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PROFESSIONAL INFORMATION

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE

TURANTO 50 mg (Capsules)
TURANTO 100 mg (Capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TURANTO 50 Capsules
Each capsule contains 50,0 mg nitrofurantoin macrocrystals.
Contains sugar (77,50 mg lactose monohydrate).

TURANTO 100 Capsules
Each capsule contains 100,0 mg nitrofurantoin macrocrystals.
Contains sugar (155 mg lactose monohydrate).

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule.
TURANTO 50 Capsules
Yellow opaque cap and white opaque body, size 3 hard gelatin capsule, imprinted with "C 69" on cap, "50 mg" and two lines encircling the capsules on body with black ink, filled with yellowish powder.
TURANTO 100 Capsules
Yellow opaque cap and body, size 2 hard gelatin capsule, imprinted with "C 70" on cap, "100 mg" and three lines encircling the capsules on body with black ink, filled with yellowish powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
TURANTO is indicated for the treatment and prevention of recurrence of uncomplicated lower urinary tract infections, e.g. pyelonephritis, pyelitis and cystitis.
It is not indicated for the treatment of associated renal, cortical or perinephric abscesses.

4.2 Posology and method of administration
Posology:
Adults
Acute urinary tract infections: 50 - 100 mg four times a day, with meals and at bedtime.
To prevent recurrences: 50 - 100 mg per day.
Children
Acute urinary tract infections: Should be calculated on the basis of 5 - 7 mg/kg of body mass per 24 hours to be given in divided doses four times a day (contraindicated for children under one month).
To prevent recurrences: 1 mg/kg/day for long-term therapy.

Method of administration:
Oral
Therapy should be continued for at least one week and for at least 3 days after sterility of the urine is obtained. Continued infection indicates need for re-evaluation.
Nitrofurantoin is highly soluble in urine, to which it may impart a brown colour.

TURANTO may be given with meals (food or milk) to minimise gastric upset.

4.3 Contraindications
- Hypersensitivity to nitrofurantoin or other nitrofurans or to any of the excipients listed in section 6.1.
- Patients with a deficiency of glucose-6-phosphate dehydrogenase or breastfeeding mothers of infants with this deficiency.
- Anuria, oliguria and renal impairment are contraindications to therapy with **TURANTO.**
- Treatment of this type of patient carries an increased risk of toxicity because of impaired excretion of **TURANTO.**
- Pregnant women at term, as well as infants under one month of age, because of the possibility of haemolytic anaemia due to immature enzyme systems (glutathione instability).
- Safe use in earlier pregnancy has not been established.
- Acute porphyria.

4.4 Special warnings and precautions for use
A course of therapy should not exceed 14 days and repeated courses should be separated by rest periods.

Patients with a history of asthma may experience acute asthmatic attacks.

Acute, subacute or chronic pulmonary reaction has been observed in patients treated with **TURANTO.** If these reactions occur, **TURANTO** should be withdrawn and appropriate measures should be taken.

Elderly patients are especially susceptible to the pulmonary intoxication of **TURANTO.** Elderly patients and patients undergoing prolonged therapy should be monitored for changes in pulmonary function.

Cases of haemolytic anaemia of the primaquine sensitivity type have been induced by **TURANTO.** The haemolysis appears to be linked to a glucose-6-phosphate dehydrogenase deficiency in the red blood cells of the affected patients. Any sign of haemolysis is an indication to discontinue the **TURANTO.**

Nitrofurantoin is not effective for the treatment of parenchymal infections of unilaterally nonfunctioning kidneys. A surgical cause for infection should be excluded in recurrent or severe cases.

Pseudomonas is the organism most commonly implicated in superinfections in patients treated with **TURANTO.**

Peripheral neuropathy and susceptibility to peripheral neuropathy which may become severe or irreversible, has occurred and may be life-threatening. Patients should therefore be warned to report early signs of peripheral neuropathy. If peripheral neuropathy occurs the treatment should be discontinued. Care is required in patients with predisposing pulmonary, hepatic, neurological or allergic disorders and in those with conditions such as anaemia, diabetes mellitus, electrolyte imbalance, debility or vitamin B deficiency, which may predispose to peripheral neuropathy.

