APPROVED PACKAGE INSERT Reference No.: P100.11
Date: 2007-11-05

SCHEDULING STATUS:

Schedule 5

PROPRIETARY NAME:

PROZAC 20 (Capsules)

PROZAC TABLETS (Tablets)

COMPOSITION:

Each PROZAC 20 capsule contains fluoxetine hydrochloride equivalent to 20 mg fluoxetine.

PROZAC TABLETS contain fluoxetine hydrochloride equivalent to 20 mg fluoxetine per tablet.

PROZAC (fluoxetine hydrochloride) is an antidepressant for oral administration. It is chemically unrelated to tricyclic or tetracyclic antidepressant agents. Chemically it is (±)-N-methyl-3-phenyl-3- [(α,α,α-trifluoro-p-tolyl)-oxy]- propylamine hydrochloride, with the empirical formula of $C_{17}H_{18}F_3NO.HCl$. Its molecular mass is 345,79.

PHARMACOLOGICAL CLASSIFICATION:

A 1.2 Psychoanaleptics (antidepressants)

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

The antidepressant and anti-obsessive-compulsive action of fluoxetine is presumed to be linked to its inhibition of central nervous system (CNS) neuronal uptake of serotonin. Studies at clinically relevant doses in man have demonstrated that fluoxetine blocks the uptake of serotonin into human platelets.

Pharmacokinetics:

Fluoxetine is well absorbed after oral administration. Peak plasma concentration is reached in 6 to 8 hours after a single dose of 40 mg. Because of the long elimination half-lives of the parent drug (4 to 6 days) and its major active metabolite, norfluoxetine (4 to 16 days), changes in dose will not be fully reflected in plasma for several weeks (approximately 4 half-lives). This is to be

taken into consideration during dose titration or cessation of treatment. Fluoxetine is extensively bound to plasma proteins (about 95%) and is widely distributed (volume of distribution : 2- 40 l/kg). Steady-state plasma concentrations are achieved after dosing for several weeks.

The elderly: The disposition of single doses of fluoxetine in healthy elderly subjects (>65 years of age) did not differ significantly from that in younger normal subjects. However, given the long half-life and non-linear disposition of the medicine, a single-dose study is not adequate to rule out the possibility of altered pharmacokinetics in the elderly, particularly if they have systemic illness or are receiving multiple medicines for concomitant diseases. The effects of age upon the metabolism of fluoxetine have been investigated in 260 elderly but otherwise healthy depressed patients (≥60 years of age) who received 20 mg fluoxetine for 6 weeks. Combined fluoxetine plus norfluoxetine plasma concentrations were 209,3 ± 85,7 ng/ml at the end of 6 weeks. No unusual age-associated pattern of adverse events was observed in those elderly patients.

INDICATIONS:

Major depressive episodes: i.e. single episode and recurrent depression with associated anxiety.

Bulimia nervosa: PROZAC has been shown to significantly decrease binge-eating and purging activity.

Obsessive-compulsive disorder: PROZAC is indicated for the treatment of obsessive-compulsive disorder. The obsessions or compulsions must be experienced as intrusive, markedly distressing, time consuming or interfering significantly with the person's social or occupational functioning.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients.

PROZAC should not be administered to patients with severe renal failure (GFR <10 ml/min) because accumulation may occur in these patients during chronic treatment.

Monoamine oxidase inhibitors: There have been reports of serious, sometimes fatal, reactions (including hyperthermia, rigidity, myoclonus, 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 PROZAC in combination with a monoamine oxidase inhibitor (MAOI) and in patients who have recently discontinued PROZAC and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome. Therefore, PROZAC should not be used in combination with an MAOI, or within 14 days of discontinuing therapy with an MAOI. Since PROZAC and its major metabolite have very long elimination half-lives, at least 5 weeks should be allowed after stopping fluoxetine hydrochloride before starting an MAOI. If PROZAC has been prescribed chronically and/or at a high dose, a longer interval should be considered. Serious and fatal cases of serotonin syndrome (which may resemble and be diagnosed as neuroleptic malignant syndrome) have been reported in patients treated with PROZAC and an MAOI in temporal proximity (see 'WARNINGS').

Thioridazine: Thioridazine should not be administered with PROZAC or within a minimum of 5 weeks after PROZAC has been discontinued. Thioridazine administration produces a dose related prolongation of the QTc interval which is associated with serious ventricular arrythmias, such as torsades de pointes - type arrythmias and sudden death. This risk is expected to increase with fluoxetine-induced inhibition of thioridazine metabolism.

Paediatric use: Safety and efficacy in children have not been established.

WARNINGS:

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.

Isolated cases of suicidal ideation and suicidal behaviours have been reported during PROZAC therapy or early after treatment discontinuation. Although a causal role for PROZAC alone in inducing such behaviours has not been established, pooled analyses from studies of some other antidepressants in psychiatric conditions indicate a potential increased risk for suicidal ideation and suicidal behaviours in paediatric patients compared to placebo.

Patients being treated with PROZAC should 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.

Medical Practitioners should encourage patients of all ages to report any distressing thoughts or feelings at any time.

Because of the possibility of comorbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions should be observed when treating patients with major depressive disorder 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 PROZAC 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, PROZAC should be tapered. (see PRECAUTIONS AND DOSAGE AND DIRECTIONS FOR USE).

Serotonin syndrome: A serotonin syndrome, which may be confused with neuroleptic malignant syndrome, may occur with the use of PROZAC. This syndrome is characterised by the clustering of clinical features of changes in mental state (confusion, disorientation, agitation) and neuromuscular activity (myoclonus, hyper-reflexia, tremor, rigidity, inco-ordination), in combination with auto-immune dysfunction (especially fever, sweating, diarrhoea). The serotonin syndrome has been seen in temporal association with the use of monoamine oxidase inhibitors and with other serotonergic medication, but may occur in the absence of any concomitant medication. PROZAC should be stopped immediately as serious morbidity and death may follow the serotonin syndrome.

Rash and possibly allergic events: Rash, anaphylactoid events and progressive systemic events, sometimes serious and involving skin, kidney, liver or lung, have been reported in patients taking PROZAC. Upon the appearance of rash or of other possibly allergic phenomena, PROZAC should be discontinued.

