UNITRO
P1537692

UNITRO
P1537692

Professional Information for Medicines for Human Use

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

UNITRO 50, Hard gelatin capsules.

UNITRO 100, Hard gelatin capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

UNITRO 50:

Each capsule contains 50 mg nitrofurantoin. Sugar free.

UNITRO 100:

Each capsule contains 100 mg nitrofurantoin. Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

UNITRO 50:

Hard gelatin capsules of size '4' with white opaque body imprinted with '50' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

UNITRO 100:

Hard gelatin capsules of size '2' with yellow opaque body imprinted with '100' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

UNITRO 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

Adults

Acute urinary tract infections: 50 mg to 100 mg four times a day, with meals and at bedtime.

To prevent recurrences: 50 mg to 100 mg per day.

UNITRO may be given with food or milk to further minimise gastric upset. 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.

SPECIAL POPULATION

Paediatric patients:

Acute urinary tract infections: Should be calculated on the basis of 5 to 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

UNITRO is administered orally.

4.3. Contraindications

UNITRO is contraindicated:

- In patients with known sensitivity to nitrofurantoin microcrystals and any of the excipients of **UNITRO**. listed in section 6.1
- In patients with a deficiency of glucose 6-phosphate dehydrogenase or nursing mothers of infants with this deficiency.
- Anuria, oliguria and renal impairment are contraindications to therapy with **UNITRO.** Treatment of this type of patient carries an increased risk of toxicity because of impaired excretion of nitrofurantoin.
- 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).
- Acute porphyria.
- Patients suffering from renal impairment with an eGFR of less than 45 mL/min.

4.4. Special warnings and precautions for use

Prolonged use of **UNITRO** is not recommended. 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.

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 **UNITRO**. 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 **UNITRO**.

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

During **UNITRO** treatments, there are lung and liver complications that can be life-threatening (see section 4.8). The treatment should be stopped immediately and the necessary measures should be taken.

Acute, subacute and chronic pulmonary reactions have been observed in patients treated with **UNITRO**. If these reactions occur, **UNITRO** must be discontinued immediately.

Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously, and can often occur in elderly patients. Close monitoring of the pulmonary conditions of patients receiving long-term therapy is indicated (especially in the elderly).

Patients with hepatic impairment

Patients should be closely monitored for signs of hepatitis (especially in the long term use). Existing conditions can mask pulmonary and hepatic side effects, there is caution provided when **UNITRO** is used in patients with pulmonary diseases, disturbed hepatic function, neurological disorders and allergic diathesis.

Precautions

Patients should 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.

Hepatotoxicity

Hepatic reactions, including hepatitis, autoimmune hepatitis, cholestatic jaundice, chronic active hepatitis and hepatic necrosis, can occur. Fatalities have been reported. The onset of chronic active hepatitis may be insidious, and patients should be monitored periodically for changes in biochemical tests that would indicate liver injury. If hepatitis occurs, **UNITRO** should be withdrawn immediately and appropriate measures should be taken.

Urine can be coloured yellow or brown after taking **UNITRO.** Patients who taking **UNITRO** can test false positive for urine glucose (if tested for urine reducing substances).

UNITRO is not effective for the treatment of parenchymal infections of unilateral non-functioning kigney. A surgical cause for infection should be excluded in recurrent or severe cases.

4.5 Interaction with other medicines and other forms of interaction

- Probenecid or sulphinpyrazone may reduce the excretion of **UNITRO** and should not be given concomitantly.
- Magnesium trisilicate may reduce the absorption of **UNITRO**.
- **UNITRO** may cause false positive reactions in urine tests for glucose using copper reduction methods.
- Antagonism between nitrofurantoin and nalidixic acid, and nitrofurantoin and oxolinic acid has been demonstrated *in vitro.*
- **UNITRO** should not be given concomitantly with quinolines.

