PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

TRUVALIN ® 25, TRUVALIN ® 100, TRUVALIN ® 200, TRUVALIN ® 300 (Film-coated Tablet)

Quetiapine

Contains sugar: lactose monohydrate 19 mg (25 mg tablet); 20,70 mg (100 mg tablet); 41,40 mg (200 mg tablet); 62,10 mg (300 mg tablet)

Read all of this leaflet carefully before you start taking TRUVALIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRUVALIN 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 TRUVALIN is and what it is used for

TRUVALIN belongs to a group of medicines called antipsychotics. TRUVALIN can be used to treat schizophrenia, a disease with symptoms such as hallucinations (for example unexplained voices), strange and frightening thoughts, changes in behaviour, feeling alone and confused.

TRUVALIN is also used to treat people with an illness that affects their mood, whereby they feel “high” or excited. People with this condition may find that they need to sleep less than usual, are more talkative and have racing thoughts or ideas. They may also feel unusually irritable.

2. What you need to know before you take TRUVALIN

Do not take TRUVALIN:

- If you are hypersensitive (allergic) to quetiapine fumarate or any of the other ingredients of TRUVALIN (listed in section 6)
- If you are a child or teenager
- If you have severe kidney or liver problems
- If you are pregnant or breastfeeding

Warnings and precautions

Take special care with TRUVALIN:

Before taking TRUVALIN tell your doctor, pharmacist or other health care professional:

- If you have any health problems including diabetes mellitus.
- If you have any heart problems and/or low blood pressure or have had a stroke.
- If you or a family member have a history of any problems with the way your heart beats or have a history of heart disease or heart problems or if you are taking any medicines that may have an impact on the way your heart beats.
- If you have any kidney or liver problems.
- If you know that you had a low white blood cell count in the past which may or may not have been caused by other medicines.
- If you have ever had a seizure (fit).
- If you have or have had a condition where you can't completely empty 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 "anticholinergics") that affect the way nerve cells function in order to treat certain medical conditions.
- If you are an elderly person with dementia (loss of memory/forgetfulness). TRUVALIN should not be taken because the group of medicines that TRUVALIN belongs to may increase the risk of stroke, or in some cases the risk of death in the elderly people with dementia
- If you have a history of alcohol or drug abuse

Contact your doctor immediately or go to the nearest hospital if any of the following events happens to you (these are also described in the "Possible Side Effects" section below):

- If you feel "light-headed" and think you have low blood pressure.
- A combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduced consciousness (a disorder called "neuroleptic malignant

syndrome”).

- Fits (seizures)
- Priapism (long-lasting and painful erection)
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia).

Tell your doctor as soon as possible if you have:

- If you have 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 TRUVALIN to be stopped and/or treatment to be given.
- 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.

Pancreatitis (inflammation of the pancreas) has been reported in some patients. Many of these patients also had factors which are known to be associated with pancreatitis such as increased triglyceride levels (a fatty substance in the blood), gallstones, and alcohol consumption.

Cardiomyopathy (weakening of the heart muscle) and myocarditis (inflammation of the heart) have been reported in some patients, however, it is not known if TRUVALIN treatment is related to these problems.

Thoughts of suicide and worsening of your depression or other mental illnesses

If you are depressed and/or have other mental illnesses you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two weeks but sometimes longer.

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 or have other mental illnesses and ask them to read this leaflet. You might ask them to tell you if they think your depression or mental illness is getting worse, or if they are worried about changes in your behaviour.

Severe cutaneous adverse reactions (SCARs)

Severe skin related adverse reactions including Stevens-Johnson Syndrome (SJS), Toxic Epidermal

Necrolysis (TEN), Acute Generalized Exanthematous Pustulosis (AGEP), Erythema Multiforme (EM) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) which can be life threatening, have been reported with the use of this medicine. These serious skin reactions may present with one or more combination of the following symptoms: widespread blistering (may be filled with pus) or peeling of the skin, flu-like symptoms, blood abnormalities (increase in a type of white blood cells), swollen glands (enlarged lymph nodes) or itchy skin rash with pink-red irregular spots.

