

CLEAN COPY AMENDED PATIENT INFORMATION LEAFLET

INFORMATION FOR THE PATIENT ABOUT REALIQUEL

Scheduling status

S5

Proprietary name, strength and pharmaceutical form

Realiquel 25 (film-coated tablets)

Realiquel 100 (film-coated tablets)

Realiquel 150 (film-coated tablets)

Realiquel 200 (film-coated tablets)

Realiquel 300 (film-coated tablets)

Quetiapine

Excipients with known effect:

Realiquel 25 contains 7,0 mg lactose monohydrate.

Realiquel 100 contains 28,0 mg lactose monohydrate.

Realiquel 150 contains 42,0 mg lactose monohydrate.

Realiquel 200 contains 56,0 mg lactose monohydrate.

Realiquel 300 contains 84,0 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking Realiquel film-coated tablets

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Realiquel** has been prescribed for you personally. Do 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 **Realiquel** is and what it is used for

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

1. What Realiquel is and what it is used for

Realiquel contains quetiapine which belongs to a class of medicines called antipsychotics.

Realiquel can be used to treat:

- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.
- Mania phase in bipolar disorder where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.

2. What you need to know before you take Realiquel

Do not take Realiquel:

- if you are allergic (hypersensitive) to the active ingredient quetiapine or to any of the other ingredients in the film-coated tablets.
- if you are pregnant or breastfeeding.
- if you are below 18 years of age (children or adolescents).
- if you have severe liver and kidney problems.
- if you are taking any of the following medicines:
 - some medicines for HIV called protease inhibitors
 - azole medicines (for fungal infections)
 - erythromycin or clarithromycin (for infections)
 - nefazodone (for depression).

If you are not sure, talk your doctor or pharmacist before taking **Realiquel**.

Warnings and precautions:

Take special care with **Realiquel**

- if you have low blood pressure.
- if you, or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart or if you are taking any medicines that may have an impact on the way your heart beats.
- if you have had a stroke, especially if you are elderly.
- if you have problems with your liver.
- if you have or have had a condition where you stop breathing for short periods during your normal nightly sleep (called “sleep apnoea”) and are taking medicines that slow down the normal activity of the brain (“depressants”).
- if you have ever had a fit (seizure).
- if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- if you have or have had a condition where you have difficulty in emptying your bladder (urinary retention), have an enlarged prostate, a blockage in your intestines, or increased pressure inside your eye. These conditions are sometimes caused by medicines called “anti-cholinergics”.
- if you have diabetes or have a risk of getting diabetes.
- if you or someone else in your family has a history of blood clots.
- if you are an elderly person with dementia (loss of brain function).
- if you have a history of alcohol or drug abuse.

Tell your doctor immediately if you experience any of the following after taking **Realiquel**:

- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- Uncontrollable movements, mainly of your face or tongue.
- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called “neuroleptic malignant syndrome”). Immediate medical treatment may be needed.
- Difficulty swallowing.
- A long-lasting and painful erection (priapism). These conditions can be caused by this medicine.
- 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 these medicines 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. 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.

- A 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 **Realiquel** to be stopped and/or treatment to be given.
- Weight gain has been seen in patients taking **Realiquel**. You and your doctor should check your weight regularly.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.

Children and adolescents

Realiquel is not for use in children and adolescents below 18 years of age.

Taking other medicines with Realiquel

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

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

- epilepsy medicines (such as phenytoin or carbamazepine).
- high blood pressure medicines.
- barbiturates (for difficulty sleeping).
- thioridazine or lithium (other antipsychotic medicines).
- medicines that have an impact on the way your heart beats, for example, medicines that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (medicines to treat infections).
- medicines that can cause constipation.
- medicines called “anti-cholinergics”.

Realiquel with food and drink

Realiquel can be taken with or without food.

Realiquel should be taken with liquid (a glass of water).

Do not take **Realiquel** together with grapefruit juice.

