SCHEDULING STATUS: S5

PROPRIETARY NAME AND DOSAGE FORM:
FLUOXETINE 20 OETHMAAN Capsules

COMPOSITION:
Each **FLUOXETINE 20 OETHMAAN Capsule** contains:
fluoxetine hydrochloride equivalent to 20 mg fluoxetine.
Sugar free.

EXCIPIENTS:
Microcrystalline cellulose, pregelatinised starch, talc, gelatin capsule shell.

PHARMACOLOGICAL CLASSIFICATION
A 1.2 Psychoanaleptics (antidepressants)

PHARMACOLOGICAL ACTION:
Pharmacodynamic Properties
Fluoxetine is a selective serotonin (5-HT) uptake inhibitor in the central nervous system.
The antidepressant and anti-obsessive-compulsive effects of fluoxetine are thought to be related to its effect on serotonergic neurotransmission.

Pharmacokinetic Properties:
Fluoxetine is well absorbed after oral administration and metabolised by demethylation in the liver to the active metabolite, norfluoxetine, and other unidentified metabolites.
The involvement of cytochrome P450 2D6 (CYP2D6) has been identified in fluoxetine metabolism. The elimination half-life of fluoxetine is 4 to 6 days, whereas that of the active metabolite, norfluoxetine, is 4 to 16 days. Excretion is about 80 % renal andapproximately 15 % in the faeces.

Pharmacode Reading Direction

2124

INDICATIONS:
FLUOXETINE 20 OETHMAAN is indicated for the treatment of:
- Major depressive disorders
- Obsessive-compulsive disorder
- Bulimia nervosa

CONTRA-INDICATIONS:
- Hypersensitivity to fluoxetine or to any of the ingredients.
- **Concomitant use of a monoamine oxidase inhibitor (MAOI).**

At least 14 days should elapse between discontinuing a MAOI and initiating therapy with **FLUOXETINE 20 OETHMAAN.** In view of the long half-life of **FLUOXETINE 20 OETHMAAN** at least 5 weeks should elapse after stopping therapy with **FLUOXETINE 20 OETHMAAN** before starting a MAOI. If **FLUOXETINE 20 OETHMAAN** has been prescribed chronically and/or at a high dose, a longer interval should be considered.
There have been reports of serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, the serotonin syndrome, autonomic instability with possible rapid fluctuations of vital signs and mental status changes that include extreme agitation, progressing to delirium and coma in patients receiving **FLUOXETINE 20 OETHMAAN** with a MAOI and in patients who have recently discontinued **FLUOXETINE 20 OETHMAAN** and are then started on a MAOI. Serious and fatal cases of the serotonin syndrome, some with features resembling neuroleptic malignant syndrome, have been reported in patients treated with **FLUOXETINE 20 OETHMAAN** and a MAOI in temporal proximity (see **"Warnings and Special Precautions"**).
- Severe renal function impairment (GFR < 10 ml/min), as accumulation may occur during chronic treatment.

WARNINGS AND SPECIAL PREAUTIONS:
The serotonin syndrome- characterised by the clustering of clinical features of changes of mental state (agitation, confusion, disorientation) and neuromuscular activity (myoclonus, hyper-reflexia, tremor, rigidity, incoordination), in combination with auto-immune dysfunction (especially fever, sweating, diarrhoea) – may occur in patients who receive **FLUOXETINE 20 OETHMAAN** either alone or in temporal association with the use of a MAOI and other selective serotonin re-uptake inhibitors (SSRIs) or serotonergic agents. Since death and serious morbidity may follow the serotonin syndrome, **FLUOXETINE 20 OETHMAAN** should be stopped.
FLUOXETINE 20 OETHMAAN should be discontinued in patients who develop a rash or other allergic reactions. Anaphylactoid reactions and serious systemic events involving the skin, kidney, liver or lung have been reported in patients receiving **FLUOXETINE 20 OETHMAAN.**
Patients with major depressive disorder, both adults and children, may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicines in inducing such behaviour has not been established. Patients being treated with **FLUOXETINE 20 OETHMAAN** should, nevertheless be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy, or at any time of dose changes, either increases or decreases.
Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorder should be observed when treating patients with other psychiatric and non-psychiatric disorders.
The following symptoms have been reported in patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility (aggressiveness, impulsivity, akathisia, hypomania, and mania). Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, consideration should be given to changing the therapeutic regimen, including possibly discontinuing **FLUOXETINE 20 OETHMAAN**, in patients for whom such symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.
If the decision is made to discontinue treatment, **FLUOXETINE 20 OETHMAAN** should be tapered.
Close monitoring of patients during the first two or more weeks of treatment with **FLUOXETINE 20 OETHMAAN** is recommended, as improvement may not occur during this period. Close supervision of high risk patients, e.g. patients with suicidal tendencies due to major depressive episodes, is recommended.
The same precautions observed when treating patients with depression should be applied when treating patients with obsessive–compulsive disorders, as co-morbidity between these conditions is well established.

