

SERRAPRESS 20

SERRAPRESS 30

SCHEDULING STATUS: S5

PROPRIETARY NAME AND DOSAGE FORM:

SERRAPRESS 20 tablets

SERRAPRESS 30 tablets

COMPOSITION:

SERRAPRESS 20: Each tablet contains paroxetine hydrochloride equivalent to
paroxetine 20 mg.

SERRAPRESS 30: Each tablet contains paroxetine hydrochloride equivalent to
paroxetine 30 mg.

PHARMACOLOGICAL CLASSIFICATION:

A 1.2 Psychoanaleptics (Antidepressants)

PHARMACOLOGICAL ACTION:

Paroxetine is a selective serotonin re-uptake inhibitor (SSRI). The antidepressant effect of paroxetine is thought to be related to its effect on serotonergic neurotransmission.

Pharmacokinetics:

After oral administration, paroxetine is readily absorbed from the gastrointestinal tract. Absorption is not influenced by the presence of food, milk or antacids.

Paroxetine is highly protein bound (95%) and undergoes extensive first-pass metabolism in the liver where it is metabolised in part by cytochrome P450 2D6 (CYP2D6). The metabolites appear to be clinically inactive. The elimination half-life

is about 24 hours, but there is wide intersubject variability. Steady-state is achieved in 7 to 14 days in most patients. Paroxetine is excreted renally (approximately 64%) and in the faeces (approximately 36%) mainly as inactive metabolites.

INDICATIONS:

- Depression
- Obsessive Compulsive Disorder (OCD)
- Social phobia
- Panic disorder

CONTRA-INDICATIONS:

- Hypersensitivity to paroxetine or any of the ingredients of **SERRAPRESS**.
- **MAO-Inhibitors:** **SERRAPRESS** should not be used in combination with MAO-inhibitors or within 2 weeks of terminating treatment with MAO-inhibitors. MAO-inhibitors should not be introduced within 2 weeks of cessation of therapy with **SERRAPRESS**.
- Children under the age of 18 years (see **WARNINGS** and **SIDE-EFFECTS AND SPECIAL PRECAUTIONS**).
- Co-administration with thioridazine.

WARNINGS:

Safety and efficacy in children under 18 years have not been established (See **CONTRA-INDICATIONS** and **SIDE-EFFECTS AND SPECIAL PRECAUTIONS**).

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 **SERRAPRESS** 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 **SERRAPRESS**, 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, **SERRAPRESS** should be tapered (See PRECAUTIONS and DOSAGE AND DIRECTIONS FOR USE).

SERRAPRESS should be used with caution in: -

- Patients with a history of mania.

- Patients already receiving neuroleptics, since symptoms suggestive of Neuroleptic Malignant Syndrome may occur with this combination.
- Patients concomitantly treated with medicines that give an increased risk for bleeding, and in patients with a known tendency for bleeding or those with predisposing conditions. Treatment with **SERRAPRESS** may cause skin and mucous membrane bleedings.

Co-administration with risperidone may lead to increased toxicity thereof (see INTERACTIONS).

Patients should be cautioned about their ability to drive a car and operate machinery.

The concomitant use of **SERRAPRESS** and alcohol is not advised.

INTERACTIONS:

Cimetidine, a drug metabolising inhibitor, can increase the bioavailability of **SERRAPRESS**, whereas the drug metabolising inducer phenytoin can decrease it.

When **SERRAPRESS** is to be co-administered with a known drug metabolising enzyme inhibitor, consideration should be given to using doses at the lower end of the range. No initial dosage adjustment of **SERRAPRESS** is considered necessary when the medicine is to be co-administered with known drug metabolising enzyme inducers. Any subsequent dosage adjustment should be guided by clinical effects (tolerability and efficacy).

SERRAPRESS inhibits the specific hepatic cytochrome P450 isozyme CYP2D6 responsible for the metabolism of debrisoquine and sparteine. This may lead to

enhanced plasma levels of those co-administered medicines which are metabolised by this isozyme.