Alcohol consumption should be restricted when taking **Realiquel**, as you may feel drowsy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while taking **Realiquel**, please consult your doctor, pharmacist or other healthcare professional for advice.

You must not take **Realiquel** if you are pregnant.

You must not take **Realiquel** if you are breastfeeding your baby.

Driving and using machines

Realiquel may make you feel sleepy. You should not drive or use machinery until you know how these tablets affect you.

Important information about some of the ingredients of Realiquel

Realiquel contains lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

Effect on urine substance screens

If you are having a urine substance screen, taking **Realiquel** may cause positive results for methadone or certain medicines for depression called tricyclic antidepressants (TCAs) when certain test methods are used.

3. How to take Realiquel

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

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

Your doctor will decide on your starting dose. Your maintenance dose (daily dose) will depend on your illness and needs, but will usually be between 150 mg and 800 mg.

- You will take your tablets once a day, at bedtime or twice a day, depending on your illness.
- Swallow your tablets whole with drink of water.
- You can take your tablets with or without food.
- Do not drink grapefruit juice while you are taking **Realiquel**. It can affect the way the medicine works.

- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

Liver problems:

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

Elderly:

The starting dose may be reduced if you are elderly.

Children:

As experience is insufficient, use of **Realiquel** in children and adolescents (below 18 years old) is not recommended.

If you have the impression that the effects of **Realiquel** are too strong or too weak, talk to your doctor or pharmacist.

If you take more Realiquel than you should

If you accidentally take too many tablets, you may experience sleepiness, dizziness, abnormal heart beats or hypotension.

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take Realiquel

If you have forgotten to take a tablet, you can still take it as soon as you remember. Never take a double dose of **Realiquel** to make up for the dose that you have missed.

If you stop taking Realiquel

The treatment must only be changed or stopped in consultation with your doctor.

If you suddenly stop taking **Realiquel**, you may be unable to sleep (insomnia), you may feel sick (nausea), or you may experience headache, diarrhoea, being sick (vomiting), dizziness or irritability. Your doctor may suggest you reduce the dose gradually before stopping treatment.

4. Possible side effects:

Realiquel can have side effects.

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

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

- swelling of the hands, feet, ankles, mouth, throat, face, lips or eyes
- shortness of breath or wheezing
- rash or itching.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you have thoughts of harming or killing yourself at any time.

These are serious side effects and may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently occurring side effects:

- Dizziness (may lead to falls), headache, dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking **Realiquel**) (may lead to falls).

- Discontinuation symptoms (symptoms which occur when you stop taking **Realiquel**) include not being able to sleep (insomnia), feeling sick (nausea), headache, diarrhoea, being sick (vomiting), dizziness and irritability.
- Putting on weight.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Changes in the amount of certain fats (triglycerides and total cholesterol).
- Decreases in the number of certain types of blood cells.
- Changes in the amount of thyroid hormones in your blood.
- Increases in the amount of the hormone prolactin in the blood.
- Abnormal dreams and nightmares.
- Thoughts of suicide and worsening of your depression.
- Rapid heartbeat.
- Feeling like your heart is pounding, racing or has skipped beats.
- Blurred vision.
- Low blood pressure when standing up.
- Shortness of breath.
- Constipation, upset stomach (indigestion).
- Vomiting (mainly in the elderly).
- Increases in the amount of liver enzymes measured in the blood.
- Feeling weak.
- Swelling of arms or legs.
- Feeling irritated.
- Fever.
- Increased levels of sugar in the blood.
- Feeling more hungry.
- Disturbance in speech and language.

