PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DESLAFEKS 50 mg, (EXTENDED RELEASE FILM COATED TABLETS)

DESLAFEKS 100 mg, (EXTENDED RELEASE FILM COATED TABLETS)

Desvenlafaxine succinate

Sugar free

Read all of this leaflet carefully before you start taking DESLAFEKS

- 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.
- **DESLAFEKS** 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 **DESLAFEKS** is and what it is used for
2. What you need to know before you take **DESLAFEKS**
3. How to take **DESLAFEKS**
4. Possible side effect
5. How to store **DESLAFEKS**
6. Contents of the pack and other information

1. WHAT DESLAFEKS IS AND WHAT IT IS USED FOR:

DESLAFEKS contains desvenlafaxine, a selective serotonin and norepinephrine reuptake inhibitor (SNRI). It is indicated for the treatment of major depressive

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disorder (MDD). MDD is a mental health disorder characterised by persistent feelings of sadness. **DESLAFEKS** works on the central nervous system (CNS) to elevate mood by increasing the amount of two neurotransmitters called serotonin and norepinephrine that are available in certain parts of the brain.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Do not take DESLAFEKS:

- If you are hypersensitive to desvenlafaxine or to any ingredients of **DESLAFEKS.**
- If you are taking medicines called Monoamine oxidase inhibitors (MAOIs), another class of medicines used for depression e.g. Linezolid (an antibiotic), methylene blue (a dye used in certain surgeries), selegiline
- Within at least 14 days of stopping treatment with an MAOI. If **DESLAFEKS** is stopped, wait at least 7 days before starting a MAOI.
- If you are pregnant or breastfeeding
- If you are under 18 years of age.

Warnings and precautions

Tell your healthcare professional if you:

- If you feel worse than you did before taking the medicine.
- If you have high blood pressure or develop high blood pressure during use of **DESLAFEKS**
- If you feel suicidal or have suicidal thoughts
- If you or someone in your family has had of mania/hypomania. (Mania is a type of mood where a person has a feeling of elevated mood with more energy than usual.)

- If you suffer from narrow -angle glaucoma or increased pressure in your eyes.
- If you suffer from heart problems
- If you were taking **DESLAFEKS** and stopped abruptly
- If you have a history of fits
- If you have kidney problems
- If you have liver problems
- If you have abnormal bleeding problems
- If you have problems of low sodium (salt) in blood
- If you are pregnant or thinking about becoming pregnant or if you are breast feeding

Other medicines and DESLAFEKS

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

Do not use **DESLAFEKS** if you are taking or have recently taken monoamine oxidase inhibitors:

- Monoamine oxidase inhibitors (MAOI) including linezolid, an antibiotic, and methylene blue, a dye used in certain surgeries. Do not take **DESLAFEKS with** an MAOI or within 14 days of stopping an MAOI. Taking an MAOI together with many prescription medicines, including **DESLAFEKS** , can cause serious or even life-threatening side effects. Also, you need to wait at least 7 days after you stop taking **DESLAFEKS** before you take an MAOI.

Serotonin syndrome or a neuroleptic malignant syndrome (NMS)-like reaction: Less frequent, but potentially life-threatening conditions called serotonin syndrome or NMS-like reactions can cause serious changes in how your brain, muscles and

digestive system work and can happen when medicines like **DESLAFEKS** are taken, particularly when taken with certain other medications such as:

- medicines to treat migraine headaches known as triptans
- medicines used to treat mood or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors (SSRIs); or serotonin norepinephrine reuptake

  inhibitors (SNRIs), or dopamine antagonists, including antipsychotics
- sibutramine (used for weight loss)
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat

  chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine
- certain medicines used to treat cough, such as dextromethorphan
- St. John's Wort (used to treat depression)
- MAOIs (including linezolid, an antibiotic and methylene blue, a dye sometimes injected before surgery to guide the surgeon)
- tryptophan supplements (amino acid supplements used to help control your mood and sleep)
- Alcohol and other sedative medicines
- Other antidepressants

  Certain laboratory results may be affected by use of **DESLAFEKS,** discuss with your doctor if you receive any unusual lab reports

  DESLAFEKS with food and drink and alcohol

DESLAFEKS can be taken with or in the absence of food. **DESLAFEKS** should not be taken with alcohol.

Pregnancy and 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 this medicine.

The effect of **DESLAFEKS** in pregnant women and those who are breastfeeding have not been established.

You should not use **DESLAFEKS** if you are pregnant (see Do not use **DESLAFEKS** above).

