

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

NOPTIQUEL™ XR 50 (Prolonged release tablets)

NOPTIQUEL™ XR 150 (Prolonged release tablets)

NOPTIQUEL™ XR 200 (Prolonged release tablets)

NOPTIQUEL™ XR 300 (Prolonged release tablets)

NOPTIQUEL™ XR 400 (Prolonged release tablets)

Quetiapine

Contains sugar (lactose)

Lactose content per tablet:

NOPTIQUEL XR 50:	14,21 mg
NOPTIQUEL XR 150:	42,63 mg
NOPTIQUEL XR 200:	56,84 mg
NOPTIQUEL XR 300:	85,26 mg
NOPTIQUEL XR 400:	113,68 mg

Read all of this leaflet carefully before you start taking NOPTIQUEL XR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NOPTIQUEL XR 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 NOPTIQUEL XR is and what it is used for
2. What you need to know before you take NOPTIQUEL XR

3. How to take NOPTIQUEL XR
4. Possible side effects
5. How to store NOPTIQUEL XR
6. Contents of the pack and other information

1. What NOPTIQUEL XR is and what it is used for

NOPTIQUEL XR belongs to a group of medicines called antipsychotics.

NOPTIQUEL XR can be used to treat several illnesses, such as schizophrenia, bipolar disorder and major depression.

Ask your doctor if you are unsure why NOPTIQUEL XR has been prescribed for you.

2. What you need to know before you take NOPTIQUEL XR

Do not take NOPTIQUEL XR:

- if you are hypersensitive (allergic) to quetiapine or any of the other ingredients of NOPTIQUEL XR (listed in section 6);
- if you are elderly (above 65 years) and you have dementia (memory disorders, personality changes, and impaired reasoning) with changes in behaviour;
- if you are taking any of the following medicines:
 - some medicines for HIV infection (examples are indinavir, nelfinavir, ritonavir);
 - azole type of antifungal medicines (examples are ketoconazole, fluconazole, itraconazole);
 - antibiotics for infections (examples are erythromycin or clarithromycin);
 - nefazodone (for depression).

See also “Other medicines and NOPTIQUEL XR”.

Warnings and precautions

Special care should be taken with NOPTIQUEL XR if you -

- have Alzheimer's disease or dementia (loss of brain function). The group of medicines that NOPTIQUEL XR tablets belongs to may increase the risk of stroke, or in some cases the risk of death, in elderly people with dementia;
- have problems swallowing;
- have bowel obstruction or constipation;
- have been diagnosed with diabetes or have a family history of diabetes, as NOPTIQUEL XR may cause high blood sugar and diabetes mellitus (see section 4 – Possible side effects);
- have high blood cholesterol (fats in your blood), as NOPTIQUEL XR may also increase your blood fats;
- have low levels of white blood cells or neutropenia (an abnormally low level of neutrophils, a type of white blood cell). NOPTIQUEL XR may further decrease white blood cells. (White blood cells help the body to fight infection, therefore a low count will make you more susceptible to disease);
- have been diagnosed with heart rhythm disorders or heart failure (see section 4);
- have low blood pressure, as NOPTIQUEL XR may further reduce your blood pressure and may cause you to become dizzy and to fall;
- recently had a stroke or a heart attack;
- have a history of blood clots in your veins (or if someone else in your family has been diagnosed with thrombosis), as medicines like NOPTIQUEL XR have been associated with the formation of blood clots;
- have, or previously had, thoughts of harming or killing yourself at any time. Contact your doctor, or go to a hospital straight away if this is the case;
- have ever had a seizure (fit);
- have a history of sleep apnoea (temporary stopping of breathing);
- have a history of alcohol or substance abuse;

- take medicines such as carbamazepine, phenytoin or any of the medicines listed under “Other medicines and NOPTIQUEL XR”;
- have urinary retention;
- have an enlarged prostate;
- have narrow angle glaucoma or increased eye pressure;
- have a liver problem.

Tell your doctor if you develop the following disorders during treatment (see full list under section 4 (Possible side effects)):

- Weight gain, urinate frequently and feel thirsty. These could be signs that you have high blood sugar or diabetes mellitus.