FLUOXETINE 20 OETHMAAN should be given with caution in:
- Patients with a history of seizures – there is an increased risk of seizures. **FLUOXETINE 20 OETHMAAN** should be discontinued in any patient who develops a seizure and should be avoided in those with unstable epilepsy. Patients with controlled epilepsy should be carefully monitored. Care is advised in patients receiving electroconvulsive therapy, as prolonged seizures have been reported in patients on **FLUOXETINE 20 OETHMAAN.**
- Hepatic function impairment – metabolism may be delayed. Lower doses or less frequent dosing is recommended in patients with significant hepatic impairment.
- Renal function impairment – metabolites may accumulate. Dose adjustment may be necessary in mild to moderate renal failure (GFR 10 to 50 ml/min).
- Underweight individuals - **FLUOXETINE 20 OETHMAAN** may cause weight loss.
- Diabetes mellitus – glycaemic control may be altered. Insulin and/or oral hypoglycaemic medication dosage may need to be adjusted.
- Patients with a history of bleeding disorders such as altered platelet function – there have been reports of abnormal bleeding.
- Patients with extrapyramidal disorders – **FLUOXETINE 20 OETHMAAN** may cause extrapyramidal symptoms and aggravation of Parkinson's disease.
- Patients with acute cardiac disease – clinical experience is limited.

Withdrawal symptoms - including dizziness, paraesthesia, headache, insomnia, tremor, confusion, sensory disturbances, agitation, anxiety and nausea - may occur with discontinuation of **FLUOXETINE 20 OETHMAAN.**

EFFECTS ON THE ABILITY TO DRIVE AND USE OF MACHINES
FLUOXETINE 20 OETHMAAN may impair the ability to perform activities requiring mental alertness or physical coordination (e.g. operating machinery, driving a motor vehicle). Patients should be cautioned that their ability to perform potentially hazardous tasks may be impaired.

INTERACTIONS:
Due to the long elimination half-life of **FLUOXETINE 20 OETHMAAN** and norfluoxetine, the potential for interactions exist not only with concomitantly administered medicines but also with medicines administered several weeks after discontinuation of **FLUOXETINE 20 OETHMAAN** therapy.
- Monoamine oxidase inhibitors (see "Contraindications")
- Medicines metabolised by cytochrome P450 CYP2D6 – **FLUOXETINE 20 OETHMAAN** is an inhibitor of cytochrome P450 CYP2D6. There is potential for interaction with other medicines that are metabolised by this enzyme, therefore a reduction in the dosage of such medicines, with initiation of therapy at the low dose range for medicines having a relatively narrow therapeutic index, may be needed when used concurrently with **FLUOXETINE 20 OETHMAAN** or within 5 weeks of discontinuing **FLUOXETINE 20 OETHMAAN.**
- CNS active medicines:
  - Lithium – both increased and decreased concentrations of lithium have been reported when used concurrently with **FLUOXETINE 20 OETHMAAN.** Close monitoring of lithium levels is recommended.
  - Phenytoin, carbamazepine, haloperidol, clozapine, diazepam, alprazolam, imipramine and desipramine – changes in blood levels, sometimes with clinical manifestations of toxicity, have been reported when these medicines are used concomitantly with **FLUOXETINE 20 OETHMAAN.** The use of conservative titration schedules of these medicines and monitoring of clinical status should be considered. The half-life of concurrently administered diazepam may be prolonged.
  - Tryptophan – adverse reactions, including agitation, restlessness and gastrointestinal distress have been reported when **FLUOXETINE 20 OETHMAAN** has been used in combination with tryptophan.
  - Protein bound medicines – as **FLUOXETINE 20 OETHMAAN** is bound to plasma protein, its plasma concentration or that of other protein bound medicines such as warfarin and digoxin could be altered when used concomitantly. Altered anti-coagulant effects (laboratory values and/or clinical signs and symptoms) and increased bleeding has been reported when warfarin and fluoxetine are given concurrently. Careful coagulation monitoring is recommended in this case and when **FLUOXETINE 20 OETHMAAN** is discontinued.