Less frequently occurring side effects:

- Decrease in the amount of red blood cells.
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis.
- Severe rash, blisters, or red patches on the skin.
- A severe allergic reaction (called anaphylaxis) which may cause difficulty in breathing or shock.
- Allergic reactions that may include raised lumps (weals), swelling of the skin and swelling around the mouth.
- Decrease in the amount of sodium in the blood.
- Diabetes.
- Worsening of pre-existing diabetes.
- A condition (called “metabolic syndrome”) where you have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in “good cholesterol” (HDL-C), an increase in a type of fat in your blood called triglycerides, high blood pressure and an increase in your blood sugar.
- Walking, talking, eating or other activities while you are asleep.
- Fits or seizures.
- Unpleasant sensations in the legs (also called restless legs syndrome).
- Difficulty swallowing.
- Uncontrollable movements, mainly of your face and tongue.
- Fainting (may lead to falls).
- Change in electrical activity of the heart seen on ECG (QT prolongation).
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.

- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- Stuffy nose.
- Bowel obstruction.
- Inflammation of the pancreas.
- Inflammation of the liver (hepatitis).
- Yellowing of the skin and eyes (jaundice).
- Rapid swelling of the skin, usually around the eyes, lips and throat (angioedema).
- A serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome).
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).
- Inappropriate secretion of a hormone that controls urine volume.
- Difficulty in passing urine.
- Sexual dysfunction.
- A long-lasting and painful erection (priapism).
- Swelling of breasts and unexpected production of breast milk (galactorrhoea).
- Menstrual disorder.
- A combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or faint (a disorder called “neuroleptic malignant syndrome”).
- Body temperature decreased (hypothermia).
- Increased blood creatine phosphokinase (a substance from the muscles).

Frequency unknown:

- Skin rash with irregular red spots (erythema multiforme).

- Serious, sudden allergic reaction with symptoms such as fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis).
- Symptoms of withdrawal may occur in newborn babies of mothers that have used **Realiquel** during their pregnancy.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **Realiquel**.

5. How to store Realiquel

Store at or below 25 °C. Keep blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Do not use **Realiquel** after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Realiquel contains

The active substance is quetiapine. **Realiquel** film-coated tablets contain 25 mg, 100 mg, 150 mg, 200 mg or 300 mg of quetiapine (as quetiapine fumarate).

The other ingredients are hypromellose, calcium hydrogen phosphate dihydrate, lactose monohydrate, maize starch, sodium starch glycollate, magnesium stearate, microcrystalline cellulose, talc, silica colloidal anhydrous and film-coating colourants.

Realiquel 25 contains opadry pink colourant (iron oxide red, iron oxide yellow, hypromellose, titanium dioxide, macrogol and FD+C Yellow #6/Sunset yellow FCF Aluminium lake).

Realiquel 100 contains opadry yellow colourant (iron oxide yellow, hypromellose, titanium dioxide, magrogol).

Realiquel 150 contains opadry yellow and opadry white colourants (iron oxide yellow, hypromellose, titanium dioxide, magrogol, hydroxyl cellulose and talc).

Realiquel 200 and **300** contains opadry white colourant (hydroxypropyl cellulose, hypromellose, titanium dioxide and talc).

Contains sugar (lactose monohydrate).

What Realiquel looks like and contents of the pack

Realiquel 25: Peach, round, biconvex film-coated tablets with a diameter of 5,7 mm approximately.

Realiquel 100: Yellow, round, biconvex film-coated tablets with a score line on one side and a diameter of 9,1 mm approximately.

Realiquel 150: Pale yellow, round, biconvex film-coated tablets with a diameter of 10,45 mm approximately.

Realiquel 200: White, round, biconvex film-coated tablets with a score line on one side and a diameter of 12,1 mm approximately.

Realiquel 300: White, oblong, biconvex film-coated tablets with a score line on one side.

The 100, 200 and 300 mg tablets can be divided into equal halves.

Realiquel film-coated tablets are supplied in opaque PVC/silver aluminium blister packs of 28 or 30 tablets.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein

Cape Town, 7570

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Registration numbers

Realiquel 25: (await)

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Realiquel 150: (await)

Realiquel 200: (await)

Realiquel 300: (await)