PATIENT INFORMATION LEAFLET FOR

NUZAK (CAPSULES)

SCHEDULING STATUS

S5

NUZAK (20 mg capsules)

Fluoxetine hydrochloride

Read all of this leaflet carefully before you start taking NUZAK

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

1. What NUZAK is and what it is used for:

NUZAK belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

This medicine is used to treat the following conditions:

Adults:

• Major depressive episodes.

• Obsessive- compulsive disorder (is a mental disorder most commonly characterized by intrusive, repetitive thoughts resulting in compulsive behaviours and mental acts that the person feels driven to perform).

• Bulimia nervosa (eating disorder): **NUZAK** is used for the reduction of binge-eating and purging (for exampleby making themselves vomit, by taking laxatives to get rid of the calories they have eaten).

2. What you need to know before you take NUZAK

Do not take NUZAK:

- if you are allergic (hypersensitive) to fluoxetine or any of the other ingredients of **NUZAK** (see **Section 6**). If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor Immediately
- if you have a manic episode, as it may become worse
- If you have renal (kidney) failure

- if you have heart problems
- if you have epilepsy or fits (seizures) or experience an increase in seizure frequency, contact your doctor immediately
- taking other medicines used to treat depression, known as monoamine oxidase inhibitors (MAOIs) since serious reactions such as confusion, extreme agitation that may progress to delirium and coma may occur. Gastrointestinal symptoms, hyperpyretic episodes severe convulsions, confusion, agitation, restlessness and hypertensive crises may occur.

Do not take any MAOIs for at least 5 weeks after you stop taking **NUZAK** as death has been reported following initiation of a MAOI shortly after stopping **NUZAK**.

- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

NUZAK should not be given to children.

Warnings and precautions

Take special care with **NUZAK:**

- If you have a rash.

Talk to your doctor before taking **NUZAK,** especially if you have a history of bleeding disorders, or if you are pregnant (see **"PREGNANCY AND LACTATION").**

- If you have liver problems (your doctor may need to adjust your dosage).
- If you have kidney problems
- If you have diabetes (your doctor may need to adjust your dose of insulin or other

antidiabetic treatment)

- If you have manic episode, contact your doctor immediately because **NUZAK** might need to be discontinued
- If you have heart problems
- If you have prostate problems
- if you have epilepsy or fits (seizures) (see **Do not take NUZAK)**
- If you have ongoing treatment with high blood pressure tablets
- If you have narrow-angle glaucoma (increased pressure in the eye)
- If you undergo ECT (electro-convulsive therapy) treatment
- If you experience abnormal bleeding
- If you experience undesirable loss of weight
- If you are breastfeeding your baby
- if you are pregnant.

NUZAK should not be used in the treatment of children.

Other medicines and NUZAK

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

Do not take **NUZAK** with:

- Tryptophan (used to treat mental illness) as reactions such as gastro-intestinal distress, agitation and restlessness have been reported.
- lithium, as both increases and decreases in lithium levels when used with **NUZAK** have been reported.

- monoamine oxidase inhibitors MAO-inhibitors (used to treat depression) must not be used with **NUZAK** (see **Do not take NUZAK).**

NUZAK with food and drink

NUZAK may be taken with or without food.

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 healthcare provider for advice before taking **NUZAK**.

NUZAK should not be taken while you are pregnant or breastfeeding your baby.

If you take **NUZAK** 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. You doctor or nurse should be aware that you are taking **NUZAK** so they can advise you.

Breastfeeding: **NUZAK** is excreted in breast milk and can cause side effects in babies.

Driving and using machines

Refrain from driving a motor vehicle, climb dangerous heights or operate dangerous machinery for at least several days as **NUZAK** may impair judgement or skills.

Impaired decision making could lead to accidents.

It is not always possible to predict to what extent **NUZAK** 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 **NUZAK** affects them.

3. How to take NUZAK

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

Always take **NUZAK** 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 **NUZAK** will last. If you have the impression that the effect of **NUZAK** is too strong or too weak, tell your doctor or pharmacist.

NUZAK should be taken by adults only.

The usual dose is:

Major depression:

Take 1 capsule (20 mg) daily in the morning.

Your doctor will review and adjust your dosage if necessary.

If required, the dosage can be gradually increased up to a maximum of 4 capsules (80 mg) daily, to be taken in divided doses in the morning and at noon.

Obsessive-compulsory disorders:

Take 1 capsule (20 mg) to 3 capsules (60 mg) daily.

Bulimia nervosa:

Take 3 capsules (60 mg) daily.

Elderly

A recommended maximum dose for elderly patients is 3 capsules (60 mg) daily.

If you take more NUZAK than you should

If you take more **NUZAK** than you should, you may experience an increase in side effects listed below (see **section 4**).

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 take NUZAK

Take **NUZAK** as prescribed. If you miss a dose, skip the missed dose and take only your next scheduled dose.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

NUZAK can have side effects.

Not all side effects reported for **NUZAK** are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking **NUZAK**, please consult your healthcare provider for advice.

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

- Rapid swelling of the hands, feet, ankles, face, lips and mouth, which may cause difficulty in swallowing or breathing
- rash or urticaria
- fever
- difficulty breathing
- agitation
- convulsions
- vasculitis (inflammation of a blood vessel)
- confusion
- thoughts of suicide or harming yourself

These are all very serious side effects. If you have them, you may have had a serious reaction to **NUZAK**. 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:

- changes in the way your heart beats, for example, if you notice it beating faster
- excessive sweating
- blurred vision

- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "**PREGNANCY AND LACTATION**" for more information.
- increased tendency to bruising

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

Tell your doctor if you notice any of the following:

- nausea, vomiting, dry mouth, diarrhoea, loss of appetite, heartburn
- anxiety, insomnia (difficulty falling asleep or staying asleep), drowsiness, tiredness, headache, shaking, dizziness, changes in sex drive or ability
- Low levels of salt in the blood
- reduction in blood platelets
- lung problems
- nervousness

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Side effects may also be reported directly to Cipla Medpro (Pty) Ltd:

drugsafetysa@cipla.com

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

5. How to store NUZAK

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep the blister strips in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

6. Contents of the pack and other information

What NUZAK contains

The active substance is fluoxetine hydrochloride 20 mg.

The other ingredients are: colloidal silicon dioxide, magnesium stearate, maize starch and purified talc.

Capsule cap: bronidiol, gelatin, indigo carmine, polyvinyl pyrrolidone K-30, quinoline yellow W.S, sodium lauryl sulphate, sunset yellow supra, titanium dioxide.

Capsule body: bronidiol, gelatin, polyvinyl pyrrolidone K-30, quinoline yellow W.S, sodium lauryl sulphate, titanium dioxide.

What NUZAK looks like and contents of the pack

Hard, opaque gelatin capsules of size ‘2’, with cream coloured body and a light green cap, and having ‘NZC’ printed in black on both halves.

10 capsules packed in a blister strip.

Pack sizes:- 1 x 10, 3 x 10 and 10 x 10 capsules.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD

Building 9, Parc du Cap

Mispel Street

Bellville

7530

Customer care: 080 2226662

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