HUMAN REPRODUCTION:
Safety and efficacy in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Safety and efficacy of **FLUOXETINE 20 OETHMAAN** in children has not been established.
FLUOXETINE 20 OETHMAAN can be administered with or without food. Avoid use of alcohol.
For patients who have concurrent illnesses or hepatic impairment, a lower dose or less frequent dosing should be considered.
Major depressive disorders:
Adults: 20 mg daily, preferably in the morning.
Obsessive-compulsive disorder:
Adults: 20 to 60 mg daily.
Bulimia nervosa: *Adults*: 60 mg daily.
Due to the pharmacokinetic properties of **FLUOXETINE 20 OETHMAAN**, upward dose titration is advised at intervals of several weeks. Doses above 80 mg daily are not recommended for any of the indications.
Elderly- **FLUOXETINE 20 OETHMAAN** should be used with caution in the elderly: dosages above 20 mg daily are not recommended.

SIDE EFFECTS:
Cardiovascular system:
Less frequent: palpitations.
Central nervous system: Frequent: headache, nervousness, anxiety, drowsiness.
Less frequent: fatigue, insomnia, tremor, asthenia, dizziness, abnormal dreams, agitation, seizures, hypomania, mania, dyskinesias.
Endocrine/metabolic:
Frequent: weight loss.
Less frequent: hyponatraemia, hypothyroidism, fever.
Gastrointestinal:
Frequent: diarrhoea, nausea, dyspepsia, anorexia, vomiting.
Less frequent: dry mouth.
Kidney/genitourinary:
Frequent: decreased libido, sexual dysfunction (delayed or inhibited orgasm).
Liver: raised transaminase levels.
Musculoskeletal system: arthralgia, myalgia.
Ocular: visual disturbances.
Respiratory tract: dyspnoea, pulmonary inflammation and/or fibrosis.
Skin:
Frequent: rash, urticaria, pruritus, excessive sweating.
Less frequent: anaphylactoid reactions, serum sickness.
Other: The following have been reported in association with **FLUOXETINE 20 OETHMAAN**, but no causal relationship has been established: aplastic anaemia, cerebral vascular accident, confusion, ecchymoses, eosinophilic pneumonia, gastrointestinal haemorrhage, hyperprolactinaemia, neuroleptic malignant syndrome-like events, pancreatitis, suicidal ideation, pancytopenia, thrombocytopenia, purpura, immune-related haemolytic anaemia, vaginal bleeding (after withdrawal of the medication) and violent behaviour.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: (See **"SIDE EFFECTS AND SPECIAL PRECAUTIONS"**).
Symptoms of overdose:
Symptoms that have been reported include tachycardia, drowsiness, tremor, nausea and vomiting as well as agitation, restlessness, hypomania and seizures.
Treatment of overdose: Treatment is symptomatic and supportive. There is no specific antidote for **FLUOXETINE 20 OETHMAAN** overdose. Dialysis, haemoperfusion, exchange transfusion and measures to increase urine production are considered unlikely to be of benefit. Activated charcoal may be given by mouth if the amount ingested was large and treatment is within an hour of ingestion.

IDENTIFICATION:
FLUOXETINE 20 OETHMAAN Capsules have an opaque ivory body and an opaque green cap. Capsules contain a white to off-white crystalline powder.

PRESENTATIONS:
Blister packs, sealed aluminium bags or securitainers of 28, 30 or 100 capsules.
Blister packs or securitainers of 120 or 300 capsules.