Drugs metabolised by this isozyme include certain tricyclic antidepressants (e.g. nortriptyline, amitriptyline, imipramine and desipramine), phenothiazine neuroleptics (e.g. perphenazine and thioridazine), risperidone, Type 1c antiarrhythmics (e.g. propafenone) and metoprolol.

Co-administration with risperidone may lead to increased toxicity thereof.

Interaction between **SERRAPRESS** and monoamine oxidase (MAO) inhibitors (See CONTRA-INDICATIONS), and also between **SERRAPRESS** and tryptophan medication may occur, resulting in a “serotonin syndrome”.

Concurrent administration of **SERRAPRESS** and lithium should be undertaken with caution. Lithium levels should be monitored.

Co-administration of **SERRAPRESS** and phenytoin is associated with decreased plasma concentrations of paroxetine and increased adverse experiences (diarrhoea, indifference, imbalance, nervousness, ataxia and vertigo). No initial dosage adjustment of paroxetine is considered necessary when these agents are co-administered. Any subsequent adjustments should be guided by clinical effect.

Co-administration of **SERRAPRESS** with anti-convulsants may be associated with an increased incidence of adverse events.

Daily administration of **SERRAPRESS** may significantly increase the plasma levels of procyclidine; other anti-cholinergic drugs may be similarly affected. If anti-cholinergic effects are seen, the dose of procyclidine should be reduced.

SERRAPRESS should be administered with great caution to patients receiving oral anticoagulants (See WARNINGS).

Co-administration of **SERRAPRESS** with warfarin may result in increased bleeding in the presence of unaltered prothrombin times.

PREGNANCY AND LACTATION:

The safety of **SERRAPRESS** in pregnancy or lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

It is recommended that **SERRAPRESS** be administered in the morning with food.

SERRAPRESS should be swallowed rather than chewed.

Depression: 20 mg daily. This dose can be increased gradually if needed by 10 mg increments to a maximum of 50 mg daily according to the patient's response.

Panic Disorder: The recommended dose is 40 mg daily. The initial starting dose is 10 mg daily, which may be increased by 10 mg increments. The maximum dose is 60 mg daily.

The low initial starting dose is recommended to minimise the potential worsening of panic symptoms when initiating treatment with **SERRAPRESS**.

Obsessive Compulsive Disorder: The recommended dose is 40 mg daily. The initial starting dose is 20 mg daily, which may be increased by 10 mg increments to a maximum of 60 mg daily.

Social Phobia: The recommended daily dose is 20 mg. This dose may be increased gradually if needed by 10 mg increments to a maximum of 60 mg according to the patient's response.

Children: The safety and efficacy of **SERRAPRESS** in children under the age of 18 years have not been established. In children hostility, suicide ideation and self-harm may occur with **SERRAPRESS**.

Elderly: Elderly subjects may experience increased plasma concentrations with **SERRAPRESS**. Dosing should commence at the adult starting dose and may be increased gradually by 10 mg increments up to 40 mg daily.

Hepatic and renal impairment: Increased plasma concentrations of **SERRAPRESS** may occur in patients with severe renal impairment (creatinine clearance < 30 ml/min) or severe hepatic impairment. The dosage should therefore be restricted to the lower end of the dosage range.

Patients should be treated for a sufficient period to ensure that they remain free from symptoms. This may be several months or longer.

Abrupt discontinuation of **SERRAPRESS** should be avoided (See SIDE-EFFECTS AND SPECIAL PRECAUTIONS).

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects:

Definition of frequencies:

Rare ($\geq 1/10\ 000$, $< 1/1000$)

Very rare ($< 1/10\ 000$), including isolated reports

Very common ($\geq 1/10$)

Common ($\geq 1/100$, $< 1/10$)

Uncommon ($\geq 1/1000$, $< 1/100$)

Blood and lymphatic system disorders:

Uncommon: Abnormal bleeding, predominantly of the skin and mucous membranes (mostly ecchymosis, but also in the gastrointestinal tract, central nervous system and eye).

Endocrine disorders:

Very rare: Syndrome of inappropriate anti-diuretic hormone secretion (SIADH).