You and your doctor should check your weight regularly.

- Increased blood cholesterol (determined by blood tests).
- Pancreatitis (inflammation of the pancreas): some signs may be abdominal pain that radiates to your back, nausea and vomiting. See section 4.
- Problems with body temperature control: if you feel colder or warmer than usual or have an abnormal level of thyroid hormone in the blood.
- Fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require NOPTIQUEL XR to be stopped and/or treatment to be given.
- Sleepiness and sedation.
- Feeling dizzy when getting up, as your blood pressure may be very low and you may fall.
- Fever, muscular rigidity and an altered mental status. These signs may point to neuroleptic malignant syndrome (NMS), which is a relatively rare but potentially fatal complication of the use of neuroleptic medicines such as NOPTIQUEL XR.

Withdrawal symptoms:

You may have withdrawal symptoms if you suddenly stop taking NOPTIQUEL XR. You should follow your doctor's instructions. Withdrawal symptoms are listed under “If you stop taking NOPTIQUEL XR”.

Thoughts of suicide and worsening of your depression

If you are depressed you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since medicines like NOPTIQUEL XR take time to work; usually about two weeks, but sometimes longer. These thoughts may also be increased if you suddenly stop taking your medicine. You may be more likely to think like this if you are a young adult. An increased risk of suicidal thoughts and/or suicidal behaviour have been reported in young adults aged less than 25 years with depression.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

DRESS - “Drug Rash with Eosinophilia and Systemic Symptoms”

Symptoms of DRESS include widespread rash, high body temperature, increased liver enzymes, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement.

Stop using NOPTIQUEL XR if you develop these symptoms and contact your doctor or seek medical attention immediately.

See section 4 for a more complete list of side effects reported during use of NOPTIQUEL XR.

Children and adolescents:

NOPTIQUEL XR is not recommended for children below 18 years, as adequate information is not available on this age group.

Other medicines and NOPTIQUEL XR

Always tell your healthcare provider if you are taking any other medicine. This includes complementary or traditional medicines.

Do not take NOPTIQUEL XR if you are taking any of the following medicines:

- certain medicines to treat fungal infections (such as ketoconazole, fluconazole or itraconazole);
- medicines to treat HIV infections (protease inhibitors, for example ritonavir, saquinavir);
- certain antibiotic medicines (such as erythromycin or clarithromycin), for infections;

- nefazodone (a medicine for depression).

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

- medicines for epilepsy (carbamazepine or phenytoin);
- medicines for high blood pressure;
- barbiturates (for sleeping);
- medicines to relieve stomach cramps or bladder spasms (anticholinergics), such as hyoscyamine, hyoscine butylbromide;
- “water pills” to reduce blood pressure but may cause an electrolyte (salt balance) disorder;
- medicines to regulate the heartbeat (such as amiodarone);
- medicines for anxiety, depression;
- lithium, a medicine used for mental disorders;
- thioridazine (another antipsychotic medicine, may be used for serious mental disorders).

Before you stop taking any of your medicines, please talk to your doctor first.

Laboratory tests:

Certain laboratory tests may show false positive results for methadone (a potent medicine for pain) and certain antidepressant medicines. Tell the person performing the test that you are taking NOPTIQUEL XR.

NOPTIQUEL XR with food, drink and alcohol

You may take NOPTIQUEL XR with or without food.

Avoid alcoholic beverages, as the combined effect of NOPTIQUEL XR and alcohol may make you feel sleepy. If you drink alcohol, please mention this to your doctor before you start to take NOPTIQUEL XR.

Avoid grapefruit juice, as it may strengthen the effect of NOPTIQUEL XR.

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 NOPTIQUEL XR.

You should not take NOPTIQUEL XR if you are pregnant or breastfeeding your baby, as safety has not been demonstrated.

NOPTIQUEL XR is excreted into breastmilk. You should not breastfeed your baby while taking NOPTIQUEL XR.

The effects of NOPTIQUEL XR on fertility is not known.

Driving and using machinery

NOPTIQUEL XR may make you feel sleepy and dizzy. Do not drive, operate hazardous machinery or perform hazardous tasks until you know how the tablets affect you.

NOPTIQUEL XR contains lactose

NOPTIQUEL XR contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking NOPTIQUEL XR.

3. How to take NOPTIQUEL XR

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

Always take NOPTIQUEL XR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take your tablets once a day and swallow whole with a drink of water. Do not chew or crush the tablets. You may take NOPTIQUEL XR with or without food.

The usual maintenance (daily) dose depends on your illness and needs but usually between 50 mg and 800 mg.

Your doctor will decide on your starting dose, and which maintenance dose is suitable for you.

If you have liver problems your doctor may change your dose.

If you are elderly, your doctor may change your dose.

Your doctor will tell you how long your treatment with NOPTIQUEL XR will last. Do not stop taking NOPTIQUEL XR even if you are feeling better, unless your doctor tells you to stop.

Do not drink grapefruit juice while you are taking NOPTIQUEL XR. It can affect the way the medicine works.

If you have the impression that NOPTIQUEL XR is too strong or too weak, you should talk to your doctor or pharmacist.

Use in children:

NOPTIQUEL XR should not be used by children and adolescents aged under 18 years.

If you take more NOPTIQUEL XR than you should

If you take more NOPTIQUEL XR than prescribed by your doctor, you may feel drowsy, sleepy, dizzy and experience abnormal heartbeats.

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

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take NOPTIQUEL XR

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then.

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

If you stop taking NOPTIQUEL XR

If you suddenly stop taking NOPTIQUEL XR, you may have withdrawal symptoms. Some of these symptoms are feeling sick (nausea), trouble sleeping (insomnia), being sick (vomiting), headache, diarrhoea, dizziness or irritability. Your doctor may suggest that you reduce the dose gradually before stopping treatment.

4. Possible side effects

NOPTIQUEL XR can have side effects.

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

If any of the following happens, stop taking NOPTIQUEL XR and contact your doctor immediately or go to the department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Severe skin reactions with swelling below the skin, red welts, burning, painful, itchy skin areas, rash, fever, blistering and peeling.
- Swelling, pain and redness in the leg (blood clots in the veins).
- Chest pain and difficulty in breathing (if a blood clot travels through the blood vessels to the lungs).
- Stroke (sudden numbness or weakness in the face, arm or leg, confusion, trouble seeing, dizziness).
- Severe abdominal pain, radiating to your back (pancreatitis).
- Painful and/or prolonged erection (priapism).

These are all very serious side effects. If you have them, you may have had a serious reaction to NOPTIQUEL XR. 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 the following:

- Wheezing and breathlessness, night sweats, skin rashes (blood tests may show excessive amounts of certain white blood cells (eosinophilia)).

- A low blood platelet count – you may get bruised easier and excessively, get purple spots in skin, have prolonged bleeding from cuts, spontaneous bleeding from nose or gums (thrombocytopenia)
- Sore throat, chills, fever and infections – you may have a severe reduction in the number of white blood cells. Your doctor will order blood tests and treat you suitably.
- Weight gain
- Thinking about suicide
- Tremor, twisting and repetitive movements or abnormal body posture, slurred speech, restlessness and stiff muscles
- Fits (seizures), involuntary and abnormal movements, especially of the tongue, mouth and jaw, facial grimacing, rapid eye blinking and uncontrollable movements of arms, legs, fingers and toes
- Fever, muscular rigidity, change in mental status and a malfunction of the autonomic nervous system (the nerves that control involuntary bodily functions may be damaged)
- Abdominal pain with inability to pass a stool (obstruction)
- Jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems).
- Inflammation of the liver (hepatitis). Signs may be nausea, vomiting, loss of appetite, abdominal pain, dark urine, light coloured stools and tiredness.
- Muscle pains, weakness, vomiting, and confusion (rhabdomyolysis)
- Inability to urinate
- Unusual tiredness or weakness.