STORAGE INSTRUCTIONS:
Store below 25 °C. Protect from moisture.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER: 32/1.2/0040

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Oethmaan Biosims (Pty) Ltd
1st Floor
207A Sherwood House
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Johannesburg
2195

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I828002

500 mm

130 mm

SKEDULERINGSTATUS: S5

EIENDOMSNAAM EN DOSEERVORM
FLUOXETINE 20 OETHMAAN kapsules

SAMESTELLING
Elke kapsule bevat fluoksetienhidrochloried gelykstaande aan 20 mg fluoksetien.
Suikervry.
Hulpstowwe: mikrokristallyne sellulose, voorafgeswelde stysel, talk, gelatienkapsuledop

FARMAKOLOGIESE KLASSIFIKASIE
A.1.2 Psigoanaleptika (antidepressante)

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Fluoksetien is 'n selektiewe serotonienheropnameremmer (5-HT) in die sentrale senustelsel.
Dit word gereken dat die effek van fluoksetien as antidepressant en as middel teen obsessiewe kompulsiewe gedrag verband hou met die effek daarvan op serotonergiese neurotransmissie.

Farmakokinetiese eienskappe
Fluoksetien word na orale toediening goed geabsorbeer en deur demetilering in die lewer na die aktiewe metaboliet norfluoksetien en ander ongeïdentifiseerde metaboliete omgeskakel.
Die betrokkenheid van sitochroom P450 2D6 (CYP2D6) is in die metabolisme van fluoksetien geïdentifiseer. Die eliminasiehalfleeftyd van fluoksetien is 4 tot 6 dae terwyl dié van die aktiewe metaboliet norfluoksetien, 4 tot 16 dae is. Ongeveer 80% word deur die niere en ongeveer 15% in die feses uitgeskei.

Pharmacode Reading Direction

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INDIKASIES
FLUOXETINE 20 OETHMAAN is aangedui vir die behandeling van:
- Major depressiewe versteurings
- Obsessiewe kompulsiewe versteuring
- Bulimia nervosa

KONTRA-INDIKASIES
- Hipersensitiwiteit teenoor fluoksetien of enige van die bestanddele
- **Gelyktydige gebruik van 'n monoamienoksidaseremmer (MAOR)**