INTERACTIONS:

Medicines metabolised by cytochrome P450IID6 isoenzyme: Because PROZAC has the potential to inhibit the cytochrome P450IID6 isoenzyme, therapy with medications that are predominantly metabolised by the P450IID6 system and that have a relatively narrow therapeutic index should be initiated at the low end of the dose range if a patient is receiving PROZAC concurrently or has taken it in the previous 5 weeks. If PROZAC is added to the treatment regimen of a patient already receiving such a medicine, the need for decreased dose of the original medication should be considered.

PROZAC should not be used concomitantly with monoamine oxidase inhibitors (see 'CONTRA-INDICATIONS').

CNS active medicines: Caution is advised if the concomitant administration of PROZAC and CNS active drugs, including lithium, is required. There have been reports of both increased and decreased lithium levels when used concomitantly with fluoxetine.

Lithium levels should be monitored. Changes in blood levels of phenytoin, carbamazepine, haloperidol, clozapine, diazepam, alprazolam, imipramine and desipramine, and in some cases clinical manifestations of toxicity, have been observed. Consideration should be given to using conservative titration schedules of the concomitant medicine and monitoring of clinical status.

Concomitant use of other drugs with serotonergic activity (e.g. Serotonin and Norepinephrine Reuptake Inhibitors, Selective Serotonin Reuptake Inhibitors, triptans or tramadol) may result in serotonin syndrome.

There have been greater than 2-fold increases of previously stable plasma levels of other antidepressants when PROZAC has been administered in combination with these agents.

Patients receiving PROZAC in combination with tryptophan have been reported to experience adverse reactions, including agitation, restlessness and gastrointestinal distress.

Altered anticoagulant effects (laboratory values and/or clinical signs and symptoms), with no consistent pattern, but including increased bleeding, have been reported uncommonly when fluoxetine is co-administered with warfarin. As is prudent in concomitant use of warfarin with

many other medicines, patients receiving warfarin therapy should receive careful coagulation monitoring when PROZAC is initiated or stopped.

The long elimination half-lives of fluoxetine and its active metabolite should be borne in mind (see 'Pharmacokinetics') when considering pharmacodynamic or pharmacokinetic medicine interactions, or the potential consequence when medicines are prescribed that might interact with either substance following the discontinuation of PROZAC.

The half-life of concurrently administered diazepam may be prolonged.

Fluoxetine is bound to plasma protein and concurrent administration may alter plasma concentrations of other plasma protein bound medicines, e.g. warfarin, digitoxin, or conversely, fluoxetine binding may be changed by other agents.
There have been reports of prolonged seizures in patients on PROZAC receiving ECT treatment. (See 'PRECAUTIONS')

PREGNANCY AND LACTATION:
Safety in pregnancy has not been demonstrated.

Lactation: The safety of PROZAC has not been established in breastfeeding women. PROZAC is secreted in human milk.

DOSAGE AND DIRECTIONS FOR USE:
For oral administration to adults only.

A major depressive episode: adults and elderly : A dose of 20 mg/day is recommended, preferably in the morning.

Bulimia nervosa: A dose of 60 mg/day is recommended.

Obsessive-compulsive disorder: A dose of 20 to 60 mg/day is the recommended dose for the treatment of obsessive-compulsive disorder.

The recommended dose may be increased or decreased. Doses above 80 mg/day are not

recommended for any indication. Upward dose titration is advised at intervals of several weeks due to the kinetic properties of PROZAC (see 'PHARMACOKINETICS'').

PROZAC may be administered with or without food. The tablets may be swallowed whole or be dispersed in approximately 100 ml water.

Usage in the elderly: PROZAC should be used with caution in all elderly patients, particularly if they have systemic illness or are receiving multiple medications for concomitant diseases. Dosages over 20 mg per day are not recommended. (See also 'Pharmacokinetics'.)

Concurrent disease: A lower or less frequent dose should be considered in patients with hepatic impairment and concurrent diseases.

Discontinuation of PROZAC may lead to withdrawal symptoms, including dizziness, paraesthesia, headache, insomnia, tremor, confusion, sensory disturbances, agitation, anxiety and nausea. (See 'PRECAUTIONS')

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

Clinical Trial Data :

Events are classified within body system categories using the following definitions: common adverse events are defined as those occurring on one or more occasions in at least 1/100 patients; uncommon adverse events are those occurring in 1/100 to 1/1 000 patients; rare events are those occurring in less than 1/1 000 patients.

System Organ Class/Adverse Event	Common Events occurring on one or more occasions in at least 1/100 patients.	Uncommon Events occurring on one or more occasions in 1/100 to 1/1 000 patients.	Rare Events occurring on one or more occasions in less than 1/1 000 patients.
Body as a Whole			
Chest pain, chills	X		
Chills and fever, face oedema, intentional overdose, malaise, pelvic pain, suicide attempt		X	
Acute abdominal syndrome, hypothermia, intentional injury, neuroleptic malignant syndrome[1], photosensitivity reaction			X

System Organ Class/Adverse Event	Common Events occurring on one or more occasions in at least 1/100 patients.	Uncommon Events occurring on one or more occasions in 1/100 to 1/1 000 patients.	Rare Events occurring on one or more occasions in less than 1/1 000 patients.
Cardiovascular System			
Haemorrhage, hypertension, palpitation	X		
Angina pectoris, arrhythmia, congestive heart failure, hypotension, migraine, myocardial infarct, postural hypotension, syncope, tachycardia, vascular headache		X	
Atrial fibrillation, bradycardia, cerebral embolism, cerebral ischaemia, cerebrovascular accident, extrasystoles, heart arrest, heart block, pallor, peripheral vascular disorder, phlebitis, shock, thrombophlebitis, thrombosis, vasospasm, ventricular arrhythmia, ventricular extrasystoles, ventricular fibrillation			X
Digestive System			
Increased appetite, nausea and vomiting	X		
Aphthous stomatitis, cholelithiasis, colitis, dysphagia, eructation, oesophagitis, gastritis, gastroenteritis, glossitis, gum haemorrhage, hyperchlorhydria, increased salivation, liver function tests abnormal, melena, mouth ulceration, nausea/vomiting/diarrhoea, stomach ulcer, stomatitis, thirst		X	
Biliary pain, bloody diarrhoea, cholecystitis, duodenal ulcer, enteritis, oesophageal ulcer, faecal incontinence, gastrointestinal haemorrhage, hematemesis, haemorrhage of colon, hepatitis, intestinal obstruction, liver fatty deposit, pancreatitis, peptic ulcer, rectal haemorrhage, salivary gland enlargement, stomach ulcer haemorrhage, tongue oedema			X
Endocrine System			
Hypothyroidism		X	
Diabetic acidosis, diabetes mellitus			X
Haemic and Lymphatic System			
Anaemia, ecchymosis		X	
Blood dyscrasia, hypochromic anaemia, leucopenia, lymphoedema, lymphocytosis, petechia, purpura, thrombocythaemia, thrombocytopenia			X
Metabolic and Nutritional			
Weight gain	X		
Dehydration, generalised oedema, gout, hypercholesteraemia,		X	