The effect of other medicines on nitrofurantoin:

- Food or medicines that delays gastric emptying increase the bioavailability of **UNITRO**.
- Carbonic anhydrase inhibitors and alkalising medicines can reduce the antibacterial activity of **UNITRO**.
- Magnesium trisilicate, co-administered with **UNITRO**, reduces the absorption of **UNITRO**.
- There may be an antagonism between quinolones and **UNITRO**: simultaneous administration is not recommended.
- Probenecid and sulfinpyrazone can reduce the renal clearance of **UNITRO**.

The effect of nitrofurantoin on other medicines/laboratoy tests:

- Typhoid fever vaccine (oral): antibacterial medicines make the oral typhoid fever vaccine ineffective.
- Nitrofurantoin can affect certain laboratory tests. False positive results or incorrect high reading can occur with urinary glucose tests based on the reduction of copper sulphate, such as Benedict's reagent and Clinitest (Ames). However, there is no interference with the Clinistix test.

4.6 Fertility, pregnancy and lactation

Pregnancy

Data in pregnant women indicate no teratogenicity or fetal/neonatal toxicity. Animal studies do not show reproductive toxicity as clinically relevant doses. Therefore, **UNITRO** can be used during pregnancy, except in 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).

Breastfeeding

UNITRO is excreted in breast milk. **UNITRO** can be used during breastfeeding, but it is contraindicated in those patients with a deficiency of glucose 6-phosphate dehydrogenase or nursing mothers of infants with this deficiency.

Fertility

In men, at supra-therapeutic doses, a temporary stoppage in spermatogenesis and reduced sperm counts. Clinical doses are not associated with male infertility. No reduced fertility was observed in animal studies. In rats, at high doses observed a temporary stoppage in spermatogenesis.

4.7. Effects on ability to drive and use machines

UNITRO can cause dizziness and drowsiness. Patient should be advised not to drive or operate machines until the symptoms disappear.

4.8. Undesirable effects

A tabulated list of undesirable effects is outlined below:

a. **Tabulated list of adverse reactions**

Reported adverse reactions for nitrofurantoin are listed below according to organ systems.

System organ class and undesirable effects	Frequency
Infections and infestations	
Superinfections by fungi or resistant organisms such as Pseudomonas. However, these are limited to the genitourinary tract.	Frequency unknown
Blood and Lymphatic system disorders	
Aplastic anaemia	Frequent
Agranulocytosis, leucopenia, granulocytopenia, haemolytic anaemia, thrombocytopenia, glucoze-6-phosphate dehydrogenase deficiency anaemia, megaloblastic anaemia and eosinophilia.	Frequency unknown
Immune system disorders	
Allergic skin reactions, angioneurotic oedema and anaphylaxis.	Frequency unknown
Psychiatric disorders	
Depression, euphoria, confusion, psychotic reactions.	Frequency unknown
Nervous system disorders	
Peripheral neuropathy including optic neuritis (sensory as well as motor involvement), nystagmus, vertigo, dizziness, headache and drowsiness. Benign intracranial hypertension.	Frequency unknown
Cardiac disorders	
Collapse and cyanosis.	Frequent
Respiratory, thoracic and mediastinal disorders	
Acute pulmonary reactions, subacute pulmonary reactions*, chronic pulmonary reactions, cough, dyspnoea, pulmonary fibrosis; possible association with lupus-erythematous-like syndrome.	Frequency unknown
Gastrointestinal disorders	
Sialadenitis, pancreatitis, nausea, anorexia, emesis, abdominal pain, diarrhoea.	Frequency unknown
Hepatobiliary disorders	
Cholestatic jaundice, chronic active hepatitis (fatalities have been reported), hepatic necrosis, autoimmune hepatitis.	Frequency unknown
Skin and subcutaneous tissue disorders	
Transient alopecia,exfoliative dermatitis and erythema multiforme (including Stevens-Johnson Syndrome), maculopapular, erythematous or eczematous eruptions, urticaria, rash, and pruritus. Lupus-like syndrome associated with pulmonary reaction. Medicine Rash With Eosinophilia And Systemic Symptoms (DRESS syndrome), cutaneous vasculitis.	Frequency unknown

DETACH BEFORE DISPENSING

- swelling of the eyelids, face or lips,
- rash or itching (especially affecting your whole body).

