Patient Information Leaflet for DEFITON 20

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DEFITON 20 capsules

Fluoxetine hydrochloride

Contains sugar (140 mg lactose monohydrate per capsule).

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

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

DEFITON contains fluoxetine which belongs to a group of medicines called antidepressants.

DEFITON will relieve the symptoms of depression. It may also be used to treat the eating disorder bulimia nervosa and the condition obsessive compulsive disorder.

2. What you need to know before you take DEFITON

Do not take DEFITON if you:

- Are allergic (hypersensitive) to fluoxetine or any of the other ingredients of DEFITON (listed in section 6).
- Are taking, or have taken within the last two weeks, any irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. iproniazid).
- Are taking metoprolol for heart failure.
- Are taking thioridazine for schizophrenia, or within a minimum of 5 weeks after you have stopped taking DEFITON.
- Suffer from severe kidney failure.
- Are a child younger than 18 years of age.

Warnings and precautions:

Tell your doctor before taking DEFITON if you:

- Suffer from epilepsy or if you have had a fit in the past. DEFITON may increase the likelihood of an epileptic fit. If after taking DEFITON, you develop a fit for the first time or get more fits than usual, seek medical advice from your doctor.
- Have a history of mental illness known as mania or hypomania.
- Suffer from heart, kidney or liver problems.
- Have glaucoma (increased pressure in the eye).
- Suffer from diabetes. DEFITON may alter your blood sugar levels. Your doctor may need to

alter the dose of your insulin or other diabetes control medicine.

- Have a history of bleeding disorders or develop unexpected bruising, reddening under the skin or bleeding from any other part of the body, or if you are pregnant (see “Pregnancy and breastfeeding”).
- Are having electroconvulsive therapy (ECT).
- Are taking buprenorphine/naloxone. The use of these medicines together with DEFITON can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and DEFITON”).

DEFITON will not work straight away:

Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first started treatment. Tell your doctor if you are not yet feeling better.

Thoughts of suicide and worsening of your depression or anxiety disorder:

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These thoughts may increase when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions, who were treated with an antidepressant.

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.

DEFITON may cause serotonin syndrome:

See section 4. If you experience fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation, tell your doctor immediately.

If you are starting to feel restless and cannot sit or stand still (akathisia): Tell your doctor. Increasing your dose of DEFITON may make this worse.

DEFITON may cause symptoms of sexual dysfunction:

See section 4. In some cases, these symptoms have continued after stopping treatment.

Children and adolescents:

DEFITON is not intended for use in children under the age of 18 years.

Other medicines and DEFITON:

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

Do not take DEFITON with:

- Irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. iproniazid). DEFITON should only be started at least 2 weeks after stopping an irreversible non-selective MAOI. Do not take any irreversible non-selective MAOIs for at least 5 weeks after you stopped taking DEFITON.
- Metoprolol (used for heart failure).

Tell your doctor or pharmacist if you are taking:

- Medicines that may affect the heart's rhythm, e.g. digoxin, class IA and III antidysrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment, particularly halofantrine, or certain antihistamines (astemizole, mizolastine). Taking one or more of these medicines with DEFITON may increase the risk of changes in the electrical activity of the heart.
- Lithium, for mental illness.
- Diazepam (used to treat anxiety, fits and muscle spasms).
- Linezolid, methylthioninium chloride (methylene blue) and monoamine oxidase inhibitors (MAOIs).
- Nebivolol (used to treat high blood pressure).
- Propafenone or flecainide (used to treat heart problems).
- Atomoxetine (used to treat attention deficit hyperactivity disorder (ADHD)).
- Risperidone (used to treat psychotic disorders).
- Diuretics (water tablets).
- Desmopressin (used to reduce the amount of urine produced by the kidneys).
- Mefloquine, chloroquine (anti-malaria).
- Mequitazine, cyproheptadine (antihistamines).
- Oxcarbazepine, carbamazepine or phenytoin for epilepsy or other conditions.
- Any other medicines for depression, e.g. SSRIs (selective serotonin reuptake inhibitors).
- Selegiline for Parkinson's disease.
- Tramadol for pain relief.
- Bupropion (used to help stop smoking).
- Triptans (e.g. sumatriptan) for migraine or cluster headaches.
- Medicines to thin the blood (e.g. warfarin).

- Nonsteroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) or aspirin (for pain relief).
- Tryptophan (an amino acid).
- Buprenorphine/naloxone (used to treat opioid overdose). These medicines may interact with DEFITON and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C. Contact your doctor when experiencing such symptoms.
- Tamoxifen (used to treat breast cancer).
- The herbal remedy St John's wort (*Hypericum perforatum*). This should not be taken at the same time as DEFITON. Stop taking the St John's wort and mention it to your doctor at your next visit.

DEFITON with food, drink and alcohol:

You should avoid alcohol while taking DEFITON.

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 DEFITON.

Safe use in pregnancy and breastfeeding has not been established.

If you take DEFITON 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. Your doctor or midwife should be aware that you are taking DEFITON so they can advise you.

When taken during pregnancy, particularly in the last 3 months of pregnancy, DEFITON 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.

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports suggesting an increased risk of birth defects affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took fluoxetine.

Fluoxetine has been shown to reduce the quality of sperm in animal studies. This could affect fertility, but impact on human fertility has not been observed yet.

Driving and using machines:

DEFITON can affect your judgement or coordination. Do not drive or use machinery unless you are sure that you are not affected.

DEFITON contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DEFITON.