System Organ Class/Adverse Event	Common Events occurring on one or more occasions in at least 1/100 patients.	Uncommon Events occurring on one or more occasions in 1/100 to 1/1 000 patients.	Rare Events occurring on one or more occasions in less than 1/1 000 patients.
hyperlipaemia, hypokalaemia, peripheral oedema			
Alcohol intolerance, alkaline phosphatase increased, BUN increased, creatine phosphokinase increased, hyperkalaemia, hyperuricaemia, hypocalcaemia, iron deficiency anaemia, ALT increased			X
Musculoskeletal System			
Arthritis, bone pain, bursitis, leg cramps, tenosynovitis		X	
Arthrosis, chondrodystrophy, myasthenia, myopathy, myositis, osteomyelitis, osteoporosis, rheumatoid arthritis			X
Nervous System			
Agitation, amnesia, confusion, emotional lability, sleep disorder	X		
Abnormal gait, acute brain syndrome, akathisia, apathy, ataxia, buccoglossal syndrome, CNS depression, CNS stimulation, depersonalization, euphoria, hallucinations, hostility, hyperkinesia, hypertonia, hypesthesia, incoordination, libido increased, myoclonus, neuralgia, neuropathy, neurosis, paranoid reaction, personality disorder [2], psychosis, vertigo		X	
Abnormal electroencephalogram, antisocial reaction, circumoral paraesthaesia, coma, delusions, dysarthria, dystonia, extrapyramidal syndrome, foot drop, hyperaesthesia, neuritis, paralysis, reflexes decreased, reflexes increased, stupor			X
Respiratory System			
Asthma, epistaxis, hiccup, hyperventilation		X	
Apnoea, atelectasis, cough decreased, emphysema, haemoptysis, hypoventilation, hypoxia, larynx oedema, lung oedema, pneumothorax, stridor			X
Skin and Appendages			
Acne, alopecia, contact dermatitis, eczema, maculopapular rash, skin discolouration, skin ulcer,vesiculobullous rash		X	
Furunculosis, herpes zoster, hirsutism, petechial rash, psoriasis, purpuric rash, pustular rash, seborrhoea			X
Special Senses			
Ear pain, taste perversion, tinnitus	X		
Conjunctivitis, dry eyes, mydriasis, photophobia		X	

System Organ Class/Adverse Event	Common Events occurring on one or more occasions in at least 1/100 patients.	Uncommon Events occurring on one or more occasions in 1/100 to 1/1 000 patients.	Rare Events occurring on one or more occasions in less than 1/1 000 patients.
Blepharitis, deafness, diplopia, exophthalmos, eye haemorrhage, glaucoma, hyperacusis, iritis, parosmia, scleritis, strabismus, taste loss, visual field defect			X
Urogenital System			
Urinary frequency	X		
Abortion[3], albuminuria, amenorrhoea[3], anorgasmia, breast enlargement, breast pain, cystitis, dysuria, female lactation[3], fibrocystic breast[3], haematuria, leucorrhoea[3], menorrhagia[3], metrorrhagia[3], nocturia, polyuria, urinary incontinence, urinary retention, urinary urgency, vaginal haemorrhage[3]		X	
Breast engorgement, glycosuria, hypomenorrhoea[3], kidney pain, oliguria, priapism[3], uterine haemorrhage[3], uterine fibroids enlarged[3]			X

1 Neuroleptic malignant syndrome is the COSTART term which best captures serotonin syndrome.

2 Personality disorder is the COSTART term for designating non-aggressive objectionable behaviour.

3 Adjusted for gender.

The following have been reported in association with PROZAC, but no causal relationship has been established: Aplastic anaemia, cerebral vascular accident, confusion, seizures, dyskinesia (including, for example, a case of buccal-lingual-masticatory syndrome, which resolved following drug discontinuation), eosinophilic pneumonia, gastrointestinal haemorrhage, hyperprolactinaemia, erythema multiforme, angioedema, movement disorders developing in patients with risk factors (including drugs associated with such events) and worsening of pre-existing movement disorders, neuroleptic malignant syndrome-like events, pancreatitis, suicidal ideation, pancytopenia, immune related haemolytic anaemia, thrombocytopenia, thrombocytopenic purpura, vaginal bleeding after withdrawal of the medication and violent behaviour.

Precautions:

PROZAC should be introduced cautiously in patients who have a history of seizures.

PROZAC should be discontinued in any patient who develops seizures. PROZAC should be avoided in patients with unstable epilepsy; patients with controlled epilepsy should be carefully monitored.

There have been reports of prolonged seizures in patients on PROZAC receiving ECT treatment. (See 'INTERACTIONS')

PROZAC is extensively metabolised by the liver and excreted by the kidneys. A lower dose, e.g. alternate day dosing, is recommended in patients with significant hepatic dysfunction or mild to moderate renal failure (GFR 10-50 ml/min).

Clinical experience in acute cardiac disease is limited, therefore caution is advisable.

PROZAC may cause loss of mass which could be undesirable in underweight depressed patients.

In patients with diabetes, PROZAC may alter glycaemic control. Hypoglycaemia has occurred during therapy with fluoxetine and hyperglycaemia has developed following discontinuation. Insulin and/or oral hypoglycaemic dosage may need to be adjusted when fluoxetine therapy is initiated or discontinued.

There have been reports of altered platelet function and/or abnormal results from laboratory studies in patients taking fluoxetine. While there have been reports of abnormal bleeding in several patients taking fluoxetine, it is unclear whether PROZAC had a causative role.

Although PROZAC has been shown not to affect psychomotor performance in healthy volunteers, any psychoactive agent may impair judgement, thinking or motor skills. Therefore patients should be cautioned that their ability to perform potentially hazardous tasks (e.g. driving a motor vehicle or operating machinery) may be impaired.