Although hepatic reactions such as hepatitis, cholestatic jaundice, and hepatic necrosis occur less frequently, fatalities have been reported. Patients should be monitored and **TURANTO** stopped immediately if hepatitis occurs.

Lactose: **TURANTO** contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption should not take **TURANTO.**
Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction
Probenecid or sulphinpyrazone may reduce the excretion of **TURANTO** and should not be given concomitantly.

Magnesium trisilicate may reduce the absorption of **TURANTO.**

TURANTO may cause false positive reactions in urine tests for glucose using copper reduction methods.

Antagonism between **TURANTO** and nalidixic acid, and **TURANTO** and oxolinic acid has been demonstrated *in vitro* and **TURANTO** should not be given concomitantly with quinolones.

Oestrogens: **TURANTO** may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of oestrogen-containing contraceptive medicines. Therefore, patients should be warned appropriately and extra contraceptive precautions taken.

Typhoid vaccine (oral): **TURANTO** inactivates oral typhoid vaccine.

Increased absorption with food or agents delaying gastric emptying.

Decreased antibacterial activity by carbonic anhydrous inhibitors and urine alkalisation.

4.6 Fertility, pregnancy and lactation

<u>Pregnancy</u>
TURANTO is contraindicated in pregnant women during labour and delivery because of the possible risk of haemolysis of the infant's immature red cells. Safe use in earlier pregnancy has not been established (see section 4.3).

Breastfeeding
Breastfeeding an infant known or suspected to have an erythrocyte enzyme deficiency (including G6PD deficiency), must be temporarily avoided, since nitrofurantoin is detected in trace amounts in breast milk.

4.7 Effects on ability to drive and use machines
TURANTO may cause dizziness or drowsiness.
Patients should be aware of how they react to **TURANTO** before driving or operating machinery.

4.8 Undesirable effects
The following adverse reactions have been reported in association with **TURANTO** Capsules:

System Organ Class	Frequency	Undesirable effects
Infections and infestations:	Less frequent	Superinfection by resistant organisms may occur, however, these are limited to the genitourinary tract because suppression of normal bacterial flora elsewhere in the body does not occur.
Blood and lymphatic system disorders:	Less frequent	Haemolytic anaemia, granulocytopenia or agranulocytosis, eosinophilia and megaloblastic anaemia, leucopenia, thrombocytopenia in persons with a genetic deficiency of glucose-6-phosphate dehydrogenase.
Immune system disorders:	Less frequent	Anaphylaxis, aladenitis, drug fever, a lupus-like syndrome and angioedema
Psychiatric disorders:	Less frequent	Depression, euphoria, confusion, psychotic reactions.
Nervous system disorders:	Less frequent	Peripheral neuropathy (including optical neuritis), reversible headache, dizziness, nystagmus, drowsiness, vertigo and asthenia. Severe polyneuropathies with demyelination and degeneration of both sensory and motor nerves have been reported. Patients should be warned to report early signs of peripheral neuropathy such as paraesthesia.
Respiratory, thoracic and mediastinal disorders	Less frequent	Pulmonary sensitivity reactions may occur, which can be acute, subacute or chronic. Acute pulmonary sensitivity reaction is commonly manifested by sudden onset of fever, chills, eosinophilia, cough, chest pain, dyspnoea, pulmonary infiltration or consolidation and pleural effusion. The acute reactions usually occur within the first week of treatment and resolve with discontinuation of **TURANTO.** More insidious subacute reactions have also been reported. Interstitial pulmonary fibrosis can occur in patients on chronic medication. Subacute or chronic pulmonary reaction is associated with prolonged therapy. Insidious onset of malaise, dyspnoea on exertion, cough, altered pulmonary function, and roentgenographic and histologic findings of diffuse interstitial pneumonitis or fibrosis or both are common manifestations. Impaired pulmonary function may result even after cessation of **TURANTO** therapy.
Gastrointestinal disorders	Frequent	Anorexia, nausea, vomiting.
	Less frequent	Abdominal pain, diarrhoea, pancreatitis.
Hepatobiliary disorders	Less frequent	Hepatotoxicity including cholestatic jaundice and hepatitis, chronic active hepatitis and hepatocellular damage.
Skin and subcutaneous tissue disorders	Less frequent	Skin rashes, erythema multiforme, exfoliative dermatitis, maculopapular, erythematous, or eczematous eruption, pruritus, urticaria, transient alopecia.
Musculoskeletal and connective tissue disorders	Less frequent	Myalgia, arthralgia
Renal and urinary disorders	Frequent	Brown discolouration of urine
General disorders and administration site conditions	Less frequent	Fever, benign intracranial hypertension