If you do become pregnant while taking this medicine, consult your doctor immediately.

Desvenlafaxine is excreted in human milk. You should not breastfeed your baby while you are taking **DESLAFEKS.**

Driving and using machines

It is not always possible to predict to what extent **DESLAFEKS** may interfere with the daily activities until they are aware of the measure to which **DESLAFEKS** affects them.

Do not drive or operate any tools or machines until you know how **DESLAFEKS affects** you. Do not drive or operate any tools or machines if **DESLAFEKS** affects you in a way that prevents you from safely performing these operations.

3. HOW TO TAKE DESLAFEKS

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **DESLAFEKS** 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 usual dose is 50 mg taken once daily, with or without food. Your doctor may increase the dose gradually at an interval of not less than 7 days, up to a maximum daily dose of 100 mg.

Your doctor will tell you how long your treatment with **DESLAFEKS** will last. Do not stop treatment early. If you have the impression that the effect of **DESLAFEKS** is too strong or too weak, tell your doctor or pharmacist.

Children:

Safety and effectiveness in children under 18 years of age has not been established.

Patients with 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. The reduction in kidney function should also be taken into consideration when you are elderly.

Patients with impaired liver function:

No dosage adjustment is necessary for patients with liver impairment.

If you stop taking DESLAFEKS

Do not stop treatment early. If you have the impression that the effect of **DESLAFEKS** is too strong or too weak, tell your doctor or pharmacist.

If you take more DESLAFEKS 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.

If you forget to take DESLAFEKS

It is important to take your medicine the same time every day. However, should you forget your dose, then take it as soon as you remember. However, if it is almost time

for your next dose, then skip the missed dose and continue with your normal scheduling. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

DESLAFEKS can have side-effects.

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

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

If you experience an allergic reaction (including red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters

- of the skin, sores or pain in the mouth or eyes).
- **Seizures:** loss of consciousness with uncontrollable shaking; “fit”
- **Severe Increased Blood Pressure**: headache, stronger and possibly faster heartbeat, chest pain, dizziness, excessive tiredness, and blurred vision
- **Serotonin syndrome:** a combination of most or all of the following:

confusion, restlessness, sweating, shaking, shivering, high fever, sudden jerking of the muscles, hallucinations, fast heartbeat

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

Tell your doctor if you notice any of the following:

Frequent side effects:

Heart pounding, heart racing, ringing in the ears, vertigo, dilated pupils, vision blurred, vomiting, diarrhoea, weakness, chills, feeling jittery, irritability,

weight decreased, weight Increased, blood pressure Increased, musculoskeletal stiffness, drowsiness, shaking, disturbance in attention, tingling sensations, taste changes, orgasm abnormal, no orgasms, anxiety, nervousness, interest in sex decreased, abnormal dreams, urinary hesitation, ejaculation delayed (in men), erectile dysfunction (in men), yawning, rash, hot flushes.

Less Frequent:

Medicine withdrawal syndrome, allergic reaction, increased blood cholesterol, increased blood prolactin, increased blood triglyceride, abnormal liver function tests, fainting, depersonalization, nose bleeds, drop in blood pressure when standing, coldness in hands and feet, loss of hair, seizures, protein in the urine, movement disorders, decreased sodium levels, swelling beneath the skin (e.g. throat, face, hands).

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. You can also report side effects to SAHPRA via the "**6.04 Adverse drug Reaction reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **DESLAFEKS**

5. HOW TO STORE DESLAFEKS

Store at or below 30 °C. Keep well closed. Protect from moisture and light.

Do not remove blister card from the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DESLAFEKS contains:

The active substance is desvenlafaxine succinate.

The other ingredients are: hypromellose, microcrystalline cellulose, povidone, talc, magnesium stearate, titanium dioxide, macrogol, iron oxide red and iron oxide black.

What DESLAFEKS looks like and contents of the pack

DESLAFEKS Tablets 50mg:

Light pink coloured, round, biconvex, film coated tablets, debossed with ‘50’ on one side and plain on other side.

DESLAFEKS Tablets 100mg:

Dark brown to red coloured, round, biconvex, film coated tablets, debossed with ‘100’ on one side and plain on other side.

DESLAFEKS extended- release tablets are available as follows: A carton containing one or more aluminium/aluminium foil blister strips containing 7, 14 or 28 tablets each.

Holder of Certificate of Registration

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Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of

DESLAFEKS.

Follow the link for the corresponding Professional Information for CONTREZ: pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below: