1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

LORIEN 20 mg capsules Fluoxetine as fluoxetine hydrochloride

Contains sugar: Lactose monohydrate 130,70 mg

LORIEN TABLETS 20 mg

Fluoxetine as fluoxetine hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking LORIEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LORIEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LORIEN is and what it is used for

2. What you need to know before you take LORIEN
3. How to take LORIEN
4. Possible side effects
5. How to store LORIEN
6. Contents of the pack and other information

1. What LORIEN is and what it is used for

LORIEN contains fluoxetine which belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants.

LORIEN is used to treat the following conditions:

- Major depressive episodes.
- Obsessive-compulsive disorder: (is a mental disorder most commonly characterized by intrusive, repetitive thoughts resulting in compulsive behaviours and mental acts that the person feels driven to perform).
- Bulimia nervosa: LORIEN is used for the reduction of binge-eating and purging.

2. What you need to know before you take LORIEN

Do not take LORIEN:

- if you are hypersensitive(allergic) to fluoxetine or any of the other ingredients of LORIEN (listed in section 6).
- if you have severe kidney failure.
- if you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor immediately.
- if you are taking other medicines used to treat depression, known as non-selective

monoamine oxidase inhibitors or reversible monoamine oxidase inhibitors type A (MAOIs), since serious or even fatal reactions can occur. Examples of MAOIs include medicines used to treat depression such as selegiline, moclobemide, phenelzine nialamide, iproniazid, moclobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood).or even fatal reactions can occur.

Treatment with LORIEN should only be started 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). However, treatment with LORIEN can be started the following day after discontinuation of certain reversible non-selective MAOIs (for instance moclobemide).

Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking LORIEN. If LORIEN has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.

- if you are taking thioridazine or have taken it in the past 5 weeks. Do not take thioridazine for at least 5 weeks after you stop taking LORIEN.
- if you are under the age of 18 years.
- if you are taking metoprolol (to treat heart failure) since there is an increased risk of your heartbeat becoming too slow.

Warnings and precautions

Take special care with LORIEN

- if you have epilepsy or seizures or experience an increase in seizure frequency, contact

your doctor immediately; LORIEN might need to be discontinued.

- if you have an episode of excessively intense enthusiasm, interest, or desire (mania) now or in the past; if you have a manic episode, contact your doctor immediately because LORIEN might need to be discontinued.
- if you have diabetes (your doctor may need to adjust your dose of insulin or another antidiabetic treatment).
- if you have liver problems (your doctor may need to adjust your dosage).
- if you have heart problems.
- if you have a low resting heart rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
- if you have glaucoma (increased pressure in the eye);
- if you are taking diuretics (water tablets), especially if you are elderly.
- if you are having ECT (electro-convulsive therapy) treatment.
- if you have a history of bleeding disorders or you develop bruises or unusual bleeding, or if you are pregnant (see 'Pregnancy').
- if you have history of bleeding disorders (e.g. von Willebrand disease, haemophilia A, deficiency in F VIII, and haemophilia B); and comorbid bleeding disorders (e.g. multiple pregnancy, gestational hypertension or preeclampsia.
- if you are taking medicines that thin the blood (see 'Taking other medicines with LORIEN').
- if you are taking ongoing treatment with tamoxifen (used to treat breast cancer) (see 'Taking other medicines with LORIEN').
- if you start to feel restless and cannot sit or stand still (akathisia). Increasing your dose of LORIEN may make this worse.
- If you start to experience fever, muscle stiffness or tremor, changes in your mental state

like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome" or "neuroleptic malignant syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; contact your doctor immediately as LORIEN might need to be discontinued.

- If you have thoughts of suicide and worsening of your depression or anxiety disorder.
- if you are taking other medicines used to treat depression, known as irreversible, non-selective monoamine oxidase inhibitors (MAOIs) or reversible monoamine oxidase inhibitors type A (MAOIs), since serious or even fatal reactions can occur. Examples of MAOIs include medicines used to treat depression such as nialamide, iproniazid, moclobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone and also linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood).

  LORIEN should only be started 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 LORIEN.
- if you experience symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.
- The use of buprenorphine together with LORIEN can lead to serotonin syndrome, a potentially life-threatening condition.

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when you first start taking LORIEN, since LORIEN takes time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.

- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital immediately

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet.

You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

- Safety and efficacy in children has not been established.
- Children under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines.
- Additionally, only limited information concerning the long-term safety of LORIEN on growth, puberty, mental, emotional and behavioural development in this age group is available.