Psychiatric disorders:

Common: Somnolence, insomnia.

Uncommon: Confusion, hallucinations.

Rare: Manic reactions.

Immune system disorders:

Very rare: Allergic reactions (including urticaria and angioedema).

Metabolism and nutrition disorders:

Common: Decreased appetite.

Rare: Hyponatraemia.

Hyponatraemia, which may occur predominantly in elderly patients, is sometimes due to syndrome of inappropriate anti-diuretic hormone secretion (SIADH).

Nervous system disorders:

Common: Dizziness, tremor.

Uncommon: Extrapyrarnidal disorders.

Rare: Convulsions.

Very rare: Serotonin syndrome (symptoms may include agitation, confusion, diaphoresis, hallucinations, hyperreflexia, myoclonus, shivering, tachycardia and tremor).

Extrapyrarnidal disorders may occur in patients using neuroleptic medication.

General disorders and administration site conditions:

Common: Asthenia.

Very rare: Peripheral oedema.

Eye disorders:

Common: Blurred vision.

Very rare: Acute glaucoma.

Respiratory, thoracic and mediastinal disorders:

Common: Yawning.

Renal and urinary disorders:

Uncommon: Urinary retention.

Reproductive system and breast disorders:

Very common: Sexual dysfunction.

Rare: Hyperprolactinaemia/galactorrhoea.

Gastrointestinal disorders:

Very common: Nausea.

Common: Constipation, diarrhoea, dry mouth.

Hepato-biliary disorders:

Rare: Elevation of hepatic enzymes.

Very rare: Hepatic events (such as hepatitis, sometimes associated with jaundice and/or liver failure).

Elevation of hepatic enzymes may occur. Hepatic events, which may be fatal (such as hepatitis, sometimes associated with jaundice, and/or liver failure) may occur.

Discontinuation of **SERRAPRESS** should be considered if there is prolonged elevation of liver function test results.

Skin and subcutaneous tissue disorders:

Common: Sweating.

Uncommon: Skin rashes.

Very rare: Photosensitivity reactions.

Symptoms seen on discontinuation of SERRAPRESS treatment:

Common: Dizziness, sensory disturbances, sleep disturbances, anxiety, headache.

Uncommon: Agitation, nausea, tremor, confusion, sweating, diarrhoea.

Abrupt discontinuation of **SERRAPRESS** may lead to withdrawal symptoms such as dizziness, sensory disturbances (including paraesthesia and electric shock sensations), sleep disturbances, insomnia, tremor, confusion, agitation or anxiety, headache, nervousness, vertigo, nausea and sweating. It is therefore advised that when **SERRAPRESS** treatment is no longer required, gradual discontinuation by dose tapering be carried out (See DOSAGE AND DIRECTIONS FOR USE, and SPECIAL PRECAUTIONS).

Special precautions:

Safety and efficacy in children under 18 years of age have not been established (See CONTRA-INDICATIONS and DOSAGE AND DIRECTIONS FOR USE).

Cardiac Condition:

Administration of **SERRAPRESS** to patients with a serious cardiovascular disorder such as (unstable) angina pectoris, poorly monitored cardiac decompensation, ventricular rhythm disorder and acute myocardial infarction, has not been studied and must therefore be avoided. If antidepressant medication is nevertheless indicated for such patients, **SERRAPRESS** should be administered with caution.

Epilepsy:

SERRAPRESS should be used with caution in patients with epilepsy.

Seizures:

Seizures may occur in patients treated with **SERRAPRESS**.

SERRAPRESS should be discontinued in any patient who develops seizures.

Electro-Convulsive Therapy (ECT):

Clinical experience of the concurrent administration of **SERRAPRESS** and electro-convulsive therapy is lacking.

Hyponatraemia:

Hyponatraemia, which is generally reversible on discontinuation of **SERRAPRESS**, may occur predominantly in the elderly.

Glaucoma:

SERRAPRESS may cause mydriasis and should be used with caution in patients with narrow angle glaucoma.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS**TREATMENT:**

(See SIDE-EFFECTS AND SPECIAL PRECAUTIONS)

Symptoms of overdose:

Vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety, tachycardia, coma and ECG changes.

