

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: GENOFINEX 20 mg Capsules
Dosage form and strength: Capsule, Each capsule contains Fluoxetine hydrochloride equivalent to 20 mg Fluoxetine

MODULE 1
 1.3.2
Date: 2020.08.17

1.3.2 Patient Information Leaflet

SCHEDULING STATUS
S5
PATIENT INFORMATION LEAFLET GENOFINEX 20 mg Capsules Fluoxetine Hydrochloride (Sugar free)
<p>Read all of this leaflet carefully before you start taking GENOFINEX.</p> <ul style="list-style-type: none"> - Keep this leaflet. You may need to read it again. - If you have further questions, please ask your doctor or your pharmacist. - GENOFINEX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
<p>What is in this leaflet:</p> <ol style="list-style-type: none"> 1. What GENOFINEX is and what it is used for 2. What you need to know before you use GENOFINEX 3. How to use GENOFINEX 4. Possible side effects 5. How to store GENOFINEX 6. Contents of the pack and other information
<p>1. What GENOFINEX is and what it is used for</p> <p>Fluoxetine belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.</p> <p>GENOFINEX is used to treat the following conditions:</p>

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MODULE 1
1.3.2
Date: 2020.08.17

Depression: a mental health disorder characterised by persistently depressed mood or loss of interest in activities, causing significant impairment in daily life. GENOFINEX is indicated for the treatment of major depressive episodes i.e. single episode and recurrent depression with associated anxiety.

Bulimia nervosa: a serious eating disorder marked by bingeing, followed by methods to avoid weight gain.

Obsessive-compulsive disorder: a mental disorder most commonly characterised by intrusive, repetitive thoughts resulting in compulsive behaviours and mental acts that the person feels driven to perform.

2. What you need to know before you take GENOFINEX

Do not take GENOFINEX:

- If you are hypersensitive (allergic) to fluoxetine or any of the ingredients of GENOFINEX.
- If you are less than 18 years of age, as safety and efficacy in children have not been established
- If you have a severe kidney disease
- If you are taking or have recently taken (within the last two weeks) another medicine known as a monoamine oxidase inhibitor (MAOI)
- If you are taking or have recently taken anti-psychotic medicine known as Thioridazine

Take special care with GENOFINEX

- If you experience worsening of your depression, or if you think of harming or killing yourself. You should contact your doctor or go to the hospital doctor immediately.
- If you experience muscle stiffness or tremor, appearance of fever, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; contact your doctor immediately

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MODULE 1
1.3.2
Date: 2020.08.17

- If you experience swollen face or tongue, or shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- If you experience epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact your doctor immediately
- If you suffer from kidney problems you should not take GENOFINEX (see Do not take)
- If you are diabetic
- If you have eye problems or suffer from, or have a history of, glaucoma
- If you have moderate or severe heart failure
- If you are taking diuretic medications (medication which increases the excretion of water and salt from the body). As this may result in hyponatraemia (a condition that occurs when the level of sodium in the blood is too low), when taken together with GENOFINEX
- If you experience abnormal bleeding
- If you feel restless and feel like you cannot sit or stand still, tell your doctor. Do not increase the dose of [PN] it may make these feelings worse.

Taking other medicines with GENOFINEX:

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

Other medicines and GENOFINEX XR:

The following combination is contraindicated:

- Certain irreversible, non-selective monoamine oxidase inhibitors (MAOIs), some used to treat depression. Irreversible, non-selective MAOIs must not be used with GENOFINEX as serious or even fatal reactions (serotonin syndrome) can occur (see section 4.4). Treatment with GENOFINEX should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI. Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking GENOFINEX. If GENOFINEX has been prescribed for a long period

Applicant: Aurogen South Africa (Pty) Ltd
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MODULE 1
1.3.2
Date: 2020.08.17

and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor.

- Selective serotonin reuptake inhibitors (SSRIs) or lithium

The following combinations require precautions for use:

- CNS-active substances
- Pimozide (used to treat Tourette syndrome) – GENOFINEX can increase the level of pimozide
- Thioridazine (used to treat schizophrenia, a disorder that affects a person's ability to think, feel and behave clearly. Thioridazine should not be administered with GENOFINEX or within a minimum of 5 weeks after GENOFINEX has been discontinued. Thioridazine administration produces a dose related prolongation of the QTc (a heart rhythm condition that can potentially cause fast, chaotic heartbeats)
- Tryptophan - there is an increased risk of mild serotonin syndrome when this medicine is taken with GENOFINEX
- Anti-depressants such as tricyclic anti-depressants
- Benzodiazepines (such as diazepam) – GENOFINEX may influence the blood levels of this medicine
- Selective serotonin reuptake inhibitors (SSRIs) such as haloperidol and clozapine
- Anti-coagulants (such as warfarin), NSAID (such as ibuprofen, diclofenac), aspirin and other medicines which can thin the blood. GENOFINEX may alter the effect of these medicines on the blood. If GENOFINEX treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently.
- Terfenadine and Astemizole, an anti-histamine used to treat allergies
- Cisapride, a medicine used to increase motility in the gut
- Metoprolol when used for heart failure; there is an increased risk of your heart beat becoming too slow.
- Midazolam, a benzodiazepine used to treat anxiety

