

FLUOXETINE BIOTECH 20

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

[55]

FLUOXETINE BIOTECH 20 Capsules Fluoxetine hydrochloride Contains sugar (140 mg lactose monohydrate per capsule).

Read all of this leaflet carefully before you start taking FLUOXETINE BIOTECH.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FLUOXETINE BIOTECH 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:

- What FLUOXETINE BIOTECH is and what it is used for
- What you need to know before your take FLUOXETINE BIOTECH
- How to take FLUOXETINE BIOTECH
- Possible side effects
- How to store FLUOXETINE BIOTECH
- Contents of the pack and other information

1. What FLUOXETINE BIOTECH is and what it is used for

FLUOXETINE BIOTECH contains fluoxetine which belongs to a group of medicines called anti-depressants. FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH

Do not take FLUOXETINE BIOTECH if you:

- Are allergic (hypersensitive) to fluoxetine or any of the other ingredients of FLUOXETINE BIOTECH (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 FLUOXETINE BIOTECH.
- Suffer from severe kidney failure.
- Are a child younger than 18 years of age.

Warnings and precautions:

Tell your doctor before taking FLUOXETINE BIOTECH if you:

- Suffer from epilepsy or if you have had a fit in the past. FLUOXETINE BIOTECH may increase the likelihood of an epileptic fit. If after taking FLUOXETINE BIOTECH, 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. FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and FLUOXETINE BIOTECH”).

FLUOXETINE BIOTECH 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.

FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH may make this worse.

FLUOXETINE BIOTECH may cause symptoms of sexual dysfunction:

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

Children and adolescents:

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

Other medicines and FLUOXETINE BIOTECH:

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

Do not take FLUOXETINE BIOTECH with:

- Irreversible, non-selective monoamine oxidase inhibitors (MAOIs, e.g. iproniazid). FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH.
- Metoprolol (used for heart failure).

Tell your doctor or pharmacist if you are taking:

- Medicines that may affect the heart’s rhythm, e.g. 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 FLUOXETINE BIOTECH may increase the risk of changes in the electrical activity of the heart.
- Lithium, for mental illness.
- Linezolid and methylthioninium chloride (methylene blue) 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 FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH. Stop taking the St John’s wort and mention it to your doctor at your next visit.

FLUOXETINE BIOTECH with food, drink and alcohol:

You should avoid alcohol while taking FLUOXETINE BIOTECH.

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 FLUOXETINE BIOTECH.

Safe use in pregnancy and breastfeeding has not been established.

If you take FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH so they can advise you.

When taken during pregnancy, particularly in the last 3 months of pregnancy, FLUOXETINE BIOTECH 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:

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

FLUOXETINE BIOTECH contains lactose monohydrate:

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

3. How to take FLUOXETINE BIOTECH

Do not share medicines prescribed for you with any other person. Always take FLUOXETINE BIOTECH 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 elderly, your doctor may prescribe a different dose.

FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH is too strong or too weak, tell your doctor or pharmacist.

If you take more FLUOXETINE BIOTECH than you should:

In the event of overdose, 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 FLUOXETINE BIOTECH:

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 FLUOXETINE BIOTECH:

Do not stop taking FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH: 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 FLUOXETINE BIOTECH, 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 FLUOXETINE BIOTECH are mild and disappear within a few weeks.

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

4. Possible side effects

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

If any of the following happens, stop taking FLUOXETINE BIOTECH 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 allergic reaction to FLUOXETINE BIOTECH. 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 FLUOXETINE BIOTECH 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.

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.
- 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.

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 **“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 FLUOXETINE BIOTECH.

5. How to store FLUOXETINE BIOTECH

- 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 FLUOXETINE BIOTECH 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 FLUOXETINE BIOTECH looks like and contents of the pack:

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

FLUOXETINE BIOTECH 20 is packed in:

White high-density polyethylene bottles containing 28, 30, 100 or 500 capsules. Or Aluminium foil and clear PVC blisters, packed in outer carton boxes containing 28, 30, 100 or 500 capsules. Not all pack sizes may be marketed.

Holder of certificate of registration and manufacturer:

Biotech Laboratories (Pty) Ltd
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FLUOXETINE BIOTECH 20

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

[5]

FLUOXETINE BIOTECH 20 Kapsules Fluoksetien hidrohloried Bevat suiker (140 mg laktosemonohidraat per kapsule).