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose
Symptoms and signs of overdose include gastric irritation, nausea and vomiting. There is no specific antidote. Nitrofurantoin can be haemodialysed. Standard treatment is symptomatic and supportive. Induction of emesis can be considered in cases of recent ingestion. Monitoring of full blood count, liver function tests and pulmonary function, are recommended. A high fluid intake should be maintained to promote urinary excretion of the medicine.

5. PHARMACOLOGICAL PROPERTIES

Pharmaceutical groups: A 18.5 Urinary tract antiseptics
ATC code: J01XE01

5.1 Pharmacodynamic properties
Nitrofurantoin is an antibacterial medicine for specific urinary tract infections.
Nitrofurantoin exerts bacteriostatic activity against certain sensitive bacteria.
Anti-bacterial activity is higher in acidic urine.

Resistance
Many strains of *Enterobacter- Serratia* species and *Klebsiella* species are resistant to nitrofurantoin.
It is not active against most strains of *Proteus* and *Pseudomonas* species.

5.2 Pharmacokinetic properties
Nitrofurantoin is completely absorbed from the GI tract. The macrocrystalline form of nitrofurantoin is absorbed and excreted more slowly. Antibacterial concentrations are not achieved in plasma following ingestion of recommended doses because of rapid elimination. The plasma $t_{\frac{1}{2}}$ is 0,3 – 1 hour; ~40 % is excreted unchanged into the urine. The average dose of nitrofurantoin yields a concentration in urine of ~200 µg/ml. This concentration is soluble at pH > 5, but the urine should not be alkalinized, because this reduces antimicrobial activity. The rate of excretion is linearly related to the creatinine clearance, so in patients with impaired glomerular function, the efficacy of nitrofurantoin may be decreased and the systemic toxicity increased. Nitrofurantoin colours the urine brown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose monohydrate (Supertab 11SD), pregelatinised starch (Starch 1500), talc and hard gelatin capsules (for 50 mg and 100 mg containing FD&C Yellow 6 (C.I. No.15985), D&C Yellow 10 (C.I. No. 47005), titanium dioxide (C.I. No. 77891), gelatin, sodium lauryl sulfate and black edible printing ink).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months from the manufacturing date

6.4 Special precautions for storage
Store at or below 25 °C.
Protect from light and moisture.
Keep the HDPE container tightly closed.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container
<u>**HDPE Container Pack:**</u>
TURANTO 50 Capsules
75 ml round, white HDPE container with screw neck with white polypropylene closure with pulp and heat seal liner containing 100 capsules packed in an outer pre-printed carton.
TURANTO 100 Capsules
100 ml round, white HDPE container with screw neck with white polypropylene closure with pulp and heat seal liner containing 100 capsules packed in an outer pre-printed carton.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Macleods Pharmaceuticals SA (Pty) Ltd
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

8. REGISTRATION NUMBER(S)

TURANTO 50: 52/18.5/0758.754
TURANTO 100: 52/18.5/0759.755

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 February 2022

10. DATE OF REVISION OF THE TEXT

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TURANTO 50 CAPSULES
Nitrofurantoin 50,0 mg
Contains sugar (77,50 mg of lactose monohydrate)

TURANTO 100 CAPSULES
Nitrofurantoin 100,0 mg
Contains sugar (155 mg of lactose monohydrate)

Read all of this leaflet carefully before you start taking TURANTO
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TURANTO** have 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 **TURANTO** is and what it is used for
2. What you need to know before you take **TURANTO**
3. How to take **TURANTO**
4. Possible side effects
5. How to store **TURANTO**
6. Contents of the pack and other information

1. What TURANTO is and what it is used for

TURANTO contains nitrofurantoin which is an antibiotic. It is used to prevent and treat infections of the bladder, and other parts of the lower urinary tract.

