

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 health care 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 you 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 antidepressants. 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.
- 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/haloxone. 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 health care 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 health care 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.

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 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 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.
All pack sizes may not necessarily be marketed at one time.

Holder of certificate of registration and manufacturer:

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FLUOXETINE BIOTECH 20

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS

S5

FLUOXETINE BIOTECH 20

Kapsules

Fluoxetienhydrochloride

Bevat suiker (140 mg laktosemonohidraat per kapsule).

Lees hierdie hele blad noukeurig deur voordat u begin om FLUOXETINE BIOTECH te drink.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog enige vrae het, moet u asseblief vir u dokter, apteker of ander gesondheidsorgverskaffer vra.
- FLUOXETINE BIOTECH is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u'sn.

WAT IN HIERDIE BLAD IS:

1. Wat FLUOXETINE BIOTECH is en waarvoor dit gebruik word
2. Wat u moet weet voordat u FLUOXETINE BIOTECH drink
3. Hoe om FLUOXETINE BIOTECH te drink
4. Moontlike newe-effekte
5. Hoe om FLUOXETINE BIOTECH te bêre
6. Inhoud van die pak en ander inliting

1. Wat FLUOXETINE BIOTECH is en waarvoor dit gebruik word

FLUOXETINE BIOTECH bevat fluoxetien, wat aan 'n groep medisyne bekend as antidepressante behoort. FLUOXETINE BIOTECH verlig die simptome van depressie. Dit kan ook gebruik word om die eetversteuring bulimia nervosa en die toestand obsessiewe kompulsiewe versteuring te behandel.

2. Wat u moet weet voordat u FLUOXETINE BIOTECH drink

Moenie FLUOXETINE BIOTECH drink nie as u:

- allergies (hipersensitiviteit) vir fluoxetien of vir enige van die ander bestanddele (gelys in afdeling 6) van FLUOXETINE BIOTECH is.
- enige onkommerbare, nie-selectiewe monoamienoksidase-remmers (MAOR's, bv. iproniasied), drink of dit in die afgelope twee weke gedrink het.
- metoprolol vir hartversaking gebruik.
- erge nierversaking het.
- 'n kind van jonger as 18 jaar oud is.

Waarskuwings en voorsorgmaatreëls:

Sê vir u dokter voordat u FLUOXETINE BIOTECH gebruik as u:

- aan epilepsie ly of u in die verlede 'n aanval gehad het. FLUOXETINE BIOTECH kan die waarskynlikheid vir epileptiese aanvalle verhoog. Raadpleeg u dokter as u nadat u FLUOXETINE BIOTECH vir die eerste keer gedrink het 'n toeval gekry het of meer toevalle as gewoonlik kry.
- 'n geskiedenis van geestesongesteldheid, bekend as manie of hipomanie, het.
- hart-, nier- of leverprobleme het.
- glokuom het (hoe druk in die oë).
- aan diabetes ly. FLUOXETINE BIOTECH kan u bloedsuikervakkie beïnvloed. U dokter moet moontlik die dosis van u insuline of ander medisyne vir beheer van diabetes verander.
- 'n geskiedenis van bloedingstoornisse het of onverwagte knieusplekke, rooiheid onder die vel of bloeding uit enige ander deel van die liggaam kry, of as u swanger is (kyk "SWANGERSKAP EN BORSVOEDING").
- elektrokonvulsieve terapie (EKT) ondergaan.
- buprenorfen/naloksoon gebruik. Die gebruik van hierdie medisyne saam met FLUOXETINE BIOTECH kan lei tot serotoninsindroom, 'n moontlik lewensgevaarlike toestand (kyk "ANDER MEDISYNE EN FLUOXETINE BIOTECH").

FLUOXETINE BIOTECH werk nie dadelik nie:

Party mense wat antidepressante drink, voel erger voordat hulle beter voel. U moet 'n paar weke nadat u met die behandeling begin het, weer na u dokter gaan. Sê vir u dokter as u nog nie beter voel nie.

Gedagtes van selfdood en verergering van u depressie of angsversteuring:

As u depressief is en/of 'n angsversteuring het, kan u soms daaraan dink om selfe te beseer of om die lewe te bring. Hierdie gedagtes kan erger word as u met behandeling met antidepressante begin, aangesien hierdie medisyne tyd neem om te werk, gewoonlik ongeveer twee weke, maar soms langer.