- Lees die hele pamflet noukeurig deur voordat jy begin om FLUOXETINE BIOTECH te neem.**
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- FLUOXETINE BIOTECH is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet:

- Wat FLUOXETINE BIOTECH is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy FLUOXETINE BIOTECH neem
- Hoe om FLUOXETINE BIOTECH te neem
- Moontlike nuwe-effekte
- Hoe om FLUOXETINE BIOTECH te bewaar
- Inhoud van die pak en ander inligting

1. Wat FLUOXETINE BIOTECH is en waarvoor dit gebruik word
FLUOXETINE BIOTECH bevat fluoksetien wat behoort aan ’n groep medisyne wat antidepressante genoem word. FLUOXETINE BIOTECH sal die simptome van depressie verlig. Dit kan ook gebruik word om die eetversteuring bulimia nervosa en die toestand obsessiewe-kompulsiewe versteuring te behandel.

- 2. Wat jy moet weet voordat jy FLUOXETINE BIOTECH neem**
Moenie FLUOXETINE BIOTECH neem nie indien jy:
- Allergies is (hipersensitief) vir fluoksetien of enige van die ander bestanddele van FLUOXETINE BIOTECH (gelys in afdeling 6).
 - Neem, of binne die afgelope twee weke enige onomkeerbare, nie-selektiewe monoamienoksidasie-inhibeerders (MAOI’s, bv. iproniasied) geneem het.
 - Metoprolol neem vir hartversaking.
 - Thioridasien neem vir skisofrenie of binne ’n minimum van 5 weke nadat jy opgehou het om FLUOXETINE BIOTECH te neem.
 - Ly aan ernstige nierversaking.
 - ’n Kind is jonger as 18-jarige ouderdom.

- Waarskuwings en voorsorgmaatreëls:**
- Vertel jou dokter voordat jy FLUOXETINE BIOTECH neem indien jy:**
- Aan epilepsie ly of as jy in die verlede ’n aanval gehad het. FLUOXETINE BIOTECH kan die waarskynlikheid van ’n epileptiese aanval verhoog. As jy na die neem van FLUOXETINE BIOTECH vir die eerste keer ’n aanval/stuiptrekking ontwikkel of meer aanvalle as gewoonlik kry, soek mediese advies by jou dokter.
 - ’n Geskiedenis het van geestesongesteldheid bekend as manie of hipomanie.
 - Aan hart-, nier- of lewerprobleme ly.
 - Gloukoom (verhoogde druk in die oog) het.
 - Aan diabetes ly. FLUOXETINE BIOTECH kan jou bloedsuikervlakke verander. Jou dokter sal dalk die dosis van jou insulien of ander diabetesbeheermedisyne moet verander.
 - ’n Geskiedenis het van bloedingsversteurings of ontwikkel onverwagte kneusing, rooiheid onder die vel of bloeding van enige ander deel van die liggaam, of as jy swanger is (sien “Swangerskap en borsvoeding”).
 - Indien jy elektrokonvulsiewe terapie (EKT) ondergaan.
 - Buprenorfien/ naloksoon neem. Die gebruik van hierdie medisyne saam met FLUOXETINE BIOTECH kan lei tot serotoniensindroom, ’n potensieel lewensgevaarlike toestand (sien “Ander medisyne en FLUOXETINE BIOTECH”).

FLUOXETINE BIOTECH sal nie dadelik werk nie:

Sommige mense wat antidepressante gebruik, voel erger voordat hulle beter voel. Jou dokter moet vra om jou weer te sien ’n paar weke nadat jy die eerste keer met behandeling begin het. Vertel jou dokter as jy nog nie beter voel nie.

- Gedagtes van selfmoord en verergering van jou depressie of angsversteuring:*
- Indien jy depressief is en/ of angsversteurings het, kan jy soms gedagtes hê om jouself te beseer of dood te maak. Hierdie gedagtes kan toeneem wanneer die eerste keer om antidepressante begin word, aangesien hierdie medisyne almal tyd neem om te werk, gewoonlik ongeveer twee weke maar soms langer. Jy sal dalk meer geneig wees om so te dink:
- Indien jy voorheen gedagtes gehad het om jouself dood te maak of skade aan te doen.
 - As jy ’n jong volwassene is. Inligting van kliniese proewe het ’n verhoogde risiko van selfmoordgedrag getoon by jong volwassene (jonger as 25 jaar oud) met psigiatriese toestande, wat met ’n antidepressant behandel is.