2. What you need to know before you take or give TURANTO

Do not take or give TURANTO:
- If you or your child are hypersensitive (allergic) to nitrofurantoin or any of the other ingredients of **TURANTO** (listed in section 6.1).
- If you or your child lacks an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your red blood cells to be more easily damaged.
- If you are breastfeeding a baby with suspected or known deficiency in glucose-6-phosphate dehydrogenase.
- If you or your child has a disease of the kidneys which is severely affecting the way they work (passing no urine or reduced volume of urine).
- If you are pregnant or if you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby.
- To infants under one month of age.
- If you or your child suffer from a blood disorder called porphyria.

Warnings and precautions
Take special care with **TURANTO:**
TURANTO should not be taken for more than 14 days. If a repeat course is prescribed by your doctor, the courses should be separated by a rest phase.

Talk to your doctor, pharmacist before taking or giving **TURANTO:**
- If you or your child have asthma as you may experience an acute asthma attack.
- if you or your child suffer from any lung disease, liver disease, nervous system disease, allergies, diabetes, weakness, anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness); or a lack of vitamin B or abnormal levels of salts in your blood (your doctor will be able to advise you). The above conditions may increase the chance of developing a side effect which results in damage to the nerves, resulting in numbness and feeling of pins and needles in the arms and legs.

While taking **TURANTO:**
- **TURANTO** may affect your lungs. Stop taking or giving **TURANTO** and inform your doctor if you or your child develop symptoms of fever, chills, cough and shortness of breath. Your doctor will monitor your lung function especially if you are elderly or have been prescribed **TURANTO** for long periods.
- If you notice any numbness or feeling of pins and needles stop taking or giving **TURANTO** and inform your doctor immediately.
- If you or your child suffer from G6PD (glucose-6-phosphate dehydrogenase) deficiency and develop signs of anaemia (pale skin, weakness and breathlessness) stop taking **TURANTO** and inform your doctor immediately.
- Stop taking **TURANTO** and inform your doctor if you develop liver disease with symptoms of yellowing of the skin or whites of the eyes.
- You may get a superinfection (a secondary infection) due to *Pseudomonas* (a bacteria resistant to **TURANTO.**

Other medicines and TURANTO
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor if you take any of the following medicines and **TURANTO** at the same time:
- Antacids for indigestion (e.g. magnesium trisilicate)
- Medicines for gout (e.g. probenecid or sulfinpyrazone)
- Medicines which slow the passage of food through the stomach (e.g., atropine, hyoscine)
- Medicines for increased/raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g., acetazolamide)
- Medicines which make the urine less acidic (e.g., potassium citrate mixture)
- Medicines for infections, known as quinolones
- Oral contraceptive or "the pill". You will need to use extra contraceptive precautions such as using a condom, as **TURANTO** can make the contraceptive pill less effective.
- Typhoid vaccine, which is given for the prevention of typhoid.
- **TURANTO** may interfere with the results of some tests for glucose in the urine.

TURANTO with food and drink:
TURANTO should be taken with food or milk. This will help to avoid stomach upset and also to help the absorption of **TURANTO.**

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **TURANTO.**
TURANTO is not recommended for use during pregnancy.

TURANTO
50 / 100
PM03934601

350 mm

335 mm

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Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed. **TURANTO** is not recommended while you are breastfeeding.

Driving and using machines
TURANTO may cause dizziness or drowsiness. Do not drive or operate machinery until you know how **TURANTO** affects you.

TURANTO contains lactose monohydrate:
Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **TURANTO.**
TURANTO contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take TURANTO

Do not share medicines prescribed for you with any other person.
Always take or give **TURANTO** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
If you have the impression that the effect of **TURANTO** is too strong or too weak, talk to your doctor or pharmacist.
The usual dose in adults is:
For treatment of infections: Either one **TURANTO 50** mg or one **TURANTO 100** mg four times a day and at bedtime.
TURANTO should be taken for at least one week and for at least 3 days after the infection has been cleared.
For prevention of further infections: Either one **TURANTO 50** mg or one **TURANTO 100** mg at bedtime.

The usual dose in children and infants over one month of age:
The dose will be provided by your child's doctor based on the weight of the child. Follow your doctor's instructions exactly.
Children below 1 month of age should not be given **TURANTO.**

If you take more TURANTO than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. You may experience stomach pains, nausea and vomiting.