Treatment of overdose:

Treatment is symptomatic and supportive.

There is no specific antidote. To decrease absorption, the stomach should be emptied by gastric lavage or induction of emesis or both. This should be followed by

administration of 20 to 30 g of activated charcoal every four to six hours during the first 24 hours after ingestion. Frequent monitoring of vital signs and careful observation is recommended.

IDENTIFICATION:

SERRAPRESS 20: White to off-white, round, coated, biconvex tablets, diameter 10 mm, scored on one side and P20 on the other side.

SERRAPRESS 30: Blue, round, coated biconvex tablets, diameter 12 mm, scored on one side and P30 on the other side.

PRESENTATION:

Aluminium blister packs of 30 tablets. Each blister strip contains 10 tablets.

STORAGE INSTRUCTIONS:

Store below 25°C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:

SERRAPRESS 20 mg: 38/1.2/0069

SERRAPRESS 30 mg: 38/1.2/0068

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

Pharma Dynamics (Pty) Ltd

F02 Grapevine House

Steenberg Office Park

Westlake

7945

DATE OF PUBLICATION OF THE PACKAGE INSERT:

8 March 2005

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SKEDULERINGSSTATUS: S5

EIENDOMSNAAM EN DOSEERVORM:

SERRAPRESS 20 tablette

SERRAPRESS 30 tablette

SAMESTELLING:

SERRAPRESS 20: Elke tablet bevat Paroksetienhydrochloried ekwivalent aan paroksetien 20 mg.

SERRAPRESS 30: Elke tablet bevat Paroksetienhydrochloried ekwivalent aan paroksetien 30 mg.

FARMAKOLOGIESE KLASSIFIKASIE:

A.1.2 Psigo-analeptika (Antidepressante)

FARMAKOLOGIESE WERKING:

Paroksetien is 'n selektiewe serotonienheropname-inhibeerder (SSRI). Die antidepressante effek van paroksetien is vermoedelik verwant aan sy uitwerking op serotonergiese neurotransmissie.

Farmakokinetika:

Na orale toediening word paroksetien maklik uit die spysverteringskanaal geabsorbeer. Absorpsie word nie deur die teenwoordigheid van voedsel, melk of teensuurmiddels beïnvloed nie. Paroksetien is hoogs proteïengebonde (95%) en ondergaan ekstensiewe presistemiese metabolisme in die lewer waar dit gedeeltelik

as deel van sitochroom P450 2D6 (CYP2D6) gemetaboliseer word. Dit wil voorkom dat die metaboliete klinies onaktief is. Die eliminasië halfleeftyd is ongeveer 24 uur, maar wyd verspreide interpersoonvariasie kom voor. Die ewewigstoestand word in die meeste pasiënte binne 7 tot 14 dae bereik. Paroksetien word deur die niere (ongeveer 64%) en in die faeces (ongeveer 36%) hoofsaaklik as onaktiewe metaboliete, uitgeskei.

INDIKASIES:

- Depressie
- Obsessief-Kompulsiewe Versteuring (OKV)
- Sosiale fobie
- Paniektoestand

KONTRA-INDIKASIES:

- Hipersensitiwiteit teenoor paroksetien of enige van die bestanddele van **SERRAPRESS**.
- **MAO-inhibeerders: SERRAPRESS** moet nie in kombinasie met MAO-inhibeerders of binne 2 weke na staking van behandeling met MAO-inhibeerders gebruik word nie. MAO-inhibeerders moet nie binne 2 weke na staking van terapie met **SERRAPRESS** begin word nie.
- Kinders jonger as 18 jaar (sien WAARSKUWINGS en NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS)
- Toediening saam met tiordiasien.

WAARSKUWINGS:

Veiligheid en doeltreffendheid in kinders jonger as 18 jaar is nie vasgestel nie (sien KONTRA-INDIKASIES en NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS).