If you experience any of the side effects detailed below stop taking **UNITRO** and consult your doctor.

- Your lungs may react to **UNITRO**. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath, jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes).
- The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles.
- In addition headache, extreme changes of mood or mental state, confusion, weakness, blurred vision may occur. These effects may be severe and in some instances permanent.
- Raised pressure in the skull (causing severe headaches).
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely. Blue or purple colouration of the skin due to low oxygen levels. A condition known as cyanosis.
- Symptoms of fever, flu, abdominal pain, diarrhoea, blood in your stool and weakness. These could be signs of a condition known as autoimmune hepatitis.

Please note that while taking **UNITRO** your urine may become dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

Other less frequent side effects include:

- Aplastic anaemia (blood stops producing enough blood cells).
- Cyanosis (a bluish discolouration of the skin).
- Loss of consciousness (collapse).

Frequency unknown:

- Superinfections (Fungi or resistant organisms caused infections).
- Granulocytopenia (loss of neutrophils in circulating blood).
- Leukopenia (lowered white blood cell count).
- Megaloblastic anaemia (many large immature and dysfunctional red blood cells).
- Thrombocytopenia (deficiency of platelets in the blood).
- Aplastic anaemia (deficiency of all types of blood cells in blood).
- Haemolytic anaemia (abnormal breakdown of red blood cells).
- A variety of skin rashes or reactions have occurred in some patients.
- Flaking skin.
- A red rash or fever accompanied by rapid heart rate.
- Severe rash with blistering.
- Feeling sick (nausea).
- Depression.
- Confusion.
- Psychiatric reactions.
- Headache.
- Loose stools.
- Loss of appetite.
- Stomach ache.
- Vomiting.
- Dizziness.
- Drowsiness.
- Blood cells have been affected in some patients. This may result in bruising, delayed clotting of the blood.
- Sore throat.
- Fever.
- Anaemia.
- A susceptibility to colds or persistent cold.
- Other reactions may include inflammation of salivary glands (causing facial pains).
- Inflammation of the pancreas (causing severe abdominal pain).
- Joint pains.
- Short-term hair loss.
- Urinary infection by germs which are not sensitive to **UNITRO**.
- Inflammation of small blood vessel walls.
- Skin lesions.
- Liver inflammation due to turn of immune system against liver cells.
- Inflammation of kidney tissue surrounding tubules.
- Renal impairment.
- Stevens - Johnson syndrome (a serious systemic (body-wide) allergic reaction with a characteristic rash involving the skin and mucous membranes, including the inside of the mouth, conjunctiva, and genital areas). The symptoms of this condition are fever, body aches, red rash, cough, blisters and sores on the skin and on mucus membranes of the mouth, throat, eyes, genitals, and anus, peeling skin, drooling (because closing the mouth is painful), eyes sealed shut (due to blisters and swelling).

Reporting of side effects

If you get side effects, talk to your doctor, 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 Reactions Reporting Form' found under SAHPRAs publications: **https://www.sahpra.org.za/Publications/Index/8.**
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store UNITRO

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 UNITRO contains

The active substance is nitrofurantoin.
The other ingredients of **UNITRO** are:
cellulose microcrystalline (Grade 101)
croscarmellose sodium (Ac-Di-Sol)
and magnesium stearate (Ligamed MF-2-V)
The capsules shell contains: iron oxide yellow (E172), titanium dioxide (E171), gelatin, purified water.
Composition of the ink: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide.