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

Other medicines and TRUVALIN

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

Tell your doctor or pharmacist if you are taking, or about to stop taking, any other medicines including those which you may have bought. In particular, tell your doctor if you are taking, or about to stop taking medicines for:

- Anxiety, depression (such as centrally acting medicines, alcohol or an antipsychotic medicine called thioridazine).
- Epilepsy (such as phenytoin, carbamazepine or sodium valproate)
- Human Immunodeficiency Virus (HIV) (such as protease inhibitors).
- Sleeplessness (such as barbiturates).
- Tuberculosis (such as rifampicin).
- Fungal infections (such as ketoconazole)
- Other infections (such as macrolide antibiotics).
- Medicines that have an impact on the way and how slow 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 (drugs to treat infections).
- Medicines that can cause constipation
- Medicines (called anticholinergics) that affect the way nerve cells function in order to treat certain medical conditions.

Effect on Urine Drug Screens

If you are having a urine drug screen, taking TRUVALIN may cause positive results for methadone or

certain drugs for depression called tricyclic antidepressants (TCAs) when some test methods are used, even though you may not be taking methadone or TCAs. Confirmation of the results by more specific tests is recommended.

TRUVALIN with food, drink and alcohol

If you drink alcohol, please mention this to your doctor before you start to take TRUVALIN. TRUVALIN can be taken with or without food.

Pregnancy and breastfeeding

Before taking TRUVALIN, tell your doctor if you are pregnant, trying to become pregnant or are breastfeeding.

Symptoms of withdrawal may occur in newborn babies of mothers that have used TRUVALIN during their pregnancy

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 health care provider for advice before taking this medicine.

Driving and using machines

Your tablets may make you feel sleepy. Do not drive or use machinery until you know how these tablets affect you.

TRUVALIN contains lactose

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TRUVALIN.

3. How to take TRUVALIN

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

- Always take TRUVALIN 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 doctor may start you on a low dose and thereafter adjust your daily dose of TRUVALIN between 150 mg and 800 mg depending on your

disease, age, and individual treatment and needs.

- If you have the impression that the effect of TRUVALIN is too strong or too weak, talk to your doctor or pharmacist.
- **TRUVALIN is to be taken twice a day either with or without food.**
- Swallow your tablets whole with a drink of water.
- TRUVALIN tablets come in different sizes, and each size is a different colour. Therefore, don't be surprised if the colour of your tablets differs from time to time.
- Do not stop taking your tablets even if you are feeling better, unless your doctor tells you.

If you take more TRUVALIN than you should

If you take more than the recommended number of tablets, you are likely to feel drowsy, sleepy, rapid heartbeat and light-headed (low blood pressure).

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 TRUVALIN

If you miss a dose, take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TRUVALIN

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

4. Possible side effects

TRUVALIN can have side effects.

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

Contact your doctor immediately or go to the nearest hospital if any of the following events happen to you (these are also described below) as you may need urgent medical attention.

- Hypersensitivity reactions such as, rapid swelling of the skin usually around the eyes, lips, and throat (angioedema).

Tell your doctor if any of the following side-effects bothers you:

Frequent side effects:

- Dizziness
- Feeling sleepy
- Headache
- Rapid heartbeat
- Dry mouth
- Constipation
- Indigestion
- Feeling like your heart is pounding, racing or has skipped beats.
- Feeling weak
- Swelling of arms and legs
- Weight gain, mainly during the first weeks of treatment
- Anxiety (this may or may not be caused by taking TRUVALIN)
- Low blood pressure in standing position, which may result in dizziness or feeling faint
- Urinary tract infection (bladder infection) (this may or may not be caused by taking TRUVALIN)
- Shortness of breath
- Vomiting (mainly in the elderly)
- Fever
- Discontinuation symptoms (i.e., symptoms which occur upon stopping TRUVALIN) include vomiting, dizziness, nausea, headache, diarrhoea, insomnia, and irritability. Gradual withdrawal over a period of at least one to 2 weeks is advisable).
- You may have abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.
- Blurred vision.
- Abnormal dreams and nightmares.
- Irritability.
- Feeling more hungry

- Disturbance in speech and language.