Other medicines and LORIEN

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

LORIEN may affect the way some other medicines work (interaction), especially the

following:

- Buprenorphine/opioids. These medicines may interact with LORIEN and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38ºC.
- certain irreversible, non-selective monoamine oxidase inhibitors (MAO-inhibitors, used to treat depression). Irreversible, Non-selective MAO-inhibitors and MAO-inhibitors type A (moclobemide) must not be used with LORIEN as serious or even fatal reactions (serotonin syndrome) can occur (see section “Do not take LORIEN”). Treatment with LORIEN should only be started at least 2 weeks after discontinuation of an irreversible MAOI (for instance tranylcypromine). Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking LORIEN. If LORIEN has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be considered by your doctor.
- metoprolol (used for heart failure) may increase the risk of your heartbeat becoming too slow.
- lithium, tryptophan (used to treat mental illness); there is an increased risk of serotonin syndrome when these medicines are taken with LORIEN. Your doctor will carry out more frequent check-ups.
- monoamine oxidase inhibitors A (MAOI-A) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride also called methylene blue (used to treat high levels of methaemoglobin in the blood): due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with LORIEN can be started the day after stopping treatment with reversible MAOIs but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A medicine. However, treatment with

LORIEN can be started the following day after discontinuation of certain reversible MAOIs (for instance moclobemide, linezolid, methylthioninium chloride (methylene blue)). Some MAO-inhibitors type B (selegiline) can be used with LORIEN provided that your doctor monitors you closely.

- phenytoin (for epilepsy) because LORIEN may influence the blood levels of this medicine, your doctor may need to introduce phenytoin more carefully and carry out check-ups when given with LORIEN.
- clozapine (used to treat certain mental disorders), tramadol (a painkiller) or triptans (for migraine); there is an increased risk of hypertension (raised blood pressure).
- carbamazepine (for epilepsy), tricyclic antidepressants (for example imipramine, desipramine and amitriptyline); because LORIEN may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with LORIEN.
- anticoagulants such as warfarin, NSAID (such as ibuprofen, diclofenac) or aspirin and other medicines used to thin the blood; LORIEN may alter the effect of these medicines on the blood. If LORIEN treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain blood tests.
- you should not use the herbal remedy St John's Wort *(Hypericum perforatum)* while you are being treated with LORIEN since this may result in an increase in side effects. If you are already taking St John's Wort when you start on LORIEN, stop taking St John's Wort and tell your doctor at your next visit.
- Mequitazine (for allergies) because taking this medicine with LORIEN may increase the risk of changes in the electrical activity of the heart.
- medicines that may affect the heart's rhythm, e.g. Class IA and III antidysrhythmic, antipsychotics (e.g. fentiazine derivatives, phenothiazine derivatives pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (e.g. sparfloxacin,

moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain antihistamines (astemizole, mizolastine). Taking one or more of these medicines with LORIEN may increase the risk of changes in the electrical activity of the heart.

- Tamoxifen (used to treat breast cancer), because LORIEN may change the blood levels of this medicine and a reduction of the effect of tamoxifen cannot be excluded, your doctor may need to consider different antidepressant treatments.
- Cyproheptadine (for allergies) because it may reduce the effect of LORIEN.
- medicines that lower sodium levels in the blood (including, medicines that causes increase in urination, desmopressin, carbamazepine and oxcarbazepine); because these medicines may increase the risk of sodium levels in the blood becoming too low when taken with LORIEN.
- anti-depressants such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, mefloquine or chloroquine (used to treat malaria), tramadol (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones because LORIEN may increase the risk of seizures when taken with these medicines.

LORIEN with food, drink and alcohol

You can take LORIEN with or without food.

You are advised NOT to drink alcohol with LORIEN

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before

taking this medicine.

Pregnancy

Safety in pregnancy has not been demonstrated.

Breastfeeding

LORIEN is excreted in breast milk and can cause side effects in babies. You should not breastfeed your baby if you are in treatment with LORIEN.

Fertility

Impact on human fertility has not been observed as yet.

Driving and using machines

Since adverse reactions such as fitting, headaches and visual disturbances have been reported in patients receiving LORIEN , you should not drive, use machinery or perform any tasks that require concentration, until you are certain that LORIEN does not adversely affect your ability to do so safely (see Possible side effects with LORIEN).
It is not always possible to predict to what extent LORIEN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LORIEN affects you (see section 4).

LORIEN capsules contain lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LORIEN capsules.

3. How to take LORIEN

Always take LORIEN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

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

Your doctor will determine the dosage for you, depending on your disease.

Do not stop treatment early as the dose should be gradually reduced over a period of at least one to two weeks

Swallow the capsules with a drink of water. Do not chew the capsules.

The tablets may be swallowed whole or be dispersed in approximately 100 ml of water.

Your doctor will tell you how long your treatment with LORIEN will last.

If you have the impression that the effect of LORIEN is too strong or too weak, tell your doctor or pharmacist.

Children:

The safety and efficacy of LORIEN in children have not been established.

If you take more LORIEN than you should

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

If you forget to take a dose of LORIEN

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of LORIEN take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking LORIEN

Do not stop taking LORIEN without asking your doctor first, even when you start to feel better. It is important that you keep taking LORIEN.

You may notice the following effects when you suddenly stop taking LORIEN: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick or being sick); tremor (shakiness); headaches.
If you experience symptoms when you suddenly stop treatment, contact your doctor.
When stopping LORIEN, your doctor will help you to reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects.
If you have any further questions on the use of LORIEN, ask your doctor or pharmacist.