What UNITRO looks like and contents of the pack

UNITRO 50: Hard gelatin capsules of size '4' with white opaque body imprinted with '50' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

UNITRO 100: Hard gelatin capsules of size '2' with yellow opaque body imprinted with '100' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

UNITRO 50 and 100:

1) Blister pack:

Clear thermo form film - aluminium foil:
Capsules are packed in thermo form clear 250 micron PVC film as the forming film and 25 micron aluminium foil with 7 g/m^2 heat seal lacquer as the lidding material.
Pack size: 50's – Each carton contains 5 blisters of 10 capsules each.

White opaque thermo form film - aluminium foil:
Capsules are packed in white thermo form rigid 250 micron PVC film as the forming film and 25 micron aluminium foil with 7 g/m^2 heat seal lacquer as the lidding material.
Pack size: 50's – Each carton contains 5 blisters of 10 capsules each.

2) HDPE Container Pack:

UNITRO 50:
Capsules are packed in white opaque round 40 mL HDPE container with 33 mm neck finish closed with white opaque polypropylene 33 mm – 400 continuous closure with wad having TEKNIPLEX HS 123 induction sealing liner.
Pack size: 50's – One HDPE container contains 50 capsules.

UNITRO 100:
Capsules are packed in white opaque round 60 ml HDPE container with 33 mm neck finish closed with white opaque polypropylene 33 mm – 400 continuous closure with wad having TEKNIPLEX HS 123 induction sealing liner.
Pack size: 50's – One HDPE container contains 50 capsules.

Holder of Certificate of Registration

AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park,
Building 1 53 Phillip Engelbrecht Avenue
Meyerstal, Ext. 12, 1448
Johannesburg
South Africa

Registration Number

UNITRO 50	55/18.5/0207
UNITRO 100	55/18.5/0208

This leaflet was last revised in

01 February 2022

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

UNITRO 50 (hard gelatin capsule)
UNITRO 100 (hard gelatin capsule)
Nitrofurantoin
Sugar free

Read all of this leaflet carefully before you start taking UNITRO.

- Keep this leaflet. You may need to read it again.
- **UNITRO** 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.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet?

1. What **UNITRO** is and what it is used for
2. What you need to know before you use **UNITRO**
3. How to use **UNITRO**
4. Possible side effects
5. How to store **UNITRO**
6. Contents of the pack and other information

1. What UNITRO is and What it is used for

UNITRO contain a medicine called nitrofurantoin. This belongs to a group of antibacterial medicine.
UNITRO is used to treat and prevent the recurrence of specific uncomplicated lower urinary tract infections like pyelonephritis, pyelitis (inflammation of the kidney and/ pelvis or its part by the result of bacterial infection) and cystitis (inflammation of the urinary bladder).

2. What you need to know before you take UNITRO

Do not take UNITRO:

- If you are allergic or sensitive to **UNITRO** or any of the ingredients of **UNITRO**.
- If your kidney completely failure to produce urine or produce a small amount of urine.
- If you are pregnant.
- Do not administer if your baby is below one year.
- If you have deficiency of glucose 6-phosphate dehydrogenase or nursing a baby with this deficiency. (It is a hereditary condition in which red blood cells break down (haemolysis) when the body is exposed to certain foods, drugs, infections or stress. It occurs when a person is missing or has low levels of the enzyme glucose-6-phosphate dehydrogenase).

Take special care with UNITRO:

- A course of therapy should not exceed 14 days.
- If your doctor suggests taking repeated doses, it should be separated by rest periods.
- If you are an older age patient.
- If you have asthma (a respiratory condition marked by attacks of spasm in the bronchi of the lungs, causing difficulty in breathing), because pulmonary function monitoring is required for prolonged therapy.
- If you observe any abnormal paleness or lack of colour of the skin, yellowish skin, eyes, and mouth (jaundice), dark-coloured urine, fever, weakness, dizziness or confusion, tell your doctor. These are symptom of haemolysis (destruction of red blood cells). **UNITRO** should be discontinued.
- If you have pulmonary (lung) disease or experience any lung related condition, treatment should be discontinued and your doctor should be consulted immediately.
- If you have liver impairment.
- If you are neurological disorder (disorder pertaining to the nervous system) patient.