Dit sal meer waarskynlik wees dat u so sal dink:

- As u al voorheen daaraan gedink het om selfe om die lewe te bring of te beseer.
- As u 'n jong volwassene is. Inliting uit kliniese proewe toon 'n hoër risiko vir selfdoodgedrag in jong volwassenes (jonger as 25 jaar) met psigiatrise toestande wat met 'n antidepressant behandel word.
- As u gedagtes het om selfe te beseer of dood te maak, moet u u dokter kontak of dadelik na die naaste hospitaal gaan. U kan dit nuttig vind om vir 'n familielid of 'n goeie vriend te sê dat u depressief is, of dat u 'n angsversteuring het, en vir hulle vra om hierdie blad te lees. U kan hulle vra om vir u te sê as hulle dink dat u depressie of angs erger word, of as hulle bekommend is oor veranderinge in u gedrag.

FLUOXETINE BIOTECH kan die serotoninsindroom veroorsaak:

Kyk afdeling 4. As u koers, spierstykheid of bewegingervaar, veranderinge in u geestestoestand soos verwardheid, prikkelbaarheid en uiterste agitasie, moet u dit onmiddellik vir u dokter sê.

As u rusteloos begin voel en nie kan sit of stilstaan nie (akatisie):

Sê vir u dokter. Die verhoging van u dosis FLUOXETINE BIOTECH kan dit vererger.

FLUOXETINE BIOTECH kan simptome van seksuele disfunksie veroorsaak:

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

Kinders en adolessente:

FLUOXETINE BIOTECH is nie bedoel vir gebruik deur kinders van jonger as 18 jaar nie.

Ander medisyne en FLUOXETINE BIOTECH:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

Moenie FLUOXETINE BIOTECH saam met die volgende drink nie:

- Onkommerbare, nie-selectiewe monoamienoksidase-remmers (MAOR's, bv. iproniasied). FLUOXETINE BIOTECH moet slegs begin word ten minste 2 weke nadat 'n onkommerbare nie-selectiewe MAOR gestaak is. Moenie onkommerbare nie-selectiewe MAOR's gebruik vir ten minste 5 weke nadat u opgehou het om FLUOXETINE BIOTECH te drink nie.
- Metoprolol (vir die behandeling van hartversaking).

Sê vir u dokter of apteker as u die volgende gebruik:

- Medisyne wat die hart se ritme beïnvloed, soos Klas 1A- en III-antidisritmika, antipsigotika (bv. fenotiasienderivate, pimosied, haloperidol), trisikliese antidepressante, sekere antimikrobiële middels (bv. sparflaksasien, moksiflaksasien, IV eritromisin, pentamidien) anti-malariamiddels, veral halofantropin, of sekere antihistaminiene (bv. astemisool, misolastien). Deur een of meer van hierdie middels saam met FLUOXETINE BIOTECH te gebruik, kan die risiko van veranderinge in die elektriese aktiwiteit van die hart verhoog word.
- Lithium, vir geestesongesteldheid.
- Linesoledien en metieltoniniumchlorid- (metileenblou) tipe monoamienoksidaserremmers (MAOR's).

- Nebivolol (om hoë bloeddruk te behandel).
- Propafenoon of flekainied (om hartprobleme te behandel).
- Atomosketien (om aandagsgevoeligheid hiperaktiwiteitsversteuring ("ADHD") te behandel).
- Risperidon (vir psigotiese afwykings).
- diureтика (waterpille)
- Desmopressien (om die hoeveelheid urien wat deur die niere geproduceer word te verminder).
- Meflokiën, chlorokinen (teen malaria).
- Mekitisien, siproheptadien (antihistaminiene).
- Okskarbasepien, karbaamasepien of fenitoïen vir epilepsie of ander toestande.
- Enige ander medisyne vir depressie, bv. SSRI's (selektyiewe serotoninerheropnameremmers).
- Selegilien vir Parkinson se siekte
- Tramadol vir pynverligting.
- Bupropioen (om te help om op te hou rook).
- Triptane (bv. sumatriptaan) vir migraine of troshoofpyn.
- Medisyne om bloed dun te maak (bv. warfarien).
- Nie-steroidi anti-inflammatoire middels (NSAIDs, bv. ibuprofeen) of aspirien (vir pynverligting).
- Triptofaan ('n aminosuur).
- Buprenorfen/naloksoon (om 'n oordosis opioïede te behandel). Hierdie medisyne kan interaksie hê met FLUOXETINE BIOTECH en kan simptome ervaar soos onwilkeurige, ritmiese sametrekking van spiere, waaronder die spiere wat die beweging van die oog beheer, agitasie, hallusinasies, coma, oormatige sweet, bewing, oormatige refleksie, hoë spierspanning, liggaamstemperatuur bo 38 °C. Skakel u dokter as u sulke simptome ervaar.
- Tamoksefine (om borskanker te behandel)
- Die kruimeddel Sint Janskruid *Hypericum perforatum* ("St John's Wort") Dit moet nie gebruik nie omdat dit tyd as FLUOXETINE BIOTECH gebruik word nie. Hou op om die Sint Janskruid te gebruik en sê dit met u volgende besoek aan u dokter.