As improvement may not occur during the first two or more weeks of treatment, patients should be closely monitored during this period. Due to the risk of suicide in major depressive episodes, close supervision of high risk patients should accompany medication therapy.

Because of well-established comorbidity between obsessive-compulsive disorder and depression,

the same precautions observed when treating patients with depression should be observed when treating patients with obsessive-compulsive disorder.

There have been reports of extrapyramidal symptoms associated with the use of PROZAC and of aggravation of Parkinson's disease in patients taking PROZAC. PROZAC should therefore be used with care in patients with extrapyramidal disorders.

Discontinuation of PROZAC may lead to withdrawal symptoms, including dizziness, paraesthesia, headache, insomnia, tremor, confusion, sensory disturbances, agitation, anxiety and nausea. (See 'DOSAGE AND DIRECTIONS FOR USE')

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms: Symptoms of overdose included nausea, vomiting, seizures, cardiovascular dysfunction ranging from asymptomatic arrhythmias to cardiac arrest, pulmonary dysfunction and signs of altered CNS status ranging from excitation to coma.

Management: Cardiac and vital signs monitoring is recommended along with general symptomatic and supportive measures.

There are no specific antidotes for PROZAC.
Due to the large volume of distribution of PROZAC, forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit. In managing overdosage, the possibility of multiple drug involvement should be considered.

IDENTIFICATION:

PROZAC 20 capsule, PU 3105, is a size 3 capsule with an opaque green cap and an opaque off-white body imprinted with Lilly and 3105.

PROZAC TABLETS, TA 4400, are white, elongated, uncoated, scored tablets embossed with 4400.

PRESENTATION:

PROZAC 20 capsules are supplied in blister packs of 30.

PROZAC TABLETS are supplied in blister packs of 30.

STORAGE INSTRUCTIONS:

Capsules: Store below 30°C in blister packs. Protect from light.

Tablets: Store below 25°C in blister packs. Protect from light.

Keep out of reach of children.

REGISTRATION NUMBERS:

S/1.2/68 for 20 mg capsules

30/1.2/0503 for 20 mg tablets

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Eli Lilly (S.A.)(Pty) Limited

1 Petunia Street

Bryanston

2021

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

26 May 2006

Zimbabwe only: PP	
PROZAC 20 CAPSULES	**PROZAC TABLETS**
Reg. No.: 93/13.2.1/2784	Reg. No.: 99/13.2.1/3625

Namibia: Schedule 5	
PROZAC 20 CAPSULES	**PROZAC TABLETS**
Reg. No.: 90/1.2/00554	Reg. No.: 04/1.2/0665

Botswana: Schedule 2	
PROZAC 20 CAPSULES	**PROZAC TABLETS**
Reg. No.: B9303335	Reg. No.: BOT0700959

APPROVAL FOR SUBMISSION TO REGULATORY AUTHORITY :		
Title :	**Signature :**	**Date :**
Medical Director/Clinical Research Physician	_____	_____
Manager, Pharmaco-Legal and Regulatory Affairs	_____	_____
Registration Pharmacist/Associate	_____	_____
Product Manager	_____	_____
APPROVAL TO PRINT :		
Title :	**Signature :**	**Date :**
Manager, Pharmaco-Legal and Regulatory Affairs	_____	_____

Reference No.: P100.11
Date: 2007-11-05

SKEDULERINGSTATUS :

Bylae 5

EIENDOMSNAAM:

PROZAC 20 (Kapsules)

PROZAC TABLETS (Tablette)

SAMESTELLING :

Elke PROZAC 20 kapsule bevat fluoksetienhidrochloried ekwivalent aan 20 mg fluoksetien.

PROZAC TABLETS bevat fluoksetienhidrochloried ekwivalent aan 20 mg fluoksetien per tablet.

PROZAC (fluoksetienhidrochloried, Dista) is ’n antidepressant vir mondelike toediening. Dit is chemies nie-verwant aan trisikliese of tetrasikliese antidepressante. Dit is chemies (±)-N-metiel-3-feniel-3-[(α,α,α-trifluoro-p-toliel)-oksi]-propielamienhidrochloried, met die empiriese formule $C_{17}H_{18}F_3NO.HCl$. Die molekulêre massa is 345,79.

FARMAKOLOGIESE KLASSIFIKASIE :

A 1.2 Psigo-analeptika (antidepressante)

FARMAKOLOGIESE WERKING :

Farmakodinamika:

Die antidepressiewe en antiobsessief-kompulsiewe werking van fluoksetien word veronderstel om aan die inhibisie van sentrale senuweestelsel (SSS) neuronale opname van serotonien te wyte

te wees. Proewe, met klinies relevante dosisse, in die mens het getoon dat fluoksetien die opname van serotonien in menslike plaatjies blokkeer.

Farmakokinetika:

Fluoksetien word goed geabsorbeer na orale toediening. Piek plasma konsentrasie word binne 6 tot 8 ure na toediening van ’n enkel 40mg dosering bereik. Aangesien die moedermiddel (4 tot 6 dae) en die hoof aktiewe metaboliet, norfluoksetien (4 tot 16 dae) lang eliminasie halfleeftye het, sal dosering aanpassing nie vir etlike weke in die plasma reflekteer nie (ongeveer 4 halfleeftye). Hierdie aspek moet inaggeneem word in geval van dosering titrasie of beëindiging van behandeling. Fluoksetien word breedvoerig gebind aan plasma proteiene (ongeveer 95%) en is wyd verspreid (volume van verspreiding: 2- 40 l/kg). Stabiele toestand konsentrasie word bereik na dosering oor etlike weke.

Gebruik by bejaardes: Die opriuming van enkel doserings fluoksetien in gesonde bejaarde persone (> 65 jaar oud) het nie beduidend verskil van dié van jonger persone nie. Nietemin, toegeskryf aan die lang halfleeftyd en nie-liniêre opruiming van die middel, is ’n enkeldosering studie nie voldoende om die moontlikheid van veranderende farmakokinetika in bejaardes, veral waar hulle sistemiese siektes of veelvoudige behandeling ontvang vir gepaardgaande siektes, uit te skakel nie. Die effek van ouderdom op metabolisme van fluoksetien is ondersoek in 260 bejaardes, maar andersins gesonde depressiewe pasiënte (≥ 60 jaar oud) wie 20 mg fluoksetien vir 6 weke ontvang het. Die kombinasie van fluoksetien en norfluoksetien plasma konsentrasies was 209,3 ± 85,7 ng/ml teen die einde van die 6 weke. Geen ongewone ouderdom-geassosieerde patroon van newe effekte was opgetel in bejaarde pasiënte nie.