Pasiënte met ernstige depressie, beide volwassenes en kinders, mag verergering van hulle depressie en/of verskyning van selfmoord idees en gedrag ondervind, of hulle antidepressante medisyne neem, of nie. Hierdie risiko mag aanhou tot betekenisvolle remissie voorkom. 'n Oorsaaklike rol van antidepressante medisyne om sulke gedrag uit te lok, is egter nie vasgestel nie. Pasiënte wat met **SERRAPRESS** behandel word, behoort nogtans versigtig gemoniteer te word vir kliniese verergering en neiging tot selfmoord, veral aan die begin van 'n terapieekursus, of ten tye van dosisveranderings, waar dosisse óf verhoog, óf verlaag word.

As gevolg van die moontlikheid van ko-morbiditeit tussen ernstige depressie en ander psigiatriese en nie-psigiatriese versteurings, moet dieselfde voorsorgmaatreëls wat nagekom word wanneer pasiënte met ernstige depressie behandel word, ook waargeneem word wanneer pasiënte met ander psigiatriese en nie-psigiatriese versteurings behandel word.

Die volgende simptome is aangemeld in pasiënte wat met antidepressante vir ernstige depressie, asook vir ander indikasies, beide psigiatres en nie-psigiatres, behandel is: angs, agitatie, paniekaanvalle, slaaploosheid, prikkelbaarheid, hostiliteit (aggressie, impulsiwiteit, akatisie, hipomanie en manie). Alhoewel 'n oorsaaklike verband tussen die ontluiking van sulke simptome en die verergering van depressie en/of ontluiking van idees van selfmoord nie vasgestel is nie, moet oorweging daaraan geskenk word om die terapeutiese regimen te verander, insluitend moontlike

staking van **SERRAPRESS** in pasiënte by wie sulke simptome ernstig is, skielik begin, of nie deel van die pasiënt se aanvanklike simptome was nie.

Indien die besluit geneem word om behandeling te staak, moet **SERRAPRESS** geleidelik verminder word (Sien VOORSORGMAATREËLS en DOSIS EN GEBRUIKSAANWYSINGS).

SERRAPRESS moet met versigtigheid gebruik word in:

- Pasiënte met 'n geskiedenis van manie.
- Pasiënte wat alreeds neuroleptika ontvang, omdat simptome suggestief van Neuroleptiese Maligne Sindroom met hierdie kombinasie mag voorkom.
- Pasiënte wat gelyktydig behandel word met medisyne wat 'n verhoogde risiko van bloeding veroorsaak, en in pasiënte met 'n bekende neiging tot bloeding en dié met toestande wat hulle daarvoor vatbaar maak. Behandeling met **SERRAPRESS** mag vel- en slymvliesbloeding veroorsaak.

Gelyktydige toediening saam met risperidoon mag lei tot verhoogde toksisiteit daarvan (sien INTERAKSIES).

Pasiënte moet gewaarsku word oor hulle vermoë om 'n motor te bestuur en om masjiene te bedien.

Die gelyktydige gebruik van **SERRAPRESS** en alkohol word nie aanbeveel nie.

INTERAKSIES:

Simetidien, 'n geneesmiddelmetaboliserende inhibeerder, kan die biobeskikbaarheid van **SERRAPRESS** verhoog, terwyl die geneesmiddelmetaboliserende induseerder fenitoïen dit kan verlaag.

Wanneer **SERRAPRESS** saam met 'n bekende geneesmiddelmetaboliserende ensieminhibeerder toegedien moet word, moet daar oorweeg word om dosisse aan die laer kant van die dosisreikwydte, te gebruik. Geen aanvanklike dosisaanpassing van **SERRAPRESS** word nodig geag wanneer die medisyne saam met bekende geneesmiddelmetaboliserende ensiemininduseerders toegedien moet word. Enige daaropvolgende dosisaanpassing moet deur die kliniese reaksies (verdraagsaamheid en doeltreffendheid) bepaal word.

SERRAPRESS inhibeer die spesifieke hepatiese sitochroom P450 isoënsiem CYP2D6 wat vir die metabolisme van debrisokeen en sparteïen verantwoordelik is. Dit mag lei tot verhoogde plasmavlakke van hierdie medisyne wat saam toegedien en deur hierdie isoënsiem gemetaboliseer word.