If you forget to take TURANTO
It is important to take your **TURANTO** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking TURANTO
Do not stop taking **TURANTO** unless your doctor tells you to. **TURANTO** should be taken for at least one week and for at least 3 days after the infection has been cleared.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

If any of the following happens, stop taking TURANTO and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Liver damage – nausea; stomach pain; low fever; loss of appetite; dark urine; clay-coloured stools; jaundice (yellowing of the skin or eyes).
- Fever with a severe blistering, peeling and red skin rash or any severe skin reaction.
- Inflammation of the pancreas (severe pain in the abdomen).
- Superinfection by bacteria not sensitive to **TURANTO.**
- Blood cells may be affected in some patients. This may result in bruising, delayed clotting of the blood, sore throat, fever, anaemia, and a susceptibility to colds or a persistent cold.
- Lung reaction with fever, chills, cough, chest pain and shortness of breath.
- Raised pressure in the skull (causing severe headaches).
- Inflammation and swelling of the salivary glands.

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

Tell your doctor if you notice any of the following serious effects:
- Feeling depressed, feeling of unusual happiness, confusion, mental illness.
- Tingling or numbness of the hands or feet (pins and needles).
- Inflammation of the optic nerve causing temporary vision loss.
- Headache, dizziness, rapid, uncontrollable movements of the eyes, drowsiness, spinning sensation, weakness.

Tell your doctor if you notice any of the following:
Frequent side effects:
- Loss of appetite, nausea, vomiting.
- Brown discoloration of urine.

Less frequent side effects:
- Stomach pain, diarrhoea.
- Rash, itching, hives, short-term hair loss.
- Muscle pain and joint pain.
- Fever.

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **TURANTO.**

5. How to store TURANTO

Store at or below 25 °C (room temperature). Protect from light and moisture.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the HDPE container tightly closed.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information
What TURANTO contains
The active substance is nitrofurantoin macrocrystals 50 mg and 100 mg.
The other ingredients include lactose monohydrate (Supertab 11SD), pregelatinised starch (Starch 1500), talc and hard gelatin capsules (for 50 mg and 100 mg containing FD & C Yellow 6 (C.I. No.15985), D&C Yellow 10 (C.I. No. 47005), titanium dioxide (C.I. No. 77891), gelatin, sodium lauryl sulfate and black edible printing ink).

What TURANTO looks like and contents of the pack
TURANTO 50 mg:
Yellow opaque cap and white opaque body, size 3 hard gelatin capsule, imprinted with "C 69" on cap, "50 mg" and two lines encircling the capsules on body with black ink, filled with yellowish powder.
TURANTO 100 mg:
Yellow opaque cap and body, size 2 hard gelatin capsule, imprinted with "C 70" on cap, " 100 mg" and three lines encircling the capsules on body with black ink, filled with yellowish powder.

2) HDPE Container Pack
TURANTO 50 mg:
75 ml round, white HDPE container with screw neck with white polypropylene closure with pulp and heat seal liner containing 100 capsules packed in an outer pre-printed carton.

TURANTO 100 mg:
100 ml round, white HDPE container with screw neck with white polypropylene closure with pulp and heat seal liner containing 100 capsules packed in an outer pre-printed carton.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East), 1 Cussonia Drive,
Bassonia Rock, Ext. 12, Alberton, South Africa.

This leaflet was last revised in
22 February 2022.

Registration number
TURANTO 50: 52/18.5/0758.754
TURANTO 100: 52/18.5/0759.755

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 11 69.

SKEDULERINGSTATUS S4

PASIËNTINLIGTINGSTUK

TURANTO 50 KAPSULES
50,0 mg Nitrofurantoïen
Bevat suiker: (77.50 mg laktosemonohidraat)
TURANTO 100 KAPSULES
100,0 mg Nitrofurantoïen
Bevat suiker: (155 mg laktosemonohidraat)

Lees hierdie inligtingstuk sorgvuldig voordat jy TURANTO begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter of apteker, indien jy verdere vrae het.
- **TURANTO** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk?
1. Wat **TURANTO** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **TURANTO** neem
3. Hoe om **TURANTO** te gebruik
4. Moontlike newe-effekte
5. Hoe om **TURANTO** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat TURANTO is en waarvoor dit gebruik word

TURANTO bevat nitrofurantoïen wat 'n antibiotikum is. Dit word gebruik vir behandeling en voorkoming van infeksies van die blaas, en ander dele van die laer urienweg.