INDIKASIES :

Major depressiewe episodes, d.w.s. enkelepisode sowel as herhalende depressie met geassosieerde angs.

Bulimie nervosa: Daar is aangetoon dat PROZAC oordadige eetgewoontes en purgeringsaktiwiteit betekenisvol verminder.

Obsessief-kompulsiewe siekte: PROZAC word aangedui vir die behandeling van obsessief-kompulsiewe siekte. Die obsessies en kompulsies moet as indringend, opvallend onrusbarend en

tydrowend ondervind word, of aansienlik met die persoon se sosiale- of beroepsfunksionering inmeng.

KONTRA-INDIKASIES :

Hipersensitiwiteit vir enige van die bestanddele.

PROZAC moet nie aan pasiënte met ernstige nierversaking (GFT <10 ml/min) toegedien word nie, aangesien opeenhoping by hierdie pasiënte tydens langdurige behandeling kan voorkom.

Monoamienoksidaseremmers: In gevalle waar pasiënte PROZAC saam met monoamien-oksidaseremmers (MAO-remmers) ontvang het en by pasiënte wat pas na staking van PROZAC met MAO-remmers behandel is, is verslae van ernstige, soms noodlottige reaksies (insluitende hipertermie, styfheid, spierklonus, outonome onstabiliteit, met moontlik snelle fluktuering van vitale tekens en veranderinge in geestesgesteldheid insluitende erge agitasie, wat lei tot delirium en koma) ontvang. In sommige gevalle het eienskappe wat met neuroleptiese maligne sindroom ooreenkom, voorgekom. PROZAC moet daarom nie saam met 'n MAO-remmer, of binne 14 dae nadat behandeling met 'n MAO-remmer gestaak is, gebruik word nie. Aangesien PROZAC en sy hoofmetaboliet baie lang eliminasie halfleeftye het, moet ten minste 5 weke verloop tussen staking van PROZAC en die aanvang van behandeling met 'n MAO-remmer. Waar PROZAC op ’n chronies basis voorgeskryf word of teen ’n hoë dosis, moet ’n langer interval oorweeg word. Ernstige en fatale gevalle van serotinien sindroom (wat mag voorkom, en gediagnoseer word as neuroleptiese maligne sindroom) is aangemeld in pasiënte wat fluoksetien en MAO behandeling kort op mekaar ontvang het. (sien ‘WAARSKUWINGS’)

Tioridasien: Tioridasien moet nie toegedien word saam met PROZAC of binne in minimum van 5 weke nadat PROZAC behandeling gestaak is nie. Tioridasien toediening veroorsaak ’n dosisverwante verlenging van die QTc interval wat geassosieer word met ernstige ventrikulêre aritmie soos torsades de pointes – tipe aritmie, en skielike dood. Hierdie risiko sal na verwagting toeneem met fluoksetien-geinduseerde onderdrukking van tioridasien metabolisme.

Pediatriese gebruik: Veiligheid en doeltreffendheid by kinders is nie vasgestel nie.

WAARSKUWINGS :

Pasiënte met major depressiewe stoornis, beide volwassenes en kinders, mag verergering van hul depressie en/of verskynsel van selfmoord gedagtes en gedrag ondervind, ongeag of hulle

anti-depressant medikasie neem of nie. Die risiko sal voortduur tot betekenisvolle verbetering waargeneem word.

Soos met ander middels van soortgelyke farmakologiese aksie (antidepressante), is geïsoleerde gevalle van selfmoord idieëring en selfmoordgedrag geraporteer tydens fluoksetien behandeling of kort na die staking daarvan. Alhoewel ’n oorsaaklike rol nog nie gevind is waar PROZAC behandeling alleen hierdie gedrag induseer nie, het gegroepeerde analise van studies met sommige ander antidepressante in psigiatriese kondisies wel getoon dat daar ’n potensiële verhoging in die risiko van selfmoord idieëring en selfmoordgedrag bestaan in pediatriese pasiënte wanneer vergelyk word met plasebo.

Aangesien die moontlikheid bestaan dat daar tydens die eerste twee weke van behandeling geen verbetering mag wees nie, moet pasiënte gedurende hierdie tydperk noukeurig dopgehou word. As gevolg van die risiko van selfmoord tydens major depressiewe episodes moet daar streng toesighouding van hoë risiko pasiënte gedurende geneesmiddelterapie wees.

Dokters moet pasiënte aanmoedig om enige onrusbarende gedagtes en gevoelens aan te meld.

As gevolg van die moontlikheid dat daar ‘n komorbiditeit bestaan tussen obsessief-kompulsiewe afwyking en depressie moet dieselfde voorsorgmaatreëls wat geld wanneer pasiënte met depressie behandel word, toegepas word wanneer pasiënte met obsessief-kompulsiewe siekte behandel word.

Die volgende simptome is aangemeld in pasiënte behandel met anti-depressante vir major depressiewe episodes sowel as vir ander indikasies, beide psigiatries en non-psigiatries: angstigheid, agitasie, paniekaanvalle, insomnie, geïrriteerdheid, hostiliteit, agressie, impulsiwiteit, akatisie, hipomanie en manie. Alhoewel daar nog nie ’n verband gevind is tussen die verskyning van simptome en die verergering van depressie en/of die verskyning van selfmoord impulse nie, moet sorg aan die dag gelê word, ingeval van verandering van die terapeutiese behandelingsplan, insluitend die moontlike staking van PROZAC in pasiënte wat erge simptome ervaar, waar simptome skielik begin of waar die pasiënt nie oorspronklik met die simptome gepresenteer het nie.

As daar besluit word om PROZAC behandeling te staak, moet die dosering stadig verminder word. (Sien 'SPESIALE VOORSORGMAATREËLS' en 'DOSIS EN GEBRUIKSAANWYSINGS')

Serotonien sindroom: Serotonien sindroom wat kan voorkom met die gebruik van PROZAC, mag verwar word met neuroleptiese maligne sindroom. Hierdie sindroom word gekarakteriseer deur 'n groep kliniese kenmerke wat verandering in geestestoestand (verwardheid, disoriëntasie, agitasie) en neuromuskulêre aktiwiteit (mioklonus, hiper-refleksie, bewing, rigiditeit, inkoördinering), in kombinasie met auto-immuun wanfunksie (veral koors, sweet, diarree). Die serotonien sindroom is gesien waar monoamienoksidasieremmers en ander serotonergiese medikasie kort na mekaar toegedien is, maar kan ook in die afwesigheid van enige kombinasie behandeling voorkom. Prozac moet dadelik gestaak word, aangesien erge morbiditeit en dood die gevolg van serotonien sindroom kan wees.