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MODULE 1
1.3.2
Date: 2020.08.17

Pregnancy, breastfeeding and fertility

GENOFINEX is not recommended to be used in pregnancy, due to the potential risk to the foetus.

GENOFINEX is excreted in human milk. Patients should be advised not to breast feed if they are taking GENOFINEX.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking GENOFINEX

Driving and using machines

GENOFINEX as psychoactive medicine may impair your judgment, thinking, and motor skills. Therefore, caution should be observed when operating hazardous machines, including motor vehicles, until you are certain that fluoxetine does not affect you adversely

3. How to take GENOFINEX

Do not share medicines prescribed for you with any other person.

Always take GENOFINEX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with GENOFINEX will last. If you have the impression that the effect of GENOFINEX is too strong or too weak, talk to your doctor or pharmacist.

GENOFINEX should be swallowed whole or dispersed in approximately 100 ml water.

For the treatment of major depressive episodes, a dose of 20mg/day is recommended, preferably in the morning

For the treatment of bulimia nervosa, a dose of 60 mg/day is recommended.

For the treatment of obsessive-compulsive disorder, a dose of 20 to 60 mg/day is the recommended dose

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

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MODULE 1
1.3.2
Date: 2020.08.17

GENOFINEX 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.

Fluoxetine Capsules should not be used in the treatment of children or adolescents under the age of 18 years.

Taking GENOFINEX with food and drink

PRODUCT NAME] may be taken with or without food. Avoid alcohol while you are taking this medicine

If you take more GENOFINEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

These are the possible signs and symptoms of overdose: nausea, vomiting, seizures, cardiovascular dysfunction ranging from asymptomatic dysrhythmias to cardiac arrest, pulmonary dysfunction and signs of altered CNS status ranging from excitation to coma.

If you forget to take GENOFINEX

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses

If you stop taking GENOFINEX

Do not stop taking GENOFINEX without asking your doctor first, even when you start to feel better. It is important that you keep taking your medicine. If needed, your doctor will gradually decrease your dose.

4. Possible side effects

GENOFINEX can have side effects.

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: GENOFINEX 20 mg Capsules
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MODULE 1
1.3.2
Date: 2020.08.17

Not all side effects reported for GENOFINEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GENOFINEX, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking GENOFINEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swollen face or tongue, or shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Rapid or irregular heartbeat, flushing or fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to GENOFINEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Seizures, fits or convulsions
- If you experience muscle stiffness or tremor, appearance of fever, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome".
- Feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water capsules)
- Chest pains
- Frequent or unusual bruising or bleeding, such as nose bleeds (this could indicate that GENOFINEX has had an effect on your blood, and this may need to be tested)

These are all serious side effects. You may need urgent medical attention.

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MODULE 1
1.3.2
Date: 2020.08.17

Tell your doctor if you notice any of the following:

Frequent side effects:

- Weight gain
- Agitation, amnesia, confusion, emotional lability, sleep disorder
- Ear pain, tinnitus (ringing in ear)
- High blood pressure, fast heart-beat
- Increased appetite, nausea and vomiting
- Urinary frequency increased
- Chest pain, chills

Less frequent side effects:

- Anaemia, discolouration of the skin
- Hypothyroidism (a condition in which the thyroid gland is not able to produce enough thyroid hormone)
- Dehydration
- Generalised oedema (a condition characterized by an excess of watery fluid collecting in the cavities or tissues of the body)
- Gout (a form of arthritis characterised by severe pain, redness and tenderness in joints)
- High cholesterol levels in the blood or high concentration of fats in the blood
- Low levels of potassium in the blood
- Impairment of your mental state or a state in which one's thoughts and feelings seem unreal or not to belong to oneself.
- Restlessness, inability to sit still, lack of interest, enthusiasm, or concern
- Impaired balance or a feeling of spinning and dizziness
- A feeling or state of intense excitement and happiness
- An experience involving the apparent perception of something not present

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MODULE 1
1.3.2
Date: 2020.08.17