2. Wat jy behoort te weet voordat jy TURANTO neem of gee

Moet nie TURANTO neem of gee nie:
- Indien jy of jou kind hipersensitief (allergies) is vir nitrofurantoïen of enige van die ander bestanddele van **TURANTO** (gelys in afdeling 6.1).
- Indien jy of jou kind 'n erstem (liggaamschemikalieë) naamlik glukose-6-fosfaatdehidrogenase ontbreek, wat veroorsaak dat jou rooibloedselle makliker beskadig word.
- Indien jy 'n baba borsvoed met 'n vermoedelike of bekende tekort aan glukose-6-fosfaatdehidrogenase.
- Indien jy of jou kind 'n niersiekte het wat die manier waarop hulle werk ernstig aantas (geen urisene of verminderde volume van urisene passeer).
- Indien jy swanger is of indien jy in die finale stadium van swangerskap (kraam of bevalling) is, aangesien daar 'n risiko is dat dit die baba kan affekteer.
- Aan babas jonger as een maand oud.
- Indien jy of jou kind aan 'n bloedafwyking, naamlik porfirie ly.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **TURANTO:**
TURANTO moet nie vir langer as 14 dae geneem word nie. Indien herhaalde kursusse deur jou dokter voorgeskryf word, moet die kursusse geskei word deur 'n rusperiode.
Praat met jou dokter of apteker voordat jy **TURANTO** neem of gee:
- Indien jy of jou kind asma het aangesien jy 'n akute asma aanval kan ervaar.
- indien jy of jou kind aan enige longsiekte, lewersiekte, senuweesteiselsiekte, allergieë, diabetes, swakheid, bloedarmoede ('n afname in rooibloedselle wat bleek vel, swakheid en kortasemheid veroorsaak); of 'n tekort aan vitamien B of abnormale vlekke van soute in jou bloed (jou dokter sal jou kan adviseer) hy. Die bogenoemde toestande kan die kans verhoog om 'n newe-effek te ontwikkel wat skade aan die senuwees tot gevolg kan hê, wat lei tot gevoelloosheid en gevoel van spalde en naalde in die arms en bene.

Terwyl jy **TURANTO** neem:
- **TURANTO** kan jou longs affekteer. Hou op om **TURANTO** te neem of te gee en lig jou dokter in indien jy of jou kind simptome van koors, kouekoors, hoes en kortasem ontwikkel. Jou dokter sal jou longfunksie monitor veral indien jy bejaard is of vir lang tydperke **TURANTO** voorgeskryf is.
- Indien jy enige gevoelloosheid of gevoel van spelde en naalde opmerk, hou op om **TURANTO** te neem of te gee en stel onmiddellik jou dokter in kennis.
- Indien jy of jou kind aan G6PD (glukose-6-fosfaatdehidrogenase) tekort ly en tekens van bloedarmoede ontwikkel (bleek vel, swakheid en kortasemheid), hou op om **TURANTO** te neem en stel onmiddellik jou dokter in kennis.
- Hou op om **TURANTO** te neem en lig jou dokter in indien jy lewersiekte ontwikkel, met simptome van vergeling van die vel of wit van die oë.
- Jy kan 'n superinfeksie ('n sekondêre infeksie) kry as gevolg van *Pseudomonas* ('n bakterie wat weerstandig teen **TURANTO** is).

Ander medisyne en TURANTO
Vertel altyd vir jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter indien jy enige van die volgende medisyne en **TURANTO** op dieselfde tyd neem:
- Teensuurmiddels vir slegte spysvertering (bv. magnesiumtrisilikaat)
- Medisyne vir jig (bv. probenesied of sulfenpirasoon)
- Medisyne wat die deurgang van voedsel deur die maag vertraag (bv. atropien, hiosien)
- Medisyne vir toegeneemde/verhoogde druk in die oog (gloukoom), soos koolsuuranhidrase inhibeerders (bv. asetasolamied)
- Medisyne wat die urisene minder asidies maak (bv. kaliumsitraat mengsel)
- Medisyne vir infeksies, bekend as kinolone
- Orale voorbehoedmiddel of "die pil". Jy sal nodig hê om ekstra voorbehoed voorsorgmaatreëls te gebruik, soos om 'n kondoom te gebruik, aangesien **TURANTO** die voorbehoedpil minder doeltreffend kan maak.
- Tifoïedvaksien, wat gegee word vir die voorkoming van tifoïed.
- **TURANTO** kan inmeng met die resultate van sommige toetse vir glukose in die urisene.