FLUOXETINE BIOTECH saam met kos, drank en alkohol:

U moet alkohol vermy terwyl u FLUOXETINE BIOTECH drink.

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of borsvoed, dink dat u daar swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidspraktisits om advies raadpleeg voordat u FLUOXETINE BIOTECH drink. Veilige gebruik van FLUOXETINE BIOTECH tydens swangerskap en borsvoeding is nie bepaal nie. As u FLUOXETINE BIOTECH teen die einde van u swangerskap drink, kan die risiko vir swaar vaginale bloeding kort na die geboorte hoë wees,veral as u 'n geskiedenis van bloedingsversteurings het. U dokter of vroedvrou moet weet dat u FLUOXETINE BIOTECH drink, sodat hulle u kan adviseer. In dierestudies is getoon dat FLUOXETINE BIOTECH die kwaliteit van sperms verlaag. Dit kan vrugbaarheid beïnvloed, maar die impak op die vrugbaarheid van mense is nog nie waargeneem nie.

Motorbestuur en gebruik van masjinerie:

FLUOXETINE BIOTECH kan u oordeel of koördinasie beïnvloed. Moenie 'n voertuig bestuur of masjine gebruik nie tensy u seker is dat u nie aangetas word nie.

FLUOXETINE BIOTECH bevat laktosemonohidraat:

As u dokter vir u gesê het dat u 'n onverdraagbaarheid vir sekere suikers het, moet u u dokter skakel voordat u FLUOXETINE BIOTECH drink.

3. Hoe om FLUOXETINE BIOTECH te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Gebruik FLUOXETINE BIOTECH altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Die gewone dosis is een (20 mg) tot drie (60 mg) kapsules een keer per dag, afhangende van u toestand.

Sluk die kapsule heel met water af.

As u nier- of leverprobleme het of bejaard is, kan u dokter 'n ander dosis voorschryf.

Dit kan wees dat FLUOXETINE BIOTECH in u die eerste 2 weke of langer nie beter laat voel nie.

Dit moet gedrink word vir so lank as wat u dokter sê.

Sê vir u dokter of apteker as u die indruk het dat die effek van FLUOXETINE BIOTECH te sterk of te swak is.

As u meer FLUOXETINE BIOTECH gedrink het as wat u moes:

Raadpleeg u dokter of apteker onmiddellik in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Tekens van 'n oordosis is onder meer naarheid, braking, toevalle, hartprobleme, longprobleme en tekens van 'n veranderde status van die sentrale senuwestelsel, wat wissel van opwindig tot komata.

As u vergeet om FLUOXETINE BIOTECH te drink:

Moenie 'n dubbele dosis drink om vir 'n vergeete dosis op te maak nie. As u vergeet om 'n dosis te drink, drink dit sodas as wat u onthou en druk die volgende dosis dan op die regte tyd.

As u ophou om FLUOXETINE BIOTECH te drink:

Moenie 'n ophou om FLUOXETINE BIOTECH te drink sonder om eers u dokter te vra nie, selfs al begin u beter voel. Dit is belangrik dat u moet aanhou om u medisyne te drink. Maak seker dat u kapsules nie opraak nie.

U kan die volgende effekte (onttrekkingssimptome) opmerk as u ophou om FLUOXETINE BIOTECH te drink: Duiselheid, tintelende gevoel soos naalde en spelde, slaapstoornisse (helder drome, nagmerries, onvermoë om te slap), voel rusteloos of opgewonde, ongewone moegheid van swakhed, voel angstig, naarheid/breaking (voel naar), bewing (bewerigheid), hoofpyn.

As u ophou om FLUOXETINE BIOTECH te drink, sal u dokter u help om u dosis oor een of twee weke stadiig te verminder - dit behoort die kans op ontrekkingseffekte te verlaag. Die meeste mense vind dat alle simptome vanwee staking van FLUOXETINE BIOTECH lig en binne 'n paar weke verdwyn.

As u simptome ervaar wanneer u die behandeling staak, moet u u dokter onmiddellik skakel.

4. Moontlike newe-effekte

FLUOXETINE BIOTECH kan newe-effekte hê.