Indien jy enige tyd gedagtes het om jouself te beseer of dood te maak, kontak jou dokter of gaan dadelik hospitaal toe. Jy sal dit dalk nuttig vind om ’n familielid of goeie vriend te vertel dat jy depressief is of ’n angsversteuring het en hulle te vra om hierdie pamflet te lees. Jy kan hulle vra om vir jou te sê as hulle dink jou depressie of angs word erger, of as hulle bekommerd is oor veranderinge in jou gedrag.

FLUOXETINE BIOTECH kan serotoniensindroom veroorsaak:

Sien afdeling 4. Indien jy koors, spierstyfheid of bewing ervaar, veranderinge in jou geestestoestand soos verwarring, geïrriteerdheid en uiterste woede, vertel jou dokter dadelik.

Indien jy rusteloos begin voel en nie kan stilstif of stilstaan nie (akatisie): Vertel jou dokter. Die verhoging van jou dosis FLUOXETINE BIOTECH kan dit vererger.

FLUOXETINE BIOTECH kan simptome van seksuele disfunksie veroorsaak:

Sien afdeling 4. In sommige gevalle het hierdie simptome voortgeduur nadat behandeling gestaak is.

Kinders en adolessente: FLUOXETINE BIOTECH is nie bedoel vir gebruik by kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en FLUOXETINE BIOTECH: Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

- Moenie FLUOXETINE BIOTECH saam met die volgende neem nie:**
- Onomkeerbare, nie-selektiewe monoamienoksidasie-inhibeerders (MAOI’s, bv. iproniasied).
 - FLUOXETINE BIOTECH moet slegs begin word ten minste 2 weke nadat ’n onomkeerbare nie-selektiewe MAOI gestaak is. Moenie enige onomkeerbare nie-selektiewe MAOI’s neem vir ten minste 5 weke nadat jy opgehou het om FLUOXETINE BIOTECH te neem nie.
 - Metoprolol (gebruik in hartversaking).

Vertel jou dokter of apteker indien jy die volgende neem:

- Medisyne wat die hart se ritme kan beïnvloed, bv. klas IA en III anti-ritmiese, antipsigotika (bv. fenotiasinderivate, pimosied, haloperidol), trisikliese antidepressante, sekere antimikrobiese middels (bv. sparfloksasien, mofloksasien, binne-aarse eritromisien, pentamidien) anti-malaria behandeling, veral halofantrien of sekere antihistamiene (astemisool, misolastien). Die neem van een of meer van hierdie medisyne saam met FLUOXETINE BIOTECH kan die risiko van veranderinge in die elektriese aktiwiteit van die hart verhoog.
- Litium, vir geestesiektes.
- Linesolied en metieltioniniumchloried (metileenblou) monoamienoksidasie-inhibeerders (MAOI’s).
- Nebivolol (gebruik om hoë bloeddruk te behandel).
- Propafenoon of flekainied (gebruik om hartprobleme te behandel).

- Atomoksetien (gebruik om aandagafleibaarheid-hiperaktiwiteitsversteuring (ADHD) te behandel).
- Risperidoon (word gebruik om psigotiese versteurings te behandel).
- Diuretika (watertablette).
- Desmopressien (word gebruik om die hoeveelheid uriene wat deur die niere geproduseer word te verminder).
- Mefloquine, chloroquine (anti-malaria).
- Mequitasien, siproheptadien (antihistamiene).
- Okskarbasepien, karbamasepien of fenitoïen vir epilepsie of ander toestande.
- Enige ander medisyne vir depressie, bv. SSRI’s (selektiewe serotonien heropname inhibeerders).
- Selegilien vir Parkinson se siekte.
- Tramadol vir pynverligting.
- Bupropion (gebruik om op te hou rook).
- Triptane (bv. sumatriptan) vir migraine of troshoofpyn.
- Medisyne om die bloed te verdun (bv. warfarien).
- Niesteroïdale anti-inflammatoriese middels (NSAID’s, bv. ibuprofen) of aspirien (vir pynverligting).
- Triptofaan (’n aminosuur).
- Buprenorfien/ naloksoon (gebruik om opioïed-oordosis te behandel). Hierdie medisyne kan interaksie hê met FLUOXETINE BIOTECH en jy kan simptome ervaar soos onwillekeurige, ritmiese sametrekking van spiere, insluitend die spiere wat beweging van die oog beheer, agitasie, hallusinasies, koma, oormatige sweet, bewing, oordrywing van refleks, verhoogde spierverspanning, liggaamstemperatuur bo 38 °C. Kontak jou dokter wanneer jy sulke simptome ervaar.
- Tamoksifen (gebruik om borskanker te behandel).
- Die kruiemiddel St John’s wort (*Hypericum perforatum*). Dit moet nie op dieselfde tyd as FLUOXETINE BIOTECH geneem word nie. Hou op om die St John’s wort te neem en noem dit by jou volgende besoek aan jou dokter.