3. How to take DEFITON:

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

Always take DEFITON exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one (20 mg) to three (60 mg) capsules once a day depending on your condition.
Swallow the capsule whole with a drink of water.
If you suffer from kidney or liver problems or are an elderly person, your doctor may prescribe a different dose.

DEFITON may not make you feel any better for the first 2 weeks or more. It should be taken for as long as your doctor tells you to.

If you have the impression that the effect of DEFITON is too strong or too weak, tell your doctor or pharmacist.

If you take more DEFITON than you should:
In the event of overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre. Signs of an overdose include nausea, vomiting, seizures, heart problems, lung problems, and signs of altered central nervous system status ranging from excitation to coma.

If you forget to take DEFITON:
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

If you stop taking DEFITON:
Do not stop taking DEFITON without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine. Make sure you do not run out of capsules.

You may notice the following effects (withdrawal symptoms) when you stop taking DEFITON: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.

When stopping DEFITON, your doctor will help you to reduce your dose slowly over one or two weeks – this should help reduce the chance of withdrawal effects. Most people find that any symptoms on stopping DEFITON are mild and disappear within a few weeks.

If you experience symptoms when you stop treatment, contact your doctor immediately.

4. Possible side effects

DEFITON can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue 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 DEFITON. 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:

- Thoughts of suicide or harming yourself (see section 2).
- A combination of symptoms (known as serotonin syndrome) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (see section 2).
- If you feel restless and cannot sit or stand still, you may have akathisia (feeling of inner restlessness, a constant urge to be moving); increasing your dose of DEFITON may make you feel worse. If you feel like this, contact your doctor (see section 2).
- A condition where your body retains too much water, resulting in weakness, drowsiness, nausea and vomiting, cramps or tremors, confusion or coma.
- Decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity), orgasm problems, persistent painful erection.
- Uncontrollable shaking movements of the mouth, tongue and limbs.
- Fits (seizures).
- Rapid or irregular heartbeat sensations. Fainting, collapsing or dizziness upon standing may indicate an abnormal functioning of the heart rate.
- Lung problems including lung inflammation and fibrosis (formation of fibrous tissue on the lungs). You may get shortness of breath before you get these signs of illness.
- Bleeding from stomach or intestines, e.g. black tarry stools, unexplained bleeding or bruising, fever, sore throat, tiredness which can be signs of decreased blood counts.
- Bleeding of mucous membranes, bleeding under the skin.
- Hepatitis (inflammation of the liver causing yellowing of the skin or eyes or tiredness, pain in abdomen, joints or muscles) and signs such as jaundice (yellowing of the whites of the eyes and skin).
- Widespread skin rash, circular, irregular red patches on the skin of the hands and arms

(erythema multiforme).

- Severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome).
- Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis).
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) (see section 2, “Pregnancy, lactation and fertility”).
- Inability to urinate, passing urine more frequently, painful urination.
- A serious condition, where the body stops producing enough new blood cells. This condition leaves you fatigued and more prone to infections and uncontrolled bleeding.
- Stroke (including symptoms such as troubled walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg).
- Inflammation of the pancreas (including symptoms such as upper abdominal pain, nausea and vomiting).
- A blood disorder in which red blood cells are destroyed faster than they can be made. You may experience an abnormal paleness of your skin, fever, weakness and dizziness.

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:

- Not feeling hungry, weight loss.
- Sleep problems, unusual dreams, having difficulty falling asleep.
- Nervousness, anxiety, restlessness, poor concentration.
- Feeling tense.
- Dizziness, headache.
- Change in taste.
- Blurred vision.

- Flushing.
- Yawning.
- Indigestion, dry mouth, nausea and vomiting, diarrhoea.
- Rash, urticaria, itching.
- Excessive sweating.
- Joint pain.
- Feeling shaky or chills.
- Weight loss.

Less frequent side effects:

- Abnormal blood test results.
- Low levels of salt in the blood.
- Feeling detached from yourself, strange thinking, elevated mood, hallucinations (seeing or hearing things), agitation, panic attacks, confusion, stuttering, aggression, violent behaviour.
- Muscle twitching, involuntary movements or problems with balance or coordination.
- Memory loss or memory problems.
- Enlarged (dilated) pupils.
- Ringing in the ears.
- Low blood pressure.
- Inflammation of the blood vessels (vasculitis), widening of blood vessels (vasodilatation).
- Sore throat (pharyngitis).
- Shortness of breath, nose bleeds.
- Difficulty swallowing, pain in the gullet (oesophageal pain).
- Hair loss (temporary).
- Sensitivity to sunlight (photosensitivity).
- Excessive production of breast milk.
- Cold sweat, feeling hot or cold.

- Muscle pains.
- Abnormal liver function tests.
- You may experience vaginal bleeding when you stop using DEFITON.
- Breast enlargement in men.

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 (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DEFITON.

5. How to store DEFITON

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the packaging.
- 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 DEFITON contains:

The active ingredient is fluoxetine hydrochloride.

Each capsule contains 20 mg fluoxetine (as fluoxetine hydrochloride).

The other ingredients are lactose monohydrate, corn starch, talc and stearic acid. The capsule shell contains gelatine, patent blue, iron oxide yellow, quinoline yellow, erythrosine, titanium dioxide.

What DEFITON looks like and contents of the pack:

Ivory opaque body, green opaque cap, hard gelatine capsules. White powder fill.

DEFITON is packed in:

White high-density polyethylene bottles containing 100 or 500 capsules.

Or

Aluminium foil & clear PVC blisters, packed in outer carton boxes containing 30 or 100 capsules.

Not all pack sizes may be marketed.

Holder of certificate of registration and manufacturer:

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