Geneesmiddels wat deur hierdie isoënsiem gemetaboliseer word, sluit sekere trisikliese antidepressante (bv. nortriptilien, amitriptilien, imipramien en desipramien), fenotiasien neuroleptika (bv. perfenasien en tioridasien), risperidoon, Tipe-1c-anti-aritmiese middels (bv. propafenoon) en metoprolol, in.

Gelyktydige toediening saam met risperidoon mag tot verhoogde toksisiteit daarvan lei.

Interaksies tussen **SERRAPRESS** en monoamienoksidase (MAO) inhibeerders (sien KONTRA-INDIKASIES), en ook tussen **SERRAPRESS** en triptofaanmedikasie mag voorkom en 'n "serotonien-sindroom" veroorsaak.

Gelyktydige toediening van **SERRAPRESS** en litium moet met omsigtigheid geskied. Litiumvlakke moet gemonitor word.

Gelyktydige toediening van **SERRAPRESS** en fenitoïen word geassosieer met verlaagde plasmakonsentrasies van paroksetien en verhoogde voorkoms van nadelige ondervindings (diarree, onverskilligheid, wanbalans, senuagtigheid, ataksie en vertigo). Geen aanvanklike dosisaanpassing van paroksetien word nodig geag wanneer hierdie middels gelyktydig toegedien word nie. Enige daaropvolgende aanpassings behoort deur die kliniese uitwerking bepaal te word.

Gelyktydige toediening van **SERRAPRESS** en antikonvulsiemiddels mag met 'n verhoogde voorkoms van nadelige insidente geassosieer word.

Daaglikse toediening van **SERRAPRESS** mag die plasmavlakke van prosiklidien beduidend verhoog; ander anticholinergiese geneesmiddels mag op soortgelyke wyse beïnvloed word. Indien anticholinergiese uitwerkings waargeneem word, moet die dosis prosiklidien verminder word.

SERRAPRESS behoort met groot omsigtigheid toegedien te word aan pasiënte wat orale antikoagulante ontvang (Sien WAARSKUWINGS).

Gelyktydige toediening van **SERRAPRESS** en warfarien mag verhoogde bloeding in die teenwoordigheid van onveranderde protrombientye veroorsaak.

SWANGERSKAP EN LAKTASIE:

Veiligheid van **SERRAPRESS** in swangerskap of laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Dit word aanbeveel dat **SERRAPRESS** in die oggend saam met voedsel toegedien word. **SERRAPRESS** behoort ingesluk, liewer as om gekou te word.

Depressie: 20 mg daagliks. Hierdie dosis kan, indien nodig, geleidelik verhoog word in 10 mg inkremente tot 'n maksimum van 50 mg daagliks soos deur die pasiënt se reaksie bepaal.

Paniektoestand: Die aanbevole dosis is 40 mg daagliks. Die aanvangsdosis is 10 mg daagliks, wat met 10 mg inkremente verhoog kan word. Die maksimum dosis is 60 mg per dag. Die lae aanvangsdosis word aanbeveel om potensiële verergering van panieksimptome tydens die begin van behandeling met **SERRAPRESS** tot 'n minimum te beperk.

Obsessief-Kompulsiewe Versteuring: Die aanbevole dosis is 40 mg daagliks. Die aanvangsdosis is 20 mg daagliks, wat met 10 mg inkremente tot 'n maksimum van 60 mg per dag verhoog kan word.

Sosiale Fobie: Die aanbevole daaglikse dosis is 20 mg. Hierdie dosis kan, indien nodig, geleidelik verhoog word in 10 mg inkremente tot 'n maksimum van 60 mg daagliks soos deur die pasiënt se reaksie bepaal.

Kinders: Die veiligheid en doeltreffendheid van **SERRAPRESS** in kinders tot die ouderdom van 18 jaar is nie vasgestel nie. In kinders mag hostiliteit, selfmoord idees en self-beskadiging met **SERRAPRESS** voorkom.