4. Possible side effects

LORIEN can have side effects.
Not all side effects reported for LORIEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LORIEN, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, or sudden swelling of skin or mucosa (angioedemas),
- if you get a rash or allergic reaction such as itching,
- fainting,

- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN),

These are all very serious side effects. If you have them, you may have had a serious reaction to LORIEN. 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:

- shortness of breath,
- lung problems (eosinophilic pneumonia)
- some patients may have a combination of symptoms (known as “serotonin syndrome”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness,
- thoughts of suicide or harming yourself. If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. If you have side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger),
- if you feel restless and cannot sit or stand still, you may have akathisia; increasing your dose of LORIEN may make you feel worse. If you feel like this, contact your doctor,
- heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart,
- rapid and irregular heartbeat sensation,
- seizures or fits (convulsions),

- inability to urinate,
- unusual bleeds, including gastrointestinal bleeds,
- high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome,

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- sleep problems,
- headache,
- feeling sick (nausea),
- diarrhoea,
- tiredness,
- not feeling hungry, weight loss,
- nervousness, anxiety,
- restlessness, poor concentration,
- feeling tense,
- decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity),
- increased appetite, increase in weight,
- unusual dreams,
- dizziness,
- change in taste,
- uncontrollable shaking movements,
- blurred vision,
- pain in muscle and joints (arthralgia and myalgia),

- flushing,
- yawning,
- indigestion, vomiting,
- dry mouth,
- urticaria,
- excessive sweating
- passing urine more frequently,
- unexplained vaginal bleeding,
- feeling shaky or chills,

Less frequent side effects:

- feeling detached from yourself,
- strange thinking,
- abnormally high mood,
- feelings of weakness, drowsiness or confusion mostly in elderly people and in people taking diuretics (water tablets),
- irritability and extreme agitation,
- orgasm problems,
- prolonged and painful erection,
- agitation, nervousness, panic attack, confusion, aggression, depersonalization (a state in which one's thoughts and feelings seem unreal or not to belong to oneself),
- teeth grinding,
- muscle twitching, involuntary movements or problems with balance or co-ordination,
- memory impairment,
- enlarged (dilated) pupils,
- ringing in the ears,

- low blood pressure,
- nose bleeds,
- difficulty swallowing,
- hair loss,
- increased tendency to bruising,
- unexplained bruising or bleeding,
- cold sweat,
- difficulty passing urine,
- feeling hot or cold,
- abnormal liver function test results,
- untypical wild behaviour,
- hallucinations,
- panic attacks,
- confusion,
- stuttering,
- vasculitis (inflammation of a blood vessel),
- rapid swelling of the tissues around the neck, face, mouth and/or throat,
- pain in the tube that takes food or water to your stomach,
- hepatitis,
- sensitivity to sunlight,
- muscle pain,
- problems urinating,

Side effects with an unknown frequency:

- low blood cells (pancytopenia and aplastic anaemia),
- low red blood cells (immune related haemolytic anaemia),

- reduction in blood platelets (thrombocytopenic purpura), which increases risk of bleeding or bruising,
- producing breast milk,
- low level of sodium in the blood (hyponatraemia),
- increased secretion of a hormone called ADH, causing the body to retain water and dilute the blood, reducing the amount of sodium (inappropriate ADH secretion),
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage),
- bone fractures - an increased risk of bone fractures has been observed in patients taking this type of medicines.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store LORIEN

Store all medicines out of reach of children.

Store in a cool, dry place, at or below 25 °C.

Protect from light and moisture.

Keep the plastic container tightly closed.

Keep in original packaging until required for use.

Do not store in bathrooms.

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

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 LORIEN contains

LORIEN capsules

The active substance is 20 mg fluoxetine as fluoxetine hydrochloride.

The other ingredients are colloidal anhydrous silica, gelatine, lactose monohydrate, magnesium stearate, maize starch, patent blue, povidone, titanium dioxide, yellow iron oxide

Contains sugar: Lactose monohydrate 130,70 mg

LORIEN tablets

The active substance is 20 mg fluoxetine as fluoxetine hydrochloride.

The other ingredients are colloidal silicon dioxide, magnesium stearate, maize starch, microcrystalline cellulose.

Sugar free

What LORIEN looks like and contents of the pack

LORIEN is a white powder encapsulated within a size “3” hard gelatine capsule with an opaque green body and opaque green cap.

LORIEN TABLETS is a round, white tablet with bevelled edges, bisected on one side.

LORIEN: 28 and 112 capsules are packed in a clear polyvinylchloride/polyethylene/Aclar blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

The capsules are packed in a white polypropylene container with a white, round, flat-topped linear low density polyethylene cap, with ridges on the side and a tamper evident seal, together with a silica gel sachet and a leaflet.

The capsules are packed in a metallised polyester/laminant/ opaque white linear low density polyethylene lay flat bag with a low density polyethylene zip.

LORIEN TABLETS: 28 or 30 tablets are packed in a clear polyvinylchloride/polyethylene/Aclar blister strip sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

28 or 30 tablets are packed in a white polypropylene container with a linear low density polyethylene tamper proof snap cap together with a white foam insert or silica gel sachet and a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

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Registration number

LORIEN: 30/1.2/0024

LORIEN TABLETS: 34/1.2/0381

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: LORIEN: 04/1.2/0180

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