FLUOXETINE BIOTECH met kos, drank en alkohol:
Jy moet alkohol vermy terwyl jy FLUOXETINE BIOTECH neem.

Swangerskap, borsvoeding en vrugbaarheid: Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om ’n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy FLUOXETINE BIOTECH neem.

Veilige gebruik tydens swangerskap en borsvoeding is nie vasgestel nie.

Indien jy FLUOXETINE BIOTECH naby die einde van jou swangerskap neem, kan daar ’n verhoogde risiko van swaar vaginale bloeding kort na geboorte wees, veral as jy ’n geskiedenis van bloedingsversteurings het. Jou dokter of vroedvrou moet bewus wees dat jy FLUOXETINE BIOTECH neem sodat hulle jou kan adviseer.

Wanneer dit tydens swangerskap geneem word, veral in die laaste 3 maande van swangerskap, kan FLUOXETINE BIOTECH die risiko van ’n ernstige toestand by babas verhoog, genaamd aanhoudende pulmonale hipertensie van die pasgeborene (PPHN), wat die baba vinniger laat asemhaal en blouerig laat lyk. Hierdie simptome begin gewoonlik gedurende die eerste 24 uur nadat die baba gebore is. Indien dit met jou baba gebeur, moet jy dadelik jou vroedvrou en/ of dokter kontak.

By babas wie se moeders fluoksetien gedurende die eerste paar maande van swangerskap geneem het, was daar sommige verslae wat dui op ’n verhoogde risiko van geboortedefekte wat die hart beïnvloed. In die algemene bevolking word ongeveer 1 uit 100 babas met ’n hartafwyking gebore. Dit het toegeneem tot ongeveer 2 uit 100 babas by moeders wat fluoksetien geneem het.

Daar is getoon dat fluoksetien die kwaliteit van sperm in dierestudies verminder. Dit kan vrugbaarheid beïnvloed, maar impak op menslike vrugbaarheid is nog nie waargeneem nie.

Bestuur en gebruik van masjiene: FLUOXETINE BIOTECH kan jou oordeel of koördinasie beïnvloed. Moenie bestuur of masjinerie gebruik nie, tensy jy seker is dat jy nie geraak word nie.

FLUOXETINE BIOTECH bevat laktosemonohidraat: Indien jy deur jou dokter gesê is dat jy ’n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy FLUOXETINE BIOTECH neem.

3. Hoe om FLUOXETINE BIOTECH te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem FLUOXETINE BIOTECH altyd presies soos jou dokter of apteker vir jou gesê het. Gaan met jou dokter of apteker as jy nie seker is nie.

Die gewone dosis is een (20 mg) tot drie (60 mg) kapsules een keer per dag, afhangend van jou toestand. Sluk die kapsule heel met ’n glas water. As jy aan nier- of lewerprobleme ly of bejaard is, kan jou dokter ’n ander dosis voorskryf.

FLUOXETINE BIOTECH laat jou dalk nie beter voel vir die eerste 2 weke of meer nie. Dit moet geneem word vir so lank as wat jou dokter vir jou vertel.

Indien jy die indruk het dat die effek van FLUOXETINE BIOTECH te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer FLUOXETINE BIOTECH neem as wat jy moet:
In die geval van oordosis, raadpleeg dadelik jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Tekens van ’n oordosis sluit in naarheid, braking, aanvalle, hartprobleme, longprobleme en tekens van veranderde sentrale senuweestelselstatus wat wissel van opwinding tot koma.