TURANTO met voedsel en drank:
TURANTO moet saam met kos of melk geneem word. Dit sal help om 'n omgekrapte maag te vermy en ook om met die opname van **TURANTO** te help.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vra asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **TURANTO** neem.
TURANTO gebruik word nie tydens swangerskap aanbeveel nie.
Vertel jou dokter of apteker indien jy borsvoed om beplan om te borsvoed. **TURANTO** word nie aanbeveel terwyl jy borsvoed nie.

Bestuur en gebruik van masjiene
TURANTO kan duiseligheid of lomerigheid veroorsaak. Moet nie bestuur of masjinerie gebruik totdat jy weet hoe **TURANTO** jou affekteer nie.

TURANTO bevat laktosemonohidraat:
Pasiënte met die seldsame oorerflike toestande van laktose/fruktose of galaktose intoleransie moet nie **TURANTO** neem nie.
TURANTO bevat laktosemonohidraat wat 'n uitwerking op die beheer van jou bloedsuiker kan hê indien jy diabetes mellitus het.

3. Hoe om TURANTO te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem of gee altyd **TURANTO** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is.
Indien jy onder die indruk is dat die effek van **TURANTO** te sterk of te swak is, praat met jou dokter of apteker.
Die gewone dosis in volwassenes is:
Vir behandeling van infeksies: Of een **TURANTO 50** mg of een **TURANTO 100** mg vier keer per dag en met slaaptyd.

TURANTO moet vir ten minste een week geneem word, en vir ten minste 3 dae nadat die infeksie opgeklaar het.
Vir die voorkoming van verdere infeksies: Of een **TURANTO 50** mg of een **TURANTO 100** mg met slaaptyd.

Die gewone dosis in kinders en babas ouer as een maand oud:
Die dosering sal deur jou kind se dokter bepaal word gebaseer op die gewig van die kind. Volg jou dokter se instruksies presies.
TURANTO moet nie gegee word aan kinders jonger as 1 maand oud nie.

Indien jy meer TURANTO neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Jy kan maagpyn, naarheid en braking ervaar.

Indien jy vergeet om TURANTO te neem
Dit is belangrik om jou **TURANTO** gereeld op dieselfde tyd van elke dag te neem. Indien jy vergeet om 'n dosering te neem, neem dit so gou as wat jy onthou, tensy dit tyd is vir jou volgende dosering. In daardie geval, gaan net aan met die volgende dosering soos normaal. Moet nie 'n dubbele dosering neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om TURANTO te gebruik
Moet nie ophou om **TURANTO** te neem nie, tensy jou dokter jou beveel om dit te doen. **TURANTO** moet vir ten minste een week geneem word, en vir ten minste 3 dae nadat die infeksie opgeklaar het.
Indien jy enige verdere vrae het oor die gebruik van hierdie produk, vra jou dokter of apteker.

4. Moontlike newe-effekte

TURANTO kan newe-effekte hê.
Nie al die newe-effekte wat vir **TURANTO** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of jy enige ongewenste effekte ondervind terwyl jy **TURANTO** gebruik, kontak asseblief jou dokter, apteker of gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om TURANTO te gebruik en vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Sketslike tekens van allergieë – insluitend veluitslag, jeuk of galbulte, swelling van die gesig, lippe of tong, kortasemheid of probleme met asemhaling

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op **TURANTO** gehad het. Jy mag dringende mediese aandag of hospitalisasie nodig hê.