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:

- Urine infections (frequent urination with burning, chills)
- Increased appetite, weight gain
- Abnormal dreams; nightmares
- Sleepiness
- Headache

- Having problems to speak properly
- Dizziness, low blood pressure when standing (orthostatic hypotension, which may result in dizziness or feeling faint). This could increase the risk of accidental injury (fall), especially in elderly patients
- Quick heartbeat
- Difficult breathing
- Constipation, dry mouth, indigestion, vomiting
- Withdrawal (discontinuation) symptoms (see “Warnings and precautions”)
- Swelling of legs and feet
- Fever, decreased strength and energy, irritability.

Less frequent side effects:

- Weight gain, fatigue (underactive thyroid gland)
- High blood sugar, worsening of pre-existing diabetes
- Sleepwalking, sleep talking
- Sleep related eating disorder
- Restless legs
- Stiff, jerky movements and smacking of lips
- Shaking, usually starting in a limb, often your hand or fingers
- Fainting
- Blurred or abnormal vision
- Irregular heartbeat
- Runny nose
- Trouble with swallowing
- Skin rash (allergic skin reaction)
- Swelling of breasts and unexpected secretion of milk
- Sexual dysfunction
- Menstrual disorder
- Feeling cold.

Laboratory tests may show:

- Eosinophilia - an increase in one type of white blood cells, which is sometimes seen in allergic reactions.
- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of NOPTIQUEL XR.
- Thrombocytopenia - a decrease in platelets, which are cells that help you stop bleeding if you get a cut.
- Increase in the amount of liver enzymes. These changes will normally disappear when continuing the treatment of NOPTIQUEL XR.
- Changes in the amount of fatty substances (lipid levels such as triglycerides and cholesterol) in the blood.
- Increase in the amount of “creatine phosphokinase” - a substance in the muscles.
- Increase in the amount of sugar (glucose) in the blood.
- Increase in the amount of hormone prolactin in the blood. Rarely this may lead to:
 - men and women to have swelling of breasts and unexpectedly produce breastmilk.
 - women to have no monthly period or irregular periods.

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 via the SAHPRA website: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of NOPTIQUEL XR.

5. How to store NOPTIQUEL XR

Store all medicines out of reach of children.

Store in the original packaging, at or below 30 °C. Keep the blisters in the carton until required for use. Keep the bottles tightly closed.

Do not use NOPTIQUEL XR after the expiry date printed on the label, container or blister.

Do not store your medicine in the bathroom.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NOPTIQUEL XR contains

The active substance is quetiapine. NOPTIQUEL XR tablets contain 50 mg, 150 mg, 200 mg, 300 mg or 400 mg of quetiapine (as quetiapine fumarate).

The other ingredients are crystalline maltose, lactose, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, talc, triethyl citrate.

What NOPTIQUEL XR looks like and contents of the pack

NOPTIQUEL XR 50 prolonged release tablets are white to off-white, round biconvex tablets, engraved with “50” on one side and plain on the other side.

NOPTIQUEL XR 150 prolonged release tablets are white to off-white, oblong biconvex tablets, engraved with “150” on one side and plain on the other side.

NOPTIQUEL XR 200 prolonged release tablets are white to off-white, oblong biconvex tablets, engraved with “200” on one side and plain on the other side.

NOPTIQUEL XR 300 prolonged release tablets are white to off-white, oblong biconvex tablets, engraved with “300” on one side and plain on the other side.

NOPTIQUEL XR 400 prolonged release tablets are white to off-white, oval biconvex tablets, engraved with “400” on one side and plain on the other side.

NOPTIQUEL XR tablet range is packed in:

A cardboard box containing 10, 30, 60 or 100 tablets, packed in white opaque PVC/PCTFE aluminium foil blister strips.

White opaque HDPE bottles, with child resistant polypropylene (PP) screw caps and induction seal liners containing 10, 30, 60 or 100 tablets.

Not all pack sizes are necessarily marketed.

Holder of the Certificates of Registration

Abex Pharmaceutica (Pty) Ltd

Suite C, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park, 0181

South Africa

Tel: 012 997 6974

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NOPTIQUEL XR 300: 53/2.6.5/0321.316

NOPTIQUEL XR 400: 53/2.6.5/0322.317

Access to the corresponding professional information

The professional information will be available on SAHPRA's website

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