Patient Information Leaflet for Medicines for Human Use:

TROLIC, tablets

SCHEDULING STATUS: S4

TROLIC 5 mg (Tablets)

Prednisone 5 mg

Sugar free

Read this entire leaflet carefully before you start taking TROLIC 5 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or pharmacist, nurse, or other health care provider.
- TROLIC 5 mg 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

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1. What Trolic 5 mg is and what it is used for

Trolic 5 mg belongs to a group of medicines called corticosteroids.

Trolic 5 mg are used in a wide range of inflammatory and autoimmune conditions including:

- inflammation of joints (rheumatoid arthritis)
- kidney disease (nephrotic syndrome)
- "auto-immune" diseases called collagen diseases (where your body fights against itself)

- a form of life-threatening disease affecting the skin, joints and kidneys (systemic lupus erythematosus)
- allergic reactions that are not controlled by a group of drugs called antihistaminics
- asthma that is not controlled by other measures
- skin diseases
- severely ill patients with long standing inflammatory diseases of the bowel (ulcerative colitis)
- low blood platelet count to decrease the bleeding tendency
- to prevent organ rejection after a transplant
- blood cell disorders including low red blood and platelet counts
- cancer of the white blood cells (leukaemia)
- an immune reaction to eating gluten
- excess glucose in the blood reducing the ability of the blood cells to absorb and use blood sugar for energy (insulin resistance)
- when the immune system is not functioning as it should be (immunosuppression)
- liver disorders.

2. What you need to know before you take Trolic 5 mg

Do not take TROLIC 5 mg:

- if you are hypersensitive (allergic) to prednisone, a class of medicines known as ‘glucocorticosteroids’ or any of the other ingredients of Trolic tablets (listed in Section 6).
- if you have a fungal infection affecting your internal organs
- if you have osteoporosis (a disease causing your bones to weaken and become brittle)
- if you have active tuberculosis (infectious disease generally affecting the lungs)
- if you have any acute infection that is not currently being treated appropriately
- if you are planning to be immunised with a live vaccine (e.g. BCG, oral polio, rotavirus or measles vaccines).

- if you have ulcers in the intestines (peptic ulcers).
- if you have a mental illness (psychoses).

Warnings and precautions

Take special care with Trolic 5 mg:

- In children and the elderly.
- If you are diabetic.
- If you suffer with high blood pressure.
- In the presence of heart failure.
- If you have kidney or liver impairment.
- If you have a compromised immune system, inactive tuberculosis or if you are currently taking any other medicine that suppresses your immune system (e.g. cyclosporine, methotrexate or anticancer medicines).
- If you have glaucoma (damage to the optic nerve in the eye).
- If you have ocular herpes simplex (viral infection in the eye).
- If you are taking high doses of TROLIC 5 mg, and are in physical contact with people that are currently infected with chickenpox or shingles.
- If your birth control method involves an intra-uterine device (device inserted into the uterus).
- If you have an adrenal tumour (pheochromocytoma).
- If you have had previous muscle weakness associated with steroid treatment, as Trolic 5 mg may result in further muscle weakness.
- If you have myasthenia gravis (characterised by weakness and rapid fatigue of the muscles under your voluntary control).
- If you have blood clotting (thromboembolic) disorders.
- If you undertake increased or strenuous physical activity you may experience unusual muscle pain and deterioration in the fibre of your muscles, your doctor will need to examine you and review your dosage of Trolic 5 mg regularly.
- If you suddenly stop treatment, increase, or reduce your dose of Trolic 5 mg, this may

cause acute adrenal insufficiency (you may experience muscle and joint pain, shortness of breath, nausea and vomiting, fever, low blood pressure, dehydration) requiring prompt, emergency medical treatment.

- If you stop taking Trolic 5 mg this could result in raised intracranial pressure which may cause headaches, blurred vision, vomiting, changes in your behaviour, weakness, or problems with moving or talking, feeling less alert than normal, lack of energy or sleepiness.
- If you have a hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating (Cushing's disease), you should avoid taking Trolic 5 mg as your symptoms may get worse.
- If you have an under active thyroid gland which can cause tiredness and weight gain.
- If you have ever had severe depression or manic-depression. This includes having had depression before or whilst taking steroid medicines such as Trolic 5 mg or if any of your close family has had these illnesses.

Bradycardia (slow heart rate) may occur at high doses Trolic 5 mg.
Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of
breath. Your health care provider will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Trolic 5 mg.

Children and adolescents

Talk to your doctor before giving this medicine to babies, children or adolescents as it may slow their growth.

Other medicines and Trolic 5 mg

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

- Medicines used for seizures (e.g. phenytoin, carbamazepine and primidone).
- Barbiturates (e.g. phenobarbital), used for anxiety and sedation.
- Antibiotics such as rifampicin, used to treat serious bacterial infections (e.g. tuberculosis and leprosy).
- Nonsteroidal anti-inflammatory medicines (e.g. indomethacin, diclofenac and ibuprofen), used for pain and inflammation.
- Medicines used to lower blood sugar levels (in diabetes) and to lower high blood pressure
- Anticoagulants (e.g. aspirin, warfarin), used to thin the blood.
- Medicines used to release excess water from the body or lower high blood pressure (e.g. thiazides and furosemide).
- Medicines used to suppress your immune system (e.g. cyclosporine).
- Medicines used to block the inflammation mediators in the body (e.g. montelukast).
- Ritonavir, indinavir or other antiviral medicines used to treat HIV.
- Cardiac blycosides used to treat heart conditions, if taken with Trolic 5 mg may increase the risk of toxicity (poison) if hypokalaemia (low potassium levels) occurs.