- Paranoid reaction, personality disorder , psychosis (disconnection from reality
- Abnormal movement of the legs while walking or involuntary movement of the body
- Muscle spasm, increased tightness of muscle tone, a decreased capacity for physical sensation, especially of the skin
- Spasmodic jerky contraction of groups of muscles, stabbing, burning, and often severe pain due to an irritated or damaged nerve
- Weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Increased sexual drive
- Inflammation or infection of the outer membrane of the eyeball and the inner eyelid., dry eyes, dilation of the pupil of the eye, pain to the eyes due to exposure to light
- An inflammation of the eyelid that affects the eyelashes or tear production, double vision, bulging of the eyes, bright red patch appearing in the white of the eye, abnormal pressure in eye, inflammation of the eye, loss of part of the usual field of vision
- Disorder in which the eyes don't look in exactly the same direction at the same time.
- Partial or complete hearing loss, condition which affects how you perceive sounds
- Condition that distorts the sense of smell
- Bleeding from nose
- Chest pain caused by reduced blood flow to the heart
- Improper beating of the heart, whether irregular, too fast or too slow
- Congestive heart failure - A chronic condition in which the heart doesn't pump blood as well as it should.
- Low blood pressure, headache, heart attack, low blood pressure when standing up or sitting or lying down
- Fainting or a sudden temporary loss of consciousness

Applicant: Aurogen South Africa (Pty) Ltd
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MODULE 1
1.3.2
Date: 2020.08.17

- Asthma (airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe)
- Hiccup, hyperventilation
- A small, shallow sore inside the mouth or at the base of the gums
- A hardened deposit within the fluid in the gallbladder
- Inflammation in the colon
- Difficulty swallowing foods or liquids, arising from the throat or oesophagus, ranging from mild difficulty to complete and painful blockage.
- Oesophagitis (Inflammation that damages the tube running from the throat to the stomach)
- Inflammation of the stomach lining, intestine, tongue and gums
- High acid levels in stomach
- Increased salivation,
- Liver function tests abnormal, melena
- Black tarry stool
- One or more painful sores on inner lips, gums, tongue, roof of the mouth or throat that may interfere with eating
- Nausea, vomiting, diarrhoea
- Acne, hair loss from the scalp or elsewhere on the body, contact dermatitis, itchy inflammation of the skin, rash, skin discolouration, skin ulcer, blisters
- Inflammation of one or more joints, causing pain and stiffness, bone pain, Inflammation of the fluid-filled pads (bursae) that act as cushions at the joints., leg cramps, Inflammation of the tendon sheath where muscle connects to bone
- Resulting in termination of pregnancy
- An excess of protein in the urine.
- Breast enlargement, breast pain,

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Dosage form and strength: Capsule, Each capsule contains Fluoxetine hydrochloride equivalent to 20 mg Fluoxetine

MODULE 1
1.3.2
Date: 2020.08.17

- Inflammation of the bladder, discomfort, pain or burning when urinating, blood in urine
- Urinating frequently at night, passing abnormally large amounts of urine, loss of bladder control or difficulty urinating and completely emptying the bladder, urine output below normal
- A whitish or yellowish discharge of mucus from the vagina
- Heavy or prolonged vaginal bleeding with menstrual cycle
- Any vaginal bleeding unrelated to normal menstruation
- Bleeding from the uterus that occurs in between periods, may occur every few weeks and the flow may be heavier than usual
- The absence of monthly menstrual periods
- Persistent inability to achieve orgasm despite responding to sexual stimulation
- Producing breastmilk
- Non-cancerous changes that give a breast a lumpy or rope-like texture
- Chills and fever, face swelling, intentional overdose
- General sense of being unwell, often accompanied by fatigue, diffuse pain or lack of interest in activities
- Pelvic pain
- Suicide attempt
- Diseases or disorders of the blood
- Diabetic acidosis, diabetes mellitus
- Alcohol intolerance, immediate unpleasant reactions after drinking alcohol
- Increased levels of alkaline phosphatase, BUN, creatine phosphokinase, potassium and uric acid,
- Low levels of calcium in the blood
- Iron deficiency anaemia

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MODULE 1
1.3.2
Date: 2020.08.17