Bejaardes: Bejaarde persone mag met **SERRAPRESS** verhoogde plasmakonsentrasies ondervind. Dosering behoort met die volwasse aanvangsdosis te begin en mag geleidelik met 10 mg inkremte tot 40 mg per dag verhoog word.

Lewer- en nierinkorting: Verhoogde plasmakonsentrasies van **SERRAPRESS** mag in pasiënte met ernstige nierinkorting (kreatinienopruiming < 30 ml/min) of ernstige lewerinkorting voorkom. Die dosering behoort dus tot die laer end van die doseringsreikwydte beperk te word.

Pasiënte moet vir 'n toereikende tydperk behandel word om te verseker dat hulle vry van simptome bly. Dit mag etlike maande of langer duur.

Skieelike staking van **SERRAPRESS** moet vermy word (Sien **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**).

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Nuwe-effekte:

Definisie van frekwensies:

Seldsaam ($\geq 1/10\ 000$, < 1/1000)

Baie seldsaam (<1/10 000), insluitend geïsoleerde berigte

Baie algemeen ($\geq 1/10$)

Algemeen ($\geq 1/100$, <1/10)

Ongewoon ($\geq 1/1000$, <1/100)

Versteurings van die bloed en limfatiese sisteem:

Ongewoon: Abnormale bloeding, veral van die vel en slymvliese (meestal eggimose, maar ook in die spysverteringskanaal, sentrale senusisteem en oog).

Endokriene versteurings:

Baie seldsaam: Sindroom van onpaslike antidiuretiese hormoon afskeiding (SOADH).

Psigiatriese versteurings:

Algemeen: Slaperigheid, slaaploosheid.

Ongewoon: Verwarring, hallusinasies.

Seldsaam: Maniese reaksies.

Versteurings van die immuunsisteem:

Baie seldsaam: Allergiese reaksies (insluitend urtikarie en angio-edeem).

Versteurings van metabolisme en voeding:

Algemeen: Verminderde aptyt.

Seldsaam: Hiponatremie.

Hiponatremie, wat veral in bejaarde pasiënte mag voorkom, is soms die gevolg van die sindroom van onpaslike antidiuretiese hormoon afskeiding (SOADH).

Versteurings van die senusisteem:

Algemeen: Duiseligheid, tremor.

Ongewoon: Ekstrapiramidale versteurings.

Seldsaam: Konvulsies.

Baie seldsaam: Serotoniensindroom (simptome mag agitاسie, verwarring, diaforese, hallusinasie, hiper-refleksie, mioklonus, bewerasies, tagikardie en tremor insluit).

Ekstrapiramidale versteuring mag voorkom in pasiënte wat neuroleptiese medikasie gebruik.

Algemene versteurings en versteurings by die plek van toediening:

Algemeen: Astenie.

Baie seldsaam: Perifere edeem.

Versteurings van die oog:

Algemeen: Versteurde visie.

Baie seldsaam: Akute gloukoom.

Respiratoriese, torakale en mediastinale versteurings:

Algemeen: Gaap.

Renale en urinêre versteurings:

Ongewoon: Urienretensie.

Versteurings van die voortplantingsstelsel en bors:

Baie algemeen: Seksuele disfunksie.

Seldsaam: Hiperprolaktienemie/galaktoree.

Gastroïntestinale verstourings:

Baie algemeen: Naarheid.

Algemeen: Hardlywigheid, diarree, droë mond.

Hepato-biliêre verstourings:

Seldsaam: Verhoging van hepatiese ensieme.

Baie seldsaam: Hepatiese insidente (soos hepatitis, soms geassosieer met geelsug en/of lewersaking).

Verhoging van hepatiese ensieme mag voorkom. Hepatiese insidente, wat noodlottig mag wees (soos hepatitis, soms geassosieer met geelsug, en/of lewersaking) mag voorkom.

Staking van **SERRAPRESS** moet oorweeg word indien langdurige verhoging van lewerfunksietoetsresultate voorkom.

Verstourings van die vel en onderhuidse weefsel:

Algemeen: Sweet.

Ongewoon: Veluitslae.