Indien jy enige van die volgende opmerk, vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Lewerskade – naarheid; maagpyn; lae koors; verlies aan eetlus; donker urisene, kleikleurige stoelgange; geelsug (vergeling van die vel of oë).
- Koors met erge blase, afskilfering en rooi veluitslag of enige ernstige velreaksie.
- Ontsteking van die pankreas (erge pyn in die buik).
- Superinfeksie deur bakterieë wat nie sensitief vir **TURANTO** is nie.
- Bloedselle kan in sommige pasiënte aangetas word. Dit kan lei tot kneusing, vertraagde stolling van die bloed, seer keel, koors, bloedarmoede en 'n vatbaarheid vir verkoue of 'n aanhoudende verkoue.
- Longreaksie met koors, kouekoors, hoes, borskaspyn en kortasemheid.
- Verhoogde druk in die skedel (veroorsaak erge hoofpyne).
- Ontsteking en swelling van die speekselkliere.

Hierdie is alles baie ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende ernstige effekte opmerk:
- Voel depressief, gevoel van ongewone gelukkigheid, verwarring, geestesongesteldheid.
- Tinteling of gevoelloosheid van die hande of voete (spelde en naalde).
- Ontsteking van die optiese senuwee wat tydelike verlies van sig veroorsaak.
- Hoofpyn, duiseligheid, vinnige, onbeheerbare bewegings van die oë, lomerigheid, draai sensasie, swakheid.

Vertel vir jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte
- Eetlus verloor, naarheid, braking.
- Bruin verkleuring van urisene.

Minder gereelde newe-effekte
- Maagpyn, diarree.
- Uitslag, jeuk, galbulte, korttermyn haarverlies.
- Spierpyn en gewrigspyn.
- Koors.

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRAse publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **TURANTO.**

5. Hoe om TURANTO te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Stoor in die oorspronklike verpakking/houer.
Hou die HDPE houer dig gesluit.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat TURANTO bevat
Die aktiewe bestanddeel is 50 mg en 100 mg nitrofurantoïen makrokristalle.
Die ander bestanddele sluit in: laktosemonohidraat (Supertab 11SD), vooraf gelatiniseerde stysel (Stysel 1 500), talk en harde gelatienkapsules (vir 50 mg en 100 mg bevat FD & C Geel 6 (C.I. No. 15985), D&C Geel 10 (C.I. No. 47005), titaniumdioksied (C.I. No. 77891), gelatien, natriumlaurielsulfaat en swart eetbare drukink).

Hoe TURANTO lyk en inhoud van die pak
TURANTO 50:
Grootte 3 harde gelatien kapsule gevul met gelerige poeier, met geel ondeursigtige dopple en wit ondeursigtige liggaam, gedruk met "C 69" op dopple, "50 mg" en twee lyne in swart ink wat die kapsules op liggaam omring.
TURANTO 100:
Grootte 2 harde gelatien kapsule gevul met gelerige poeier, met geel ondeursigtige dopple en liggaam, gedruk met "C 70" op dopple, "100 mg" en drie lyne in swart ink wat die kapsules op liggaam omring.

2) HDPE houer verpakking
TURANTO 50:
75 ml ronde, wit HDPE houer met skroef nek met wit polipropileen sluiting met pulp en hittesëelvoering, bevat 100 kapsules verpak in 'n buitenste voorafgedrukte karton.
TURANTO 100:
100 ml ronde, wit HDPE houer met skroef nek met wit polipropileen sluiting met pulp en hittesëelvoering, bevat 100 kapsules verpak in 'n buitenste voorafgedrukte karton.

Houer van die Registrasiesertifikaat en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos), Cussonia Weg 1,
Bassonia Rock, Uitbr. 12, Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
22 Februarie 2022

Registrasienommer
TURANTO 50: 52/18.5/0758.754
TURANTO 100: 52/18.5/0759.755

Toegang tot die ooreenstemmende Professionele inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 11 69.

350 mm

335 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product : TURANTO 50/100 (Nitrofurantoin macrocrystals 50/100 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Package Insert & Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 350 (L) x 335 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM03934601
11. Artwork has been made: Actual Size	12. Pharma code No.: 31821 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: NA
15. Revision No: 00	16. AW File name: E:\ARTWORK\Regulatory\South Africa\Turanto\SA Private Market\NITROFURANTOIN CAPSULES LEAFLET - PM03934601.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD/MEDICAL	QC	PRODN	QA
29-08-22	Vanita Rajool	29/08/2022	31/08/22	31/08/22	02/09/22

QA 01/09/22

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	PM03934601		

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