Nie al die newe-effekte wat vir FLUOXETINE BIOTECH aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u FLUOXETINE BIOTECH gebruik, moet u u dokter, apteker of ander gesondheidskundige om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om FLUOXETINE BIOTECH te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe, mond, tong of keel wat probleme met sluk of asemhalings kan veroorsaak.
- Velutslag of jeuk.
- Floutes.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksié op FLUOXETINE BIOTECH het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- Gedagtes van selfdood en verergering van u depressie of angsversteuring.
- 'n Kombinasie van simptome (bekend as die serotoniensindroom), waaronder onverklaarbare koers met vinniger asemhaling of hartklop, sweet, spierstykheid of bewing, verwardheid, uiterste opwindigheid van slaperigheid (kyk afdeling 2).
- As u rusteloos voel en nie stilletjie of stilstand nie, kan u 'n akatisie hê (gevoel van innerlike rusteloosheid, 'n konstante drang om te beweeg); as u dus FLUOXETINE BIOTECH verhoog, kan u erger voel. As u so voel, skakel u dokter (kyk afdeling 2).
- 'n Toestand waarin u liggaaam te veel water hou, wat lei tot swakhed, loemerigheid, naarheid en braking, krampe of bewing, verwardheid of koma.
- Laer sekse drang of seksuele probleme (waaronder probleme met die behoud van 'n ereksie vir seksuele aktiwiteit), orgasme-probleme, aanhoudende pynlike ereksie.

- Onbeheerbare bewegings van die mond, tong en ledemate.
- Toevalle (stuiptrekkings).
- Gevoel van vinnige of onregmatige hartklop. Floutes, ineenstorting of duiselheid wanneer staande kan dui op 'n abnormale werking van die hart.
- Longprobleme, waaronder longontsteking en fibrose (vorming van veselweefsel op die longe). U kan kortasem raak voordat u hierdie tekens van n siekte ervar.
- Bloeding uit die maag of ingewande, bv. swart teeragtige stoelgang, onverklaarbare bloeding van knieusplekke, koers, keelseer, moegheid wat tekens van lae bloedstelling kan wees.
- Bloeding van slymvliese, bloeding onder die vel.
- Hepatitis (ontsteking van die lever wat geel verkleuring van die vel of oë of moegheid veroorsaak, pyn in die buik, gewrigte of spiere) en tekens soos geelsug (geel verkleuring van die wit van die oë en vel).
- Wydverspreide veluitslag, sirkelvormige, onregmatige rooi kolle op die vel van die hande en arms (multiforme eriteme).
- Erge vorm van 'n veluitslag met gloede, koers, blase of maagserre (Stevens-Johnson syndroom).
- Erge uitslag wat rooiheid, afskilfering en swelling van die vel behels wat soos erge brandwondes ly (toksiese epidermale nekrolise).
- Swaar vaginale bloeding kort na geboorte (postpartumbloeding) (kyk afdeling 2, "SWANGERSKAP, BORSVOEDING EN VRUGBAARHEID").
- Onvermoë om te urineer, urineer meer dikwels, pynlike urinering.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Nie honing nie, gewigswierles.
- Slaapprobleme, ongewone drome, sukkel om aan die slaap te raak.
- Senueegtheid, angst, rusteloosheid, swak konsentrasie.
- Gevoel gespanne.
- Duiselheid, hoofpyn.
- Verandering in smaak.
- Dowwe visie.
- Blosing.
- Gaap.
- Slegte spysvertering, droë mond, naarheid en braking, diarree.
- Velutslag, urticarie, gejeuk.
- Oormatige sweet.
- Gewrigspyn.
- Voel bewerig of kouekroers.
- Gewigswierles.
- Newe-effekte wat minder dikwels voorkom:
- Abnormale uitslae van bloedtoetse.
- Lae vlakte sou in die bloed.
- Voel los van jouself, vreemde denke, vrolike bui, hallusinasies (dinge sien of hoor), agitasie, paniekaanvalle, verwardheid, hakkel, aggressie.
- Spiertrekkings, onwillekeurige bewegings of probleme met balans of koördinasie.
- Geheueverlies of geheueprobleme.
- Vergrote (gedilateerde) oogpupille.
- Gelui in die ore.
- Lae bloeddruk.
- Ontsteking van die bloedvate (vaskulitis), verwyding van bloedvate (vasodilatasie).
- Keelsel, horensel, neusbloeding.
- Sukkel om te sluk, pyn in die slukderm (slukdermpyn).
- Haarverlies (tydelyk).
- Sensitiviteit vir sonlig (photosensitiviteit).
- Oormatige produksie van borsmelk.
- Koue sweet, voel warm of koud.
- Spierpyn.
- Abnormale uitslae van leverfunksietoets.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of asseblief in kennis stel.

Anmeld van newe-effekte:

Praat met u dokter of apteker as u newe-effekteervaar. U kan newe-effekte ook by SAHPRA anmeld via die vorm "6.04 Adverse Drug Reaction Reporting Form" wat aanlyn by SAHPRA se publikasies gekry kan word: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van FLUOXETINE BIOTECH te gee.

5. Hoe om FLUOXETINE BIOTECH te bêre

• Bêre by of onder 25 °C.

• HOU ALLE MEDISYNE BIJTE BEREIK VAN KINDERS.

• Moenie na die vervaldaatum op