Ten minste 14 dae moet verloop na staking van 'n MAOR en begin van behandeling met **FLUOXETINE 20 OETHMAAN.** Vanweë die lang halfleeftyd van **FLUOXETINE 20 OETHMAAN** moet ten minste 5 weke verloop na staking van behandeling met **FLUOXETINE 20 OETHMAAN** voordat met 'n MAOR begin kan word. As **FLUOXETINE 20 OETHMAAN** chronies en/of teen 'n hoë dosis gegee is, moet 'n langer interval oorweeg word.
Daar was verslae van ernstige, soms dodelike, reaksies waaronder hipertermie, rigiditeit, mioklonus, die serotoniensindroom, outonome onstabiliteit met moontlike skielike fluktuasies in vitale tekens en veranderings in mentale status wat ekstreme agitasie insluit wat vorder tot delirium en koma in pasiënte wat **FLUOXETINE 20 OETHMAAN** saam met 'n MAOR ontvang en in pasiënte wat **FLUOXETINE 20 OETHMAAN** pas tevore gestaak het en dan met 'n MAOR begin het. Ernstige en dodelike gevalle van die serotoniensindroom, party met kenmerke soortgelyk aan dié van die neuroleptiese kwaadaardige sindroom, is aangemeld in pasiënte wat in 'n kort tydsbestek met **FLUOXETINE 20 OETHMAAN** en 'n MAOR behandel is (kyk **WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS**).
- Erge swak nierfunksie (GFT < 10 ml/min) omdat akkumulasie tydens chroniese behandeling kan voorkom.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREëLS
Die serotoniensindroom- gekenmerk deur die opeenhoping van kliniese tekens van veranderings in verstandelike toestand (agitasie, verwardheid, disoriëntasie) en neuromuskulêre aktiwiteit (mioklonus, hiperrefleksie, tremor, rigiditeit, inkoördinasie) in kombinasie met outo-immuundisfunksie (veral koors, sweet, diarree) – kan voorkom in pasiënte wat **FLUOXETINE 20 OETHMAAN** óf alleen óf kort na die gebruik van 'n MAOR of ander selektiewe serotonienheropnameremmers (SSHR's) of serotonergiese middels ontvang. Omdat dood en ernstige morbiditeit op die serotoniensindroom kan volg, moet **FLUOXETINE 20 OETHMAAN** gestaak word.
FLUOXETINE 20 OETHMAAN moet gestaak word vir pasiënte wat veluitslag of ander allergiese reaksies ontwikkel. Anafilaktiese reaksies en ernstige sistemiese effekte wat die vel, niere, lewer of longe betrek, is aangemeld in pasiënte wat **FLUOXETINE 20 OETHMAAN** ontvang het.
Pasiënte met major depressie, volwassenes sowel as kinders, kan 'n verergering van hulle depressie en/of selfdoodgedagtes en -gedrag ervaar of hulle antidepressante gebruik of nie. Hierdie risiko kan voortduur totdat beduidende remissie voorkom. 'n Oorsakende rol van antidepressante vir sulke gedrag is egter nie bepaal nie. Pasiënte wat met **FLUOXETINE 20 OETHMAAN** behandel word, moet nogtans noukeurig dopgehou word vir 'n kliniese verergering en selfmoordneigings, veral aan die begin van 'n kursus van behandeling of enige tyd wanneer die dosis aangepas word, hetsy dit verhoog of verlaag word.
Vanweë die moontlikheid dat major depressiewe versteurings en ander psigiatriese en niepsigiatriese versteurings selfdoodneigings kan versterk, moet dieselfde voorsorgmaatreëls getref word wanneer pasiënte met 'n major depressiewe versteuring behandel word as wanneer pasiënte met ander psigiatriese en niepsigiatriese versteurings behandel word.
Die volgende simptome is aangemeld in pasiënte wat met antidepressante vir major depressiewe versteurings asook vir ander indikasies, psigiatries sowel as niepsigiatries, behandel is: angs, agitasie, paniekaanvalle, slaaploosheid, geïrriteerdheid, vyandigheid (aggressiwiteit), impulsiwiteit, akatisie, hipomanie en manie. Hoewel die oorsakende verband tussen die ontstaan van sulke simptome en/of die verergering van depressie en/of die ontstaan van selfmoordneigings nie bepaal is nie, moet oorweeg word om die terapeutiese regimen te verander, waaronder moontlike staking van **FLUOXETINE 20 OETHMAAN** vir pasiënte wie se simptome erg is, skielik ontstaan of waar dit nie deel van die pasiënt se aanvanklike simptome was nie.
As besluit word om behandeling te staak, moet **FLUOXETINE 20 OETHMAAN** geleidelik afgeskaal word.
Noukeurige monitering van pasiënte tydens die eerste twee of meer weke van behandeling met **FLUOXETINE 20 OETHMAAN** word aanbeveel omdat dit kan wees dat geen verbetering in hierdie tydperk intree nie. Noukeurige toesig van pasiënte met hoë risiko, bv. pasiënte met selfmoordneigings vanweë major depressiewe episodes, word aanbeveel.
Dieselfde voorsorgmaatreëls wat getref word as pasiënte met depressie behandel word, moet toegepas word as pasiënte met obsessiewe kompulsiewe versteurings behandel word, omdat gesamentlike morbiditeit van hierdie toestande goed bekend is.

FLUOXETINE 20 OETHMAAN moet versigtig gebruik word in gevalle van:
- Pasiënte met 'n geskiedenis van toevalle – daar is 'n hoër risiko vir toevalle. **FLUOXETINE 20 OETHMAAN** moet gestaak word vir pasiënte wat 'n toeval ontwikkel en moet vermy word vir diegene met onstabiele epilepsie. Pasiënte met beheerde epilepsie moet noukeurig gemonitor word. Wees versigtig met pasiënte wat elektrokonvulsiewe behandeling ontvang, omdat langdurige toevalle gerapporteer is in hierdie pasiënte wat **FLUOXETINE 20 OETHMAAN** gebruik.
- Swak lewerfunksie – metabolisme kan stadiger wees. Laer dosisse of langer doseerintervalle word aanbeveel vir pasiënte met beduidende swak lewerfunksie.
- Swak nierfunksie – metaboliete kan opbou. 'n Aanpassing in die dosis kan nodig wees vir pasiënte met ligte tot matige nierversaking (GFT 10 – 50 ml/min).
- Persone wat ondergewig is – **FLUOXETINE 20 OETHMAAN** kan gewigsverlies veroorsaak.
- Diabetes mellitus – beheer oor suiker kan aangetas wees. Dit mag nodig wees om die dosis van insulien en/of orale hipoglisemiese medikasie aan te pas.
- Pasiënte met 'n geskiedenis van bloedingsversteuring soos veranderde plaatjiefunksie – daar was verslae van abnormale bloeding.
- Pasiënte met ekstrapiramidale versteurings – **FLUOXETINE 20 OETHMAAN** kan ekstrapiramidale simptome veroorsaak en Parkinson se siekte vererger.
- Pasiënte met akute hartsiekte – kliniese ervaring is beperk.