Uitslag en moontlik allergiese reaksies: Huiduitslag, anafilaktoïede gevalle en progressiewe sistemiese gevalle, soms gevaarlik en insluitend vel, niere, lewer en longe is aangemeld in pasiënte wat PROZAC neem. PROZAC moet gestaak word indien uitslag of ander moontlik allergiese verskynsels voorkom.

INTERAKSIES:

Medikamente gemetaboliseer deur sitochroom P450IID6 iso-ensiem: Aangesien PROZAC die potensiaal het om die sitochroom P450IID6 iso-ensiem te inhibeer, moet middels wat hoofsaaklik deur sitochroom P450IID6 gemetaboliseer, en 'n relatiewe nou terapeutiese indeks het, teen die laer dosis van die dosering reeks toegedien word waar die pasiënt huidiglik PROZAC behandeling ontvang, of waar die pasiënt die vorige 5 weke fluoksetien geneem het. In geval waar PROZAC behandeling by hierdie groep medikamente gevoeg word, moet daar oorweeg word om die dosis van die oorspronklike medikasie te verlaag.

PROZAC moet nie saam met monoamienoksidaseremmers gebruik word nie (sien 'KONTRA-INDIKASIES').

SSS-aktiewe middels: Versigtigheid word aanbeveel indien dit nodig is om PROZAC saam met SSS-aktiewe middels, insluitende litium, toe te dien. Verslae van beide toename en afname van litiumvlakke is ontvang, wanneer dit saam met fluoksetien geneem is. Dit is wenslik om litiumvlakke te monitor. Verandering in plasma vlakke van fenitoïen, karbamasepien,

haloperidol, klosapien, diasepam, alprasolam, imipramien, desipramien, en in sommige gevalle kliniese tekens van toksisiteit, is waargeneem. Die gebruik van konserwatiewe titrasie skedules vir die konkominante medikamente en kliniese status monitering moet oorweeg word. Bykomstige gebruik van ander middels met serotoninergiese aktiwiteit (b.v. SNHIs, SSHIs, triptans of tramadol) mag aanleiding gee tot serotinien sindroom. Voorheen stabiele plasmavlakke van ander anti-depressantes het meer as tweevoudig toegeneem, wanneer hierdie middels saam met PROZAC toegedien is.

Daar is aangemeld dat pasiënte wat PROZAC saam met triptofaan ontvang het ongewenste reaksies, insluitende agitasie, rusteloosheid en gastroïntestinale ongemak ondervind het.

Veranderde anti-koagulasie effekte (laboratorium uitslae en/of kliniese tekens en simptome), sonder konsekwente patroon, is ongereeld aangemeld waar fluoksetien saam met warfarin toegedien is. Pasiënte op warfarin behandeling moet deeglike koagulasie monitering ontvang wanneer PROZAC geïnisieer of gestaak word, soos aanbeveel waar warfarin in kombinasie met enige ander medikasie toegedien word.

Die lang eliminasiehalfleeftye van fluoksetien en sy aktiewe metaboliet, moet in gedagte gehou word waar farmakodinamiese of farmakokinetiese geneesmiddelinteraksies oorweeg word (sien 'Farmakokinetika').

Die halfleeftyd van diasepam kan verleng word wanneer dit gelyktydig toegedien word.
Fluoksetien is plasmaproteïengebonde en gelyktydige toediening kan plasmakonsentrasies van ander plasmaproteïengebonde middels, bv. warfarien en digitoksien, verander. Daarteenoor kan fluoksetienbinding deur ander middels beïnvloed word.
Langdurige stuipe is by pasiënte op PROZAC, wat EKB ontvang het, aangemeld. (Sien ‘VOORSORGMAATREËLS’)

SWANGERSKAP EN LAKTASIE:
Veiligheid tydens swangerskap is nog nie vasgestel nie.

Laktasie: Die veiligheid van PROZAC is nog nie vasgestel in moeders wat borsvoed nie. PROZAC word in borsmelk afgeskei.

DOSIS EN GEBRUIKSAANWYSINGS :

Slegs vir mondelike toediening aan volwassenes.

'n Major depressiewe episode: 'n Dosis van 20 mg/dag, verkieslik in die oggend, word aanbeveel.

Bulimie nervosa: 'n Dosis van 60 mg/dag word aanbeveel.

Obsessief-kompulsiewe siekte: 'n Dosis van 20 tot 60 mg/dag word aanbeveel vir die behandeling van obsessief-kompulsiewe siekte.

Die aanbevolle dosering kan verhoog of verlaag word. Dosisse groter as 80 mg/dag word nie aanbeveel vir enige indikasie nie. Verhoogde dosis titrasie word aanbeveel deur intervalle oor verskeie weke as gevolg van die kinetiese eienskappe van PROZAC . (Sien 'Farmakokinetika') PROZAC kan met of sonder voedsel geneem word. Die tablette kan heel ingesluk word of in ongeveer 100 ml water opgelos word.

Gebruik by bejaardes: PROZAC moet met omsigtigheid by bejaardes gebruik word, veral as hulle 'n sistemiese siekte het of veelvuldige medikasies vir gepaardgaande siektetoestande ontvang. Doserings oor 20 mg/dag word nie aanbeveel nie. (Sien ook ' FARMAKOKINETIKA')

Bestaande siektetoestand: 'n Laer of minder gereelde dosis moet oorweeg word in pasiënte met hepatiese inkorting of 'n bestaande siektetoestand.
Staking van PROZAC mag aanleiding gee tot ontrekking simptome, insluitend duiseligheid, parestesie, hoofpyn, insomnie, bewing, konfusie, sensoriese afwykings, agitasie, angstigheid en naarheid. (Sien 'VOORSORGMAATREËLS')

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS :
Newe effekte:

Kliniese Studie Data:
Gevalle word geklassifiseer onder liggaamsisteem kategorieë, met die volgende definisies: algemene newe effekte word gedefinieer as dié wat een keer of meer as een keer in ten minste 1/100 pasiënte voorkom; seldsame newe effekte is dié wat voorkom in 1/100 tot 1/1 000 pasiënte; en selde gevalle van newe effekte is dié wat voorkom in minder as 1/1 000 pasiënte.