Less frequent side effects:

- Allergic reaction that may include itchy rash, weals and swelling of the skin
- Fits (seizures)
- Restless legs (unpleasant sensations in the legs).
- Difficulty swallowing.
- Involuntary movements, mainly of your face or tongue (Tardive dyskinesia)
- Fainting (may lead to falls)
- Stuffy nose
- A slower than normal heart rate which may occur when starting treatment and which may be associated with low blood pressure and fainting.
- Difficulty in passing urine
- Confusion
- Combination of fever, very marked drowsiness, muscle stiffness, marked increase in blood pressure or heartbeats and reduces consciousness (a disorder called “neuroleptic malignant syndrome”)
- Men and women to have swelling of breasts and unexpectedly produce breast milk.
- Priapism (long-lasting and painful erection).
- Walking, talking, eating or other activities while you are asleep
- Body temperature decreased (hypothermia)
- Combination of fever, flu-like symptoms, sore throat, or any other infection with very low white blood cell count, a condition called agranulocytosis
- Bowel obstruction
- Inflammation of the liver with or without jaundice (a yellowish discoloration of skin/palms or whites of your eyes
- Anaphylaxis (severe form of allergic reaction; may include severe difficulty breathing and shock).
- Rhabdomyolysis (breakdown of muscle fibers and pain in muscles)

Side effects that are of unknown frequency (cannot be estimated from the available data):

- Symptoms of withdrawal may occur in newborn babies of mothers that have used TRUVALIN during their pregnancy.
- Combination of widespread rash, high body temperature, blood abnormalities (liver enzyme

elevations, increase in a type of white blood cells sometimes seen in allergic reactions) and enlarged lymph nodes (a condition called “drug reaction with eosinophilia and systemic symptoms”) may occur.

- Rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid called as Acute Generalized Exanthematous Pustulosis (AGEP)) and a severe form of skin rash with itchy pink-red irregular spots (a condition known as Erythema multiforme (EM)) may occur.
- Inflammation of blood vessels (vasculitis), often with skin rash with small red or purple bumps.

The following side-effects can also occur with TRUVALIN, and they are seen when a blood test is taken:

- Decrease in the amount of white blood cells. These changes will normally disappear when stopping the treatment of TRUVALIN.
- Decrease in the amount of red blood cells. These are the cells that transport oxygen throughout the body**.**
- Increase in the amount of eosinophils. These are a type of white blood cells, sometimes seen in allergic reactions.
- “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 TRUVALIN.
- Increase 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 the hormone prolactin in the blood. This may lead to:
    - Men and women to have swelling of breasts and unexpectedly
    - Women to have no monthly period or irregular periods.
- Changes in the amount of thyroid hormones in your blood. These changes usually do not affect how you feel.

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 TRUVALIN.

5. How to store TRUVALIN

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep your medicine protected from moisture.

Do not remove from carton until required for use.

Do not use TRUVALIN after the expiry date stated on the container.

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 TRUVALIN contains

TRUVALIN 25:

The active substance is quetiapine fumarate, equivalent to 25 mg of quetiapine free base

TRUVALIN 100:

The active substance is quetiapine fumarate, equivalent to 100 mg of quetiapine free base.

TRUVALIN 200:

The active substance is quetiapine fumarate, equivalent to 200 mg of quetiapine free base.

TRUVALIN 300:

The active substance is quetiapine fumarate, equivalent to 300 mg of quetiapine free base.

The other ingredients are:

Calcium hydrogen phosphate, ferric oxide, lactose monohydrate, macrogol, magnesium stearate, methylhydroxypropylcellulose, microcrystalline cellulose, povidone, sodium starch glycolate and titanium dioxide.

What TRUVALIN looks like and contents of the pack

TRUVALIN 25:

Peach, round, bi-convex, film-coated tablet intagliated with Q 25.

TRUVALIN 100:

Yellow, round, bi-convex, film-coated tablet intagliated with Q 100.

TRUVALIN 200:

White, round, bi-convex, film-coated tablet intagliated with Q 200.

TRUVALIN 300:

White, capsule-shaped, film-coated tablet intagliated with Q on one side and 300 on the other.

TRUVALIN tablets are packed into white opaque PVC aluminium foil blister with each blister strip containing 6 or 10 tablets packed into a unit carton

TRUVALIN 25: Packs of 6 or 100 tablets.

TRUVALIN 100: Packs of 60; 90 or 100 tablets.

TRUVALIN 200: Packs of 60; 90 or 100 tablets.

TRUVALIN 300: Packs of 60; 90 or 100 tablets.

Not all pack sizes may be marketed

Holder of Certificate of Registration

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Access to the corresponding Professional Information