Tell your doctor if you have any of the following conditions:

- If you are suffering from anaemia (deficiency of red blood cells).
- If you are suffering from diabetes mellitus (elevated blood glucose levels in the blood).
- If you are electrolyte imbalance patient.
- If you are vitamin B deficient patient.

Taking other medicines with UNITRO

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

Other medicines and UNITRO

UNITRO may have an effect on other medicines or other medicines may have an effect on **UNITRO**.

- Combination of **UNITRO** and quinolone antibiotic produces opposite mechanisms, so this co-administration is not recommended (levofloxacin, ciprofloxacin, moxifloxacin), also fluoroquinolones increase the nalidixic acid.
- The antibacterial activity of **UNITRO** is decreased by carbonic anhydrase inhibitors (acetazolamide, methazolamide etc).
- Probenecid or sulfinpyrazone (anti gout medicines) reduces the **UNITRO** excretion.
- Antacid medicine i.e., magnesium trisilicate reduces the absorption of **UNITRO**.
- Antibacterial medicines, like **UNITRO**, make the oral typhoid fever vaccine ineffective.
- False positive results or incorrect high reading can occur with urinary glucose tests based on the reduction of copper sulphate, such as Benedict's reagent and Clinitest (Ames).

Pregnancy and breastfeeding:

- As far as it is known **UNITRO** may be used in pregnancy.
- However, it should not be used during labour or delivery because there is a possibility that use at this stage may affect the baby. If you want to breastfeed, please consult your doctor first.

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

Driving and using machinery:

UNITRO can cause dizziness and drowsiness. In that case, the patient is not allowed to drive or operate machines until the symptoms disappear.

3. How to take UNITRO

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

Always take **UNITRO** exactly as your doctor 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 **UNITRO** will last. If you have the impression that the effect of **UNITRO** is too strong or too weak, talk to your doctor or pharmacist.

Taking UNITRO with food and drink:

UNITRO can be taken with food or milk.

Adult dose:

For acute urinary tract infection: 50 to 100 mg four times a day.

To prevent recurrences: 50 to 100 mg per day.

Children dose:

The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.

For acute urinary tract infection: Should be calculated on the basis of 5 to 7 mg/kg of body mass per 24 hours to be given in divided doses four times a day.
To prevent recurrences 1 mg/kg/day for long-term therapy.

Your doctor will tell you how long your treatment with **UNITRO** will last. Do not stop treatment early because this may increase the chance of reoccurrence of your condition. If you have the impression that the effect of **UNITRO** is too strong or too weak, tell your doctor or pharmacist.

If you take more UNITRO than you should:

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

Symptoms of Overdose
Symptoms and signs of overdose include gastric irritation, nausea and vomiting.
In the event of overdose, treatment is symptomatic and supportive.

If you forget to take UNITRO:

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBILE SIDE EFFECTS

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

UNITRO can have side effects:
Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of them are mild and disappear when you stop taking **UNITRO**.
All medicines can cause allergic reactions although serious allergic reactions are rare. If you notice any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) **STOP TAKING UNITRO** and go to a doctor immediately if you experience the following:
If you notice any

- sudden wheeziness,
- difficulty in breathing,

Renal and urinary disorders	
Yellow or brown discoloration of urine, interstitial nephritis.	Frequency unknown
General disorders and administration site conditions	
Asthenia, fever, chills, fever and arthralgia.	Frequency unknown
Investigations	
False positive urinary glucose test .	Frequency unknown

Acute pulmonary reactions usually occur within the first week of treatment and are reversible with cessation of therapy. Acute pulmonary reactions are commonly manifested by fever, chills, cough, chest pain, dyspnoea, pulmonary infiltration with consolidation or pleural effusion on chest x-ray, and eosinophilia. In subacute pulmonary reactions, fever and eosinophilia occur less