Orgaan Klassifikasie/ Newe-effekte	**Algemeen** Insidente wat 1 of meer keer in ten minste 1/100 pasiënte voorgekom het	**Seldsaam** Insidente wat 1 of meer keer in 1/100 of 1/1000 pasiënte voorgekom het	**Selde** Insidente wat 1 of meer keer in minder as 1/1000 pasiënte voorgekom het
Liggaam as Geheel			
Borskaspyn, koue rillings	X		
Koue rillings en koors, gesigsedeem, opsetlike oordosering, malaise, pelviese pyn, selfmoordpoging		X	
Akute abdominale pyn, hipotermie, opsetlike besering, neuroleptiese maligne sindroom[1], fotosensitiwiteit reaksie			X
Kardiovaskulêre Stelsel			
Hemoragie, hipertensie, palpitasies	X		
Angina pectoris, aritmie, kongestiewe hartversaking, hipotensie, migraine, miokardiale infarksie, posturale hipotensie, sinkopie, tagikardie, vaskulêre hoofpyn		X	
Atriale fibrillasie, bragikardie, serebrale isgemie, serebro-vaskulêre ongeluk, ekstrasistolieë, hartstilstand, hartblokkasie, bleekheid, perifere vaskulêre afwyking, flebitis, skok, tromboflebitis, trombose, vasospasma, ventrikulêre aritmieë, ventrikulêre ekstrasistolieë, ventrikulêre fibrillasie			X
Spysverteringstelsel			
Verhoogde aptyt, naarheid en braking	X		
Spruagtige stomatitis, galsteensiekte, kolitis, disfagie, eruktasie, esofagitis, gastritis, gastro-enteritis, glossitis, bloeiende tandvleise, hiperchloorhidrie, verhoogde speeksel afskyding, abnormale lewerfunksie toetse, melena, mond ulserasie, naarheid/vomering/diarree, maagseer, stomatitis, dors		X	
Bilière pyn, bloederige diarree, galblaasontsteking, duodenale ulser, entiritis, esofageale ulser, fekale inkontinensie, gastro-intestinale bloeding, hematemesis, bloeding van die kolon, hepatitis, intestinale obstruksie, lewer vetneerslae, pankreatitis, peptiese ulser, rektale bloeding, speekselklier vergroting, maagseer bloeding, tong edeem			X
Endokriene Stelsel			
Hipotireose		X	
Diabetiese asidose, diabetes mellitus			X
Bloed-en Limfatiese Stelsel			
Anemie, eggimose		X	
Bloed diskrasie, hipochrome anemie, leukopenia, limfedeem, limfositose, petegia, purpura, trombositopenie, trombositemie			X
Metaboliese- en Voeding Sisteem			
Gewigstoename	X		
Dehidrasie, algemene edeem, gout, hipercholesterolemia, hiperlipidemie, hipokalemie, perifere edeem		X	
Alkohol intoleransie, verhoogde alkaliese fosfatase, verhoogde BUN (plasma ureum en stikstof), verhoogde kreatien fosfokinase, hiperkalemie, hiperurisemie, hipokalsemie, ystertekort anemie, verhoogde ALT			X
Spier-skelet-stelsel			
Artritis, beenpyn, bursitis, beenkrampe, tenosinovitis		X	
Artrose, chondrodistrofie, spierswakheid, miopatie, miositis, beenmurgontsteking, osteoporose, rumatoïede artritis			X
Senuweestelsel			
Agitasie, amnesie, verwarring, emosionele labiliteit, slaapversteurings	X		
Abnormale stap, akute brein sindroom, akatisie, apatie, ataksie, bukkoglossale sindroom, SSS onderdrukking, SSS		X	

Orgaan Klassifikasie/ Newe-effekte	**Algemeen** Insidente wat 1 of meer keer in ten minste 1/100 pasiënte voorgekom het	**Seldsaam** Insidente wat 1 of meer keer in 1/100 of 1/1000 pasiënte voorgekom het	**Selde** Insidente wat 1 of meer keer in minder as 1/1000 pasiënte voorgekom het
stimulasie, depersonalisering, euforie, hallusinasie, hostiliteit, hiperkinese, hipoëstesie, inkoördinering, verlaagde libido, mioklonus, neuralgie, neuropatie, neurose, paranoïese reaksie, persoonlikheidsafwyking[2], psigose, vertigo		X	
Abnormale elektroënkefalogram, anti-sosiale reaksie, sirkumorale parestesie, koma, delusie, disartrie, distonie, ekstrapiramidale sindroom, 'foot drop', hiperestesie, neuritis, verlamming, verlaagde reflekse, gevoelloosheid			X
Respiratoriese Stelsel			
Asma, epitakse, hik, hiperventilasie		X	
Apnee, atelektase, verlaagde hoes, emfiseem, hemoptise, hipoventilasie, hipoksie, larinks edeem, long edeem, pneumotoraks, stridor			X
Vel en Bindweefsel			
Aknee, alopesie, kontak dermatitis, ekseem, makulopapulêre uitslag, velverkleuring, vel ulkusse, vesikulo-bulleuse uitslag		X	
Furunkulose, herpes zoster, hirsutisme, puntbloeding uitslag, psoriase, purpura uitslag, seboree			X
Spesiale sintuie			
Oorpyn, smaak perversie, tinnitus	X		
Konjunktivitis, droë oë, midriase, fotofobie		X	
Blefaritis, doofheid, diplopie, eksoftalmos, oog bloeding, gloukoom, hiperakoesie, iritis, parosmie, skleritis, skeelheid, smaakverlies, visuele veld defek			X
Urogenitale Stelsel			
Urinêre frekwensie	X		
Aborsie[3], albumienurie, amenoree[3], anorgasmie, borsvergroting, borspyn, sistitis, disurie, vroulike laktasie[3], fibrosistiese bors[3], hematurie, leukoree[3], menoragie[3], metroragie[3], nokturie, poliurie, urinêre inkontinensie, urinêre retensie, urinêre dringendheid, vaginale bloeding[3]		X	
Stuwing van borste, glukosurie, hipomenoree[3], nierpyn, oligurie, priapisme[3], uterusbloeding[3], vergrote uteriene fibroiede[3]			X

