZYD. 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:

- Stevens-Johnson syndrome (an extremely serious skin reaction causing blistering/peeling skin rash).
- Convulsions (fits/seizures).
- Dystonia (sustained muscle contractions causing twisting and repetitive movements or abnormal postures).
- Changes in the way your heart beats (such as beating faster than normal or skipping a beat).
- Heavy 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:

Side effects that may occur frequently:

- Decreased appetite.
- Sleepiness/sedation.
- Nervousness.
- Abnormal dreams.
- Abnormal orgasm.
- Headache.
- Tremor (uncontrolled shaking/movement).
- Paraesthesia (“pins and needles”/tingling or numb feeling of your skin).
- Loss of taste.
- Disturbance in your attention levels.
- Vertigo (loss of balance or spinning sensation).
- Blurred vision.
- Mydriasis (dilation of your pupils).
- Tinnitus (ringing or buzzing in your ears).
- Increased blood pressure.
- Hot flush.
- Excessive yawning.
- Nausea (feeling sick).
- Dry mouth.
- Constipation.
- Diarrhoea.
- Vomiting (being sick).
- Excessive sweating.
- Stiffness of your muscles and bones.
- Difficulty urinating and completely emptying your bladder.
- Increased levels of protein in your urine (proteinuria) when tests are done.

- Erectile dysfunction or failure (male).
- Delayed ejaculation (male).
- Fatigue.
- Chills.
- Lack of energy or weakness.
- Feeling jittery.
- Irritability.
- Weight gain/loss.

Side effects that may occur less frequently:

- Low levels of sodium in your blood.
- Withdrawal syndrome.
- Depersonalisation (feeling disconnected or detached from one's body and thoughts).
- Hypomania (feeling overexcited, euphoric or overly irritable), hallucinations, thoughts of harming or killing yourself.
- Orthostatic hypotension (sudden drop in blood pressure causing light-headedness or dizziness when standing up), especially in elderly persons.
- Cold hands and feet.
- Epistaxis (nosebleeds).
- Alopecia (hair loss).
- Sensitivity to sunlight.
- Abnormal ejaculation (males).
- Abnormal sexual function.
- Increased cholesterol (high levels of fat in your body) when tests are done.
- Abnormal liver function tests.
- Increased blood prolactin (prolactin is a hormone released by the pituitary gland that stimulates breast development and milk production).

Side effects with unknown frequency:

- Inflammation of the pancreas associated with severe upper stomach pain, often with nausea and vomiting.

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. 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 DENLAZYD.

5. How to store DENLAZYD

- Store at or below 30 °C in a dry place.
- Protect from light.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What DENLAZYD contains

The active substance is desvenlafaxine.

Each DENLAZYD 50 extended-release film-coated tablet contains desvenlafaxine succinate equivalent to 50 mg desvenlafaxine.
Each DENLAZYD 100 extended-release film-coated tablet contains desvenlafaxine succinate equivalent to 100 mg desvenlafaxine.

The other ingredients are:

Colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, purified stearic acid, talc, xanthan gum.

Coating materials for DENLAZYD 50 are:

Opadry Pink [containing iron oxide red (E172), iron oxide yellow (E172), macrogol/PEG (E1521), polyvinyl alcohol partially hydrolysed (E1203), talc (E1521), titanium dioxide (E171)].

Coating materials for DENLAZYD 100 are:

Opadry Brown [containing iron oxide red E172, FD&C Yellow #6/Sunset Yellow FCF aluminium lake (E110), macrogol/PEG (E1521), polyvinyl alcohol partially hydrolysed (E1203), talc (E1521), titanium dioxide (E171)].

What DENLAZYD looks like and contents of the pack

DENLAZYD 50 extended-release tablets are light pink, speckled, oval, film-coated tablets, debossed with “50” on one side and plain on the other side.

DENLAZYD 100 extended-release tablets are orange to reddish orange, speckled, oval, film-coated tablets, debossed with “100” on one side and plain on the other side.

Contents of the pack:

PVDC/PVC and aluminium blister strip containing 10 or 15 tablets packed into an outer carton.

Pack size: 30 tablets (3 strips of 10 tablets or 2 strips of 15).

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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