Onttrekkingsimptome – waaronder duiseligheid, parestesie, hoofpyn, slaaploosheid, tremor, verwardheid, versteurings in sensasie, agitasie, angs en naarheid – kan na staking van **FLUOXETINE 20 OETHMAAN** voorkom.

Effek op die vermoë om motor te bestuur of masjinerie te hanteer
FLUOXETINE 20 OETHMAAN kan die vermoë aantas om aktiwiteite uit te voer wat verstandelike wakkerheid of fisiese koördinasie vereis (soos om masjinerie te hanteer of 'n voertuig te bestuur). Pasiënte moet gewaarsku word dat hul vermoë om potensieel gevaarlike take uit te voer, aangetas kan wees.

INTERAKSIES
Vanweë die lang eliminasiehalfleeftyd van **FLUOXETINE 20 OETHMAAN** en norfluoksetien is daar nie net 'n moontlikheid vir interaksies met middels wat terselfdertyd toegedien word nie, maar ook met medisyne wat etlike weke na staking van behandeling met **FLUOXETINE 20 OETHMAAN** toegedien word.
- Monoamienoksidaseremmers (kyk "**KONTRA-INDIKASIES**")
- Medisyne wat deur sitochroom P450 CYP2D6 gemetaboliseer word – **FLUOXETINE 20 OETHMAAN** is 'n remmer van sitochroom P450 CYP2D6. Daar is 'n moontlikheid van interaksie met ander medisyne wat deur hierdie ensiem gemetaboliseer word en daarom kan 'n verlaging in die dosis van sulke medisyne nodig wees, terwyl behandeling met medisyne wat 'n relatief nou terapeutiese indeks het teen lae dosisse moet begin as dit saam met **FLUOXETINE 20 OETHMAAN** of binne 5 weke na staking van **FLUOXETINE 20 OETHMAAN** gebruik word.
- Medisyne wat op die SSS werk:
- Litium – sowel hoër as laer konsentrasies litium is aangemeld as dit saam met **FLUOXETINE 20 OETHMAAN** gebruik word. Noukeurige monitering van die litiumvlakke word aanbeveel.
- Fenitoïen, karbaamasepien, haloperidol, klosapien, diasepaam, alprasolaam, imipramien en desipramien – veranderings in bloedvlakke, soms met kliniese manifestasies van toksisiteit, is aangemeld toe hierdie medisyne saam met **FLUOXETINE 20 OETHMAAN** gebruik is. Konserwatiewe titrasie van die dosisse van hierdie middels en monitering van die kliniese status moet gedoen word. Die halfleeftyd van diasepaam wat saam toegedien word, kan langer wees.
- Triptofaan – nadelige reaksies, waaronder agitasie, rusteloosheid en gastro-intestinale ongemak is aangemeld toe **FLUOXETINE 20 OETHMAAN** in kombinasie met triptofaan gebruik is.
- Medisyne wat aan proteïene gebind is – omdat **FLUOXETINE 20 OETHMAAN** aan plasmaproteïene bind, kan die konsentrasie daarvan of van ander medisyne wat aan proteïene bind, soos warfarien en digoksien, verander as dit saam gebruik word. Veranderings in die effekte van antikoagulante (laboratoriumwaardes en/of kliniese tekens en simptome) en toename in bloeding is aangemeld toe warfarien en fluoksetien saam gebruik is. Noukeurige monitering van koagulasie word in hierdie geval aanbeveel en wanneer **FLUOXETINE 20 OETHMAAN** gestaak word.