1 Neuroleptiese maligne sindroom is die COSTART term wat serotinien sindroom die beste beskryf
2 Persoonlikheidsafwyking is die COSTART term vir nie-aggressiewe afkerende gedrag
3 Aangepas vir geslag

Die volgende is in verband met PROZAC aangemeld maar geen oorsaaklike verwantskap is vasgestel nie: Aplastiese anemie, serebrovaskulêre insident, verwarring, stuipe, diskinesie (ingeslote, byvoorbeeld, 'n geval van bukkaal-linguale-kousindroom, wat herstel het nadat die geneesmiddel onttrek is), eggimose, eosinofiliese pneumonie, gastroïntestinale bloeding, hiperprolaktienemie, veelvuldige eriteem, angioëdeem, ontwikkeling van bewegingsiektes in pasiënte met risiko faktore (insluitende geneesmiddels wat met sulke gevalle verband hou) en verslegting van voorafbestaande bewegingsiektes, neuroleptiese maligne sindroomagtige gevalle, pankreatitis, selfmoordneigings, pansitopenie, immuunverwante hemolitiese anemie, trombositopenie, trombositopeniese purpura, vaginale bloeding na geneesmiddelonttrekking en geweldadige optredes.

Voorsorgmaatreëls:

Behandeling met PROZAC moet gestaak word by enige pasiënt wat stuipe kry. PROZAC moet vermy word by epileptiese pasiënte wat nie gestabiliseer is nie; pasiënte met gekontroleerde epilepsie moet sorgvuldig gemonitor word. Langdurige stuipe is by pasiënte op PROZAC, wat EKB ontvang het, aangemeld. (Sien 'INTERAKSIES')

PROZAC word omvattend deur die lewer gemetaboliseer en deur die niere uitgeskei. Vir pasiënte met aansienlike lewerwanfunksie of ligte tot matige nierversaking (GFT 10-50 ml/min.) word 'n laer dosis, bv. dosering elke tweede dag, aanbeveel.

Aangesien kliniese ervaring in akute hartsiektes beperk is, moet versigtigheid aan die dag gelê word.

PROZAC kan massaverlies tot gevolg hê, wat ongewens kan wees by depressiewe pasiënte wat reeds ondermassa is.

PROZAC mag die beheer van bloedsuiker in pasiënte met suikersiekte wysig. Hipoglukemie het tydens behandeling met fluoksetien voorgekom en na staking van behandeling het hiperglukemie ontwikkel. Dit mag nodig wees om die insulien en/of mondelike hipoglukemiese doseringsleefreël aan te pas.

Verslae van gewysigde bloedplaatjiefunksionering en/of abnormale resultate van laboratoriumondersoeke is van pasiënte wat fluoksetien geneem het, ontvang. Verslae van abnormale bloeding by verskeie pasiënte wat fluoksetien geneem het, is ontvang. Dit is egter nie duidelik of PROZAC 'n oorsaaklike rol gespeel het nie.
Alhoewel aangetoon is dat PROZAC nie die psigomotoriese handelinge van gesonde, vrywillige proefpersone aantas nie, kan enige psigo-aktiewe middel 'n persoon se oordeel of sy vaardighede benadeel. Pasiënte moet daarom gewaarsku word dat hulle vermoë om potensieel gevaarlike take uit te voer (bv. die bestuur van 'n motorvoertuig of hantering van masjinerie) benadeel kan wees.

Aangesien verbetering nie noodwendig mag voorkom oor die eerste twee of meer weke van behandeling nie, moet pasiënte noukeurig gemoniteer word gedurende hierdie periode. As

gevolg van die risiko van selfmoord pogings tydens major depressiewe episodes, moet hoë risiko pasiënte noukeurig dopgehou word.

As gevolg van die goed vasgestelde komorbiditeit van obsessief-kompulsiewe afwyking en depressie moet dieselfde voorsorgmaatreëls wat geld wanneer pasiënte met depressie behandel word, toegepas word wanneer pasiënte met obsessief-kompulsiewe siekte behandel word.

Ekstrapiramidale simptome geassosieer met die gebruik van PROZAC en die verergering van Parkinsons siekte is aangemeld. PROZAC moet vir hierdie rede met sorg toegedien word in pasiënte met ekstrapiramidale afwykings.

Staking van PROZAC mag aanleiding gee tot ontrekking simptome, insluitend duiseligheid, parestesie, hoofpyn, insomnie, bewing, konfusie, sensoriese afwykings, agitasie, angstigheid en naarheid. (Sien 'INTERAKSIES')

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN :

Simptome: Simptome van oordosering sluit naarheid, vomering, stuipe, kardiovaskulêre wanfunksie wat strek van asimptomatiese aritmieë tot hartstilstand, pulmonêre wanfunksie en tekens van veranderde SSS status wat strek van eksitasie tot koma.

Behandeling: Monitering van kardiale en vitale tekens word aanbeveel saam met algemene simptomaties en ondersteunende maatreëls.

Daar is geen spesifieke teenmiddels vir PROZAC nie.

Weens die groot distribusievolume van PROZAC, is dit onwaarskynlik dat geforseerde diurese, dialise, hemoperfusie en uitruiltransfusie van nut sal wees. Wanneer oordosering behandel word, moet die moontlikheid van meervuldige medikasie betrokkenheid oorweeg word.

IDENTIFIKASIE :

PROZAC 20 kapsule, PU 3105, is 'n nommer 3 grootte kapsule met 'n ondeursigtige groen kappie en 'n ondeursigtige naaswit romp waarop Lilly en 3105 gedruk is.

PROZAC TABLETS, TA 4400, is wit, langwerpige, onbedekte, gekeepte tablette waarop 4400 gedruk is.

AANBIEDING :

PROZAC 20 kapsules word voorsien as stulpverpakkings met 30.

PROZAC TABLETS word voorsien as stulpverpakkings met 30.

BERGINGSAANWYSINGS :

Kapsules: Bewaar benede 30°C in stulpverpakkings. Beskerm teen lig.

Tablette: Bewaar benede 25°C in stulpverpakkings. Beskerm teen lig.

Hou buite bereik van kinders.

REGISTRASIENOMMERS :

S/1.2/68 vir 20 mg kapsules

30/1.2/0503 vir 20 mg tablette

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Eli Lilly (S.A.) (Edms) Beperk

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