Indien jy vergeet om FLUOXETINE BIOTECH te neem: Moenie ’n dubbele dosis neem om ’n vergete dosis in te haal nie. As jy vergeet om ’n dosis te neem, neem dit sodra jy dit onthou en neem dan die volgende dosis op die regte tyd.

Indien jy ophou om FLUOXETINE BIOTECH te neem: Moenie ophou om FLUOXETINE BIOTECH te neem sonder om eers jou dokter te vra nie, selfs wanneer jy beter begin voel. Dit is belangrik dat jy aanhou om jou medisyne te neem. Maak seker dat jou kapsules nie opraak nie.

Jy mag dalk die volgende effekte (onttrekkingsimptome) opmerk wanneer jy ophou om FLUOXETINE BIOTECH te neem: Duiseligheid; tintelende gevoelens soos spelde en naalde; slaapstoornisse (lewendige drome, nagmerries, onvermoë om te slaap); voel rusteloses of opgewonde; ongewone moegheid of swakheid; angstig voel; naarheid/ braking (siek voel of siek wees); bewing (bewerigheid); hoofpyn.

Wanneer jy ophou om FLUOXETINE BIOTECH te neem, sal jou dokter jou help om jou dosis stadig oor een of twee weke te verminder - dit behoort te help om die kans op onttrekkingseffekte te vermind. Die meeste mense vind dat enige simptome by die staking van FLUOXETINE BIOTECH lig is en binne ’n paar weke verdwyn.

Indien jy simptome ervaar wanneer jy behandeling stop, kontak jou dokter onmiddellik.

4. Moontlike nuwe-effekte
FLUOXETINE BIOTECH kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir FLUOXETINE BIOTECH aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy FLUOXETINE BIOTECH neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om FLUOXETINE BIOTECH te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond, tong of keel wat moeilike sluk of moeilike asemhaling mag veroorsaak.
- Uitslag of jeuk.
- Floute.

Hierdie is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk ’n ernstige allergiese reaksie op FLUOXETINE BIOTECH gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- Gedagtes van selfmoord of om jouself seer te maak (sien afdeling 2).
- ’n Kombinasie van simptome (bekend as serotoniensindroom) insluitend onverklaarbare koors met vinniger asemhaling of hartklop, sweet, spierstyfheid of bewing, verwarring, erge opwinding of slaperigheid (sien afdeling 2).
- As jy rusteloos voel en nie kan stilstif of stilstaan nie, kan jy akatisie hê (gevoel van innerlike rusteloosheid, ’n konstante drang om te beweeg); die verhoging van jou dosis FLUOXETINE BIOTECH kan jou erger laat voel. As jy so voel, kontak jou dokter (sien afdeling 2).
- ’n Toestand waar jou liggaam te veel water behou, wat lei tot swakheid, lomerigheid, naarheid en braking, krampe of bewing, verwarring of koma.
- Verminderde seksdrang of seksuele probleme (insluitend probleme om ’n ereksie te handhaaf vir seksuele aktiwiteit), orgasme probleme, aanhoudende pynlike ereksie.
- Onbeheerbare skudbewegings van die mond, tong en ledemate.
- Stuiptrekking (aanvalle).
- Vinnige of onreëlmatige hartklopsensasies. Floute, ineenstorting of duiseligheid wanneer jy staan, kan ’n abnormale funksionering van die hartklop aandui.
- Longprobleme insluitend longontsteking en fibrose (vorming van veselagtige weefsel op die longe). Jy kan kortasem kry voordat jy hierdie tekens van siekte kry.
- Bloeding uit maag of ingewande, bv. swart teeragtige stoelgang, onverklaarbare bloeding of kneusing, koors, seer keel, moegheid wat tekens van verlaagde bloedtellings kan wees.
- Bloeding van slymvliese, bloeding onder die vel.
- Hepatitis (inflammasie van die lewer wat vergeling van die vel of oë of moegheid, pyn in buik, gewrigte of spiere veroorsaak) en tekens soos geelsug (vergeling van die wit van die oë en vel).
- Wydverspreide veluitslag, sirkelvormige, onreëlmatige rooi kolle op die vel van die hande en arms (erythema multiforme).
- Ernstige vorm van veluitslag met blosing, koors, blase of ulkuse (Stevens-Johnson-sindroom).
- Erge uitslag wat rooiheid, afskilfering en swelling van die vel behels wat soos ernstige brandwonde lyk (toksiese epidermale nekrolise).
- Swaar vaginale bloeding kort na geboorte (postpartum bloeding) (sien afdeling 2, “Swangerskap, laktasie en vrugbaarheid”).
- Onvermoë om te urineer, meer gereeld urineer, pynlike urinering.