Baie seldsaam: Fotosensitiwiteitsreaksies.

Simptome wat met staking van SERRAPRESS-behandeling waargeneem word:

Algemeen: Duiseligheid, sensoriese verstourings, slaapverstourings, angs, hoofpyn.

Ongewoon: Agitasie, naarheid, tremor, verwarring, sweet, diarree.

Skielike staking van **SERRAPRESS** mag lei tot onttrekkingsimptome soos duiseligheid, sensoriese verstourings (insluitend parestesie en sensasies van elektriese skok), slaapverstourings, slaaploosheid, tremor, verwarring, agitasie of angs, hoofpyn, senuagtigheid, vertigo, naarheid en sweet. Dit word dus aanbeveel

dat wanneer **SERRAPRESS**-behandeling nie langer nodig is nie, geleidelike staking deur middel van dosisvermindering uitgevoer word (Sien DOSIS EN GEBRUIKSAANWYSINGS, en SPESIALE VOORSORGMAATREËLS).

Spesiale voorsorgmaatreëls:

Die veiligheid en doeltreffendheid in kinders tot die ouderdom van 18 jaar is nie vasgestel nie (Sien KONTRA-INDIKASIES en DOSIS EN GEBRUIKSAANWYSINGS).

Kardiale Toestand:

Toediening van **SERRAPRESS** aan pasiënte met 'n ernstige kardiovaskulêre siekte soos (onstabiele) angina pectoris, swak-gemoniteerde kardiale dekompensasie, ventrikulêre ritme-versteuring en akute miokardiale infarksie, is nie bestudeer nie en moet dus vermy word. Indien antidepressante medikasie nogtans vir sulke pasiënte aangedui is, moet **SERRAPRESS** met omsigtigheid toegedien word.

Epilepsie:

SERRAPRESS moet met omsigtigheid gebruik word in pasiënte met epilepsie.

Konvulsies:

Konvulsies mag voorkom in pasiënte wat met **SERRAPRESS** behandel word.

SERRAPRESS moet gestaak word in enige pasiënt wat konvulsies ontwikkel.

Elektro-Konvulsiewe Terapie (EKT):

Kliniese ondervinding van die gelyktydige toediening van **SERRAPRESS** en elektro-konvulsiewe terapie ontbreek.

Hiponatremie:

Hiponatremie, wat gewoonlik omkeerbaar is met staking van **SERRAPRESS**, mag veral in bejaardes voorkom.

Gloukoom:

SERRAPRESS mag midriase veroorsaak en moet met omsigtigheid gebruik word in pasiënte met nou-hoek gloukoom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

(Sien NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS)

Simptome van oordosering:

Braking, gedilateerde pupille, koors, veranderings in bloeddruk, hoofpyn, onwillekeurige spiersametrekkings, agitاسie, angs, tagikardie, koma en EKG-veranderings.

Behandeling van oordosering:

Behandeling is simptomaties en ondersteunend.

Daar is geen spesifieke teenmiddel nie.

Om absorpsie te verminder, moet die maag geledig word deur maagspoeling of induksie van emese, of albei. Dit moet deur toediening van 20 tot 30 g geaktiveerde houtskool elke vier tot ses uur gedurende die eerste 24 uur na inname, gevolg word.

Frekwente monitering van vitale tekens en versigtige observasie word aanbeveel.

IDENTIFIKASIE:

SERRAPRESS 20: Wit tot naaswit, ronde, bikonvekse, omhulde tablette met 'n deursnee van 10 mm, wat aan een kant gekeep is en P20 op die ander kant.

SERRAPRESS 30: Blou, ronde, bikonvekse, omhulde tablette met 'n deursnee van 12 mm, wat aan een kant gekeep is en P30 op die ander kant.

AANBIEDING:

Aluminium stulpverpakkings van 30 tablette. Elke stulpverpakkingstrook bevat 10 tablette.

BERGINGSAAWYSINGS

Bewaar benede 25°C. Beskerm teen lig.

HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:

SERRAPRESS 20: 38/1.2/0069

SERRAPRESS 30: 38/1.2/0068

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE

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