MENSLIKE VOORTPLANTING
Die veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS
Die veiligheid en effektiwiteit van **FLUOXETINE 20 OETHMAAN** vir kinders is nie bepaal nie.
FLUOXETINE 20 OETHMAAN kan met of sonder voedsel toegedien word. Vermy die gebruik van alkohol.
Vir pasiënte wat terselfdertyd ander siektes of swak lewerfunksie het, moet 'n laer dosis of langer doseerintervalle oorweeg word.
Major depressiewe versteurings
Volwassenes: 20 mg daagliks, verkieslik in die oggend.
Obsessiewe kompulsiewe versteuring
Volwassenes: 20 tot 60 mg/kg daagliks
Bulimia nervosa
Volwassenes: 60 mg daagliks.
Vanweë die farmakokinetiese eienskappe van **FLUOXETINE 20 OETHMAAN** word 'n opwaartse aanpassing in die dosis oor intervalle van etlike weke aanbeveel. Dosisse groter as 80 mg per dag word nie vir enige van die indikasies aanbeveel nie.
Bejaardes – **FLUOXETINE 20 OETHMAAN** moet versigtig in bejaarde persone gebruik word. Dosisse groter as 20 mg per dag word nie aanbeveel nie.

NEWE-EFFEKTE
Kardiovaskulêre stelsel
Minder dikwels: palpitasies.
Sentrale senustelsel:
Dikwels: hoofpyn, senuagtigheid, angs, lomerigheid.
Minder dikwels: moegheid, slaaploosheid, tremor, astenie, abnormale drome, agitasie, toevalle, hipomanie, manie, diskinesie.
Endokrien/metabolies:
Dikwels: gewigsverlies.
Minder dikwels: hiponatremie, hipotiroïdisme, koors.
Gastro-intestinaal:
Dikwels: diarree, naarheid, dispepsie, anoreksie, braking.
Minder dikwels: droë mond.
Niere/genito-urinêr:
Dikwels: afname in libido, seksuele disfunksie (vertraagde of onderdrukte orgasme).
Lewer: styging in vlakke van transaminases.
Muskuloskeletale stelsel: artralgie, mialgie.
Okulêr: versteurings in visie.
Lugweg: dispnee, pulmonêre inflammasie en/of fibrose.
Vel:
Dikwels: veluitslag, urtikarie, pruritus, oormagtige sweet.
Minder dikwels: anafilaktiese reaksies, serumsiekte.
Ander: Die volgende is tydens gebruik van **FLUOXETINE 20 OETHMAAN** aangemeld, maar geen oorsaaklike verband is vasgestel nie: aplastiese anemie, serebrale vaskulêre ongeluk, verwardheid, eggimose, eosinofiliese pneumonie, gastro-intestinale bloeding, hiperprolaktinemie, effekte soos van die neuroleptiese kwaadaardige sindroom, pankreatitis, selfmoordgedagtes, pansitopenie, trombositopenie, purpura, hemolitiese anemie vanweë immuunreaksies, vaginale bloeding (na onttrekking van die medikasie) en gewelddadige gedrag.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Kyk "**NEWE EFFEKTE en SPESIALE VOORSORGMAATREëLS**".
Simptome van oordosering
Simptome wat aangemeld is, is onder meer tagikardie, lomerigheid, tremor, naarheid en braking asook agitasie, rusteloosheid, hipomanie en toevalle.
Behandeling van oordosering
Behandeling is simptomaties en ondersteunend. Daar is geen spesifieke teenmiddel teen **FLUOXETINE 20 OETHMAAN** nie. Dit word nie gereken dat dialise, hemoperfusie, bloeduitruiling en maatreëls om urienafskeiding te verhoog, tot enige nut sal wees nie. Aktiewe houtskool kan oraal gegee word as 'n groot hoeveelheid ingeneem is en behandeling binne 'n uur na inname geskied.

IDENTIFIKASIE
FLUOXETINE 20 OETHMAAN-kapsules het 'n ondeursigtige ivoorkleurige romp en 'n ondeursigtige groen doppie. Die kapsules bevat 'n wit tot afwit kristallyne poeier.

AANBIEDINGS
Stulppakke, verseëlde aluminiumsakke of veiligheidshouers met 28, 30 of 100 kapsules.
Stulppakke of veiligheidshouers met 120 of 300 kapsules.

BEWARINGSINSTRUKSIES:
Bewaar onder 25°C. Beskerm teen vogtigheid.

HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER: 32/1.2/0040

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