Hierdie is almal ernstige nuwe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde nuwe-effekte:

- Nie honger voel nie, gewigsverlies.
- Slaapprobleme, ongewone drome, moeilikheid om aan die slaap te raak.
- Senuweeagtigheid, angstigheid, rusteloosheid, swak konsentrasie.
- Gespanne gevoel.
- Duiseligheid, hoofpyn.
- Verandering in smaak.
- Versteurde visie.
- Blosing.
- Gaap.
- Slegte spysvertering, droë mond, naarheid en braking, diarree.
- Uitslag, urtikaria, jeuk.
- Oormatige sweet.
- Gewrigspyn.
- Voel bewierig of koue rillings.
- Gewigsverlies.

Minder gereelde nuwe-effekte:

- Abnormale bloedtoetsresultate.
- Lae vlakke van sout in die bloed.
- Voel ’ontkoppel’ van jouself, vreemde denke, verhoogde bui, hallusinasies (sien of hoor dinge), agitasie, paniekaanvalle, verwarring, hakkel, aggressie.
- Spiertrekking, onwillekeurige bewegings of probleme met balans of koördinasie.
- Geheueverlies of geheueprobleme.
- Vergrote (verwyde) pupille.
- Lui in die ore.
- Lae bloeddruk.
- Inflammasie van die bloedvate (vaskulitis), verbreding van bloedvate (vasodilatasie).
- Seer keel (faringitis).
- Kortasem, neusbloeding.
- Moeilike sluk, pyn in die slukderm (slukdermpyn).
- Haarverlies (tydelik).
- Sensitiwiteit vir sonlig (fotosensitiwiteit).
- Oormatige produksie van borsmelk.
- Koue sweet, warm of koue gevoel.
- Spierpyn.
- Abnorme lewerfunksietoets.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van nuwe-effekte: Indien jy nuwe-effekte kry, praat met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA aanmeld deur die vorm **“Adverse Drug Reaction Reporting Form”**, wat aanlyn onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8. Deur nuwe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van FLUOXETINE BIOTECH te verskaf.

- 5. Hoe om FLUOXETINE BIOTECH te bewaar**
- Bewaar teen of benede 25 °C.
 - BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
 - Moenie gebruik na die vervaldatum wat op die verpakking gedruk is nie.
 - Gee alle ongebruikte medisyne terug aan jou apteker.
 - Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat FLUOXETINE BIOTECH bevat: Die aktiewe bestanddeel is fluoksetien hidrohloried. Elke kapsule bevat 20 mg fluoksetien (as fluoksetien hidrohloried). Die ander bestanddele is laktosemonohidraat, mieliesystel, talk en steariensuur. Die kapsuledop bevat gelatien, patentblou, ysteroksiedgeel, kinoliengeleel, eritrosien, titaandioksied.

Hoe FLUOXETINE BIOTECH lyk en die inhoud van die pak:
Ivoor ondeursigtige lyf, groen ondeursigtige doppie, harde gelatienkapsules. Wit poeier vul.

FLUOXETINE BIOTECH 20 word verpak in: Wit hoëdigtheid poliëtileenbottels wat 28, 30, 100 of 500 kapsules bevat. Of Aluminium foelie en deursigtige PVC-blase, verpak in buitekartonbokse wat 28, 30, 100 of 500 kapsules bevat. Nie alle verpakkingsgroottes word dalk bemark nie.

Houer van die sertifikaat van registrasie en vervaardiger: Biotech Laboratories (Edms) Bpk. Grondvloer, Blok K Wes, Central Park 16^{de} Weg 400, Randjespark, Midrand, 1685 Suid-Afrika Tel. nr.: 011 848 3050

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