- Ciclosporin, used to reduce pain, swelling and stiffness in rheumatoid arthritis, if taken with Trolic 5 mg may require your doctor to adjust your doses of these medicines.

- Methotrexate (medicine used to treat cancer) if taken together with Trolic 5 mg may result in haematological toxicity (a decrease in bone marrow and blood cells), which may lead to infection, bleeding, or anaemia.

- Oral contraceptives may increase the blood level of Trolic 5 mg resulting in an

increased chance of undesirable effects.

- Immunosuppressants, medicines which dampen down the activity of the body's immune system.

- Mifepristone (a medicine used to terminate pregnancy) will result in a reduced effect of Trolic 5 mg for 3 to 4 days after taking mifepristone.

- Medicines used to treat breathing difficulties, allergic rhinitis and conjunctivitis, such as salbutamol and terbutaline, as they may result in an increased risk of hypokalaemia (low potassium levels) if taken with high doses.

- Somatropin (growth hormone) as the growth promoting effect may be inhibited

- Theophylline, used to treat asthma and chronic obstructive pulmonary disease (COPD).

- Carbenoxolone which is used for ulcers.

- Acetazolamide which is used in the treatment of glaucoma and epilepsy.
- Vaccinations

Trolic 5 mg with food and drink

Avoid eating liquorice whilst taking Trolic 5 mg.

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.

You should avoid taking Trolic 5 mg if you are breastfeeding, as this medicine is excreted into breast milk and may harm your baby

Driving and using machines

If you feel dizzy or tired after taking Trolic 5 mg do not drive or operate machinery until these effects have worn off.

3. How to take Trolic 5 mg

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

Always take TROLIC 5 mg exactly as your doctor or pharmacist 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 Trolic 5 mg will last. Do not stop treatment early because it may affect your condition. If you have the impression that the effect of Trolic 5 mg is too strong or too weak, tell your doctor or pharmacist.

Do not increase or decrease your dose without prior consultation with your doctor.

Adults:

2 to 20 tablets (10 mg to 100 mg) daily, in divided doses, as determined by your doctor.

Children:

1 mg to 20 mg daily, as determined by your doctor.

If you take more Trolic 5 mg than you should

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

There is no specific antidote for an overdose of Trolic 5 mg.

Treatment of a Trolic 5 mg overdosage requires supportive medical care.

If you forget to take Trolic 5 mg

It is important to take your tablets regularly, as prescribed, in order for the desired effects of TROLIC 5 mg to be achieved. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Trolic 5 mg

Treatment with Trolic 5 mg should not be stopped abruptly in patients who have been taking high doses. Your medical doctor will stop treatment slowly, with a gradual decrease in dosage.

If treatment is stopped suddenly, acute adrenal insufficiency may be experienced. This is a life threatening condition that occurs when there is insufficient cortisol (a hormone) in the body. The symptoms of this condition include nausea, vomiting, stomach pain, dehydration,

weakness, fatigue, low blood pressure, fever and headache.

4. Possible side effects

Trolic 5 mg can have side effects.

Not all side effects reported for Trolic 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Trolic 5 mg, please consult your healthcare professional for advice.

If you have any of the following side effects occur after you take stop taking Trolic 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic skin reactions (rash, itching, facial swelling, difficulty breathing or feeling faint)
- Rupture of your Achilles (above heel) or patellar (alongside kneecap) tendon (characterised by immediate and sharp pain)
- Behavioural changes or depression
- Mood changes that have you feeling happy and then sad
- Psychosis, a mental disorder where thoughts and emotions are impaired leading to a loss of reality
- Cushing's syndrome (swollen face, fat deposits on the stomach and back, blurry vision, fatigue, raised blood pressure and raised blood sugar levels)
- Sores in the lining of the stomach that could be bleeding, characterised by extreme stomach pain, nausea, bloating and weight loss
- Vision changes such as development of cataract (clouding of eye lens) or glaucoma (optic nerve damage)
- Inflammation of the pancreas, characterised by aching pain that travels along your back, fever, vomiting, stomach tenderness and yellowing of the skin and eyes
- Tuberculosis (coughing up blood, night sweats and weight loss) that is reactivated
- Heart failure (shortness of breath, coughing or wheezing, fatigue and swelling of the ankles, legs and face).

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

The following side effects have been reported either during clinical trials or the post-

marketing experience:

- Increased blood sugar levels, characterised by a dry mouth, thirst, blurry vision and frequent urination.
- Excess water in the body, characterised by swelling of the face, legs or ankles.
- Increase in appetite and weight gain.
- Muscle weakness and pain.
- Bruising that occurs easily and a delay in wound healing.
- Blood disorders.
- Skin lesions (Calciphylaxis).
- Hiccups.
- Sweating.

If they continue or are severe, contact 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Trolic 5 mg.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

5. How to store Trolic 5 mg

Store at or below 25 °C in a cool, dry place. Protect from light and moisture.

Keep containers tightly closed. Do not remove tablets from patient ready packs until required for use.

Store Trolic 5 mg tablets in their original packaging. Do not use after the expiry date stated on the label. Do not store in a bathroom.

Return all unused or expired medicine to your pharmacist for safe disposal. Do not dispose of any medication in drains or toilets.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What Trolic 5 mg contains

- The active ingredient is prednisone.
- The other ingredients are dibasic calcium phosphate, microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

What Trolic 5 mg looks like and contents of the pack

White to off-white, round, flat tablet, scored on one side with a bitter taste.

Contents of the pack

Plastic containers (HDPE/PP) of 100, 500, 1000 or 5000 tablets.

Patient ready packs (LDPE) of 28, 40, 56 or 100 tablets.

Holder of Certificate of Registration

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