- Abnormal electroencephalogram (EEG)
- Antisocial reaction,
- Tingling around the mouth, weakness in the muscles used for speech, which often causes slowed or slurred speech.
- Coma, delusions
- Involuntary muscle contractions that cause repetitive or twisting movements
- Extrapyrimal syndrome - symptoms include continuous spasms and muscle contractions, motor restlessness, rigidity, slowness of movement, tremor and irregular, jerky movements.
- Difficulty lifting the front part of the foot
- Excessive physical sensitivity, especially of the skin
- Inflammation of a peripheral nerve or nerves, usually causing pain and loss of function
- Complete or partial loss of muscle function.
- A state of near-unconsciousness or insensibility
- Severe, destructive, vision-threatening inflammation involving the deep episclera and sclera
- Abnormal heart rhythm, slower than expected heart rate, sudden blockage of an artery, heart attack
- Insufficient blood flow to the brain,
- Unhealthy pale appearance
- Peripheral vascular disorder - is a blood circulation disorder that causes the blood vessels outside of your heart and brain to narrow, block, or spasm
- Inflammation of a vein, blood clot in vein causing inflammation, blood clots, sudden constriction of blood vessel

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MODULE 1
1.3.2
Date: 2020.08.17

- Abnormal heartbeats from the lower chambers of the heart, premature contractions of the heart and erratic rapid heart-beat
- Temporary cessation of breathing, especially during sleep
- Complete or partial collapse of a lung, damage to the air sacs (alveoli) in the lungs, small amounts of blood mixed with sputum (or more seriously, large amounts of bright red blood) brought up by a forceful cough.
- Hypoventilation, not enough oxygen in the tissues of the body
- Swelling of the larynx, excess fluid in the lungs, collapsed lung
- A high-pitched, whistling sound most often heard while taking in a breath.
- Biliary pain, pain that occurs when a gallstone is being passed and is blocking a bile duct, inflammation of the gallbladder
- Ulcers in the intestine or oesophagus, or inflammation in the intestine
- Bloody diarrhoea, leakage from the bowel, gastrointestinal bleeding, vomiting of blood, bleeding of the colon, inflammation of the liver, intestinal blockage, liver fatty deposit, inflammation of the pancreas, sores on the lining of the intestine and stomach, bleeding from the rectum, salivary gland enlargement, stomach ulcer bleeds, swelling of the tongue
- Furunculosis- A painful, pus-filled bump under the skin caused by infected, inflamed hair follicles.
- Herpes zoster resulting in painful rash,
- Hirsutism - unwanted male-pattern hair growth on a women's face
- Petechial rash - Tiny round, brown-purple spots due to bleeding under the skin),
- Psoriasis - A condition in which skin cells build up and form scales and itchy, dry patches
- Purpuric rash - small purple spots on the skin. The rash can look a lot like tiny clusters of bruises
- Seborrhoea - excessive discharge of sebum from the sebaceous glands.
- Arthrosis - A type of arthritis that occurs when flexible tissue at the ends of bones wears down.

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MODULE 1
1.3.2
Date: 2020.08.17

- Chondrodystrophy – Condition that affects the development of the cartilage,
- Myasthenia gravis - A weakness and rapid fatigue of muscles under voluntary control.
- Myopathy – a disease of the muscle in which the muscle fibers do not function properly ,
- Osteomyelitis - inflammation of bone caused by infection
- Osteoporosis - is a bone disease that occurs when the body loses too much bone
- Rheumatoid arthritis - A chronic inflammatory disorder affecting many joints, including those in the hands and feet
- Breast engorgement- breast are painfully overfull of milk
- Glycosuria – excess sugar in the urine
- kidney pain
- Priapism - A prolonged erection of the penis, usually without sexual arousal.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via

<https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store GENOFINEX

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Applicant: Aurogen South Africa (Pty) Ltd
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MODULE 1
1.3.2
Date: 2020.08.17

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GENOFINEX contains

The active substance is Fluoxetine

GENOFINEX 20 mg CAPSULES:

Each extended release capsule contains fluoxetine hydrochloride equivalent to 20 mg fluoxetine

The other ingredients are Colloidal silicon dioxide and pregelatinised starch

Composition of capsule shell:

FD&C Blue 1, gelatine, sodium lauryl sulphate, titanium dioxide, yellow iron oxide

Composition of Ink:

Black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution

What GENOFINEX looks like and contents of the pack

GENOFINEX 20 mg Capsules:

Opaque green cap/opaque off-white body, size '3' hard gelatine capsule filled with white to off-white granular powder and imprinted with 'E' on opaque green cap and '91' on opaque off-white body with black ink

30 capsules are packed in clear PVC/PVDC aluminium foil blister pack. Each carton contains 3 blisters of 10 capsules each. The blisters are further packed in preprinted cartons with leaflet

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MODULE 1
1.3.2
Date: 2020.08.17

30 capsules are packed in white opaque round HDPE container closed with a white opaque polypropylene stock ribbed closure with wad having induction dealing liner. The HDPE containers are further packed in preprinted cartons with leaflet

Not all packs and pack sizes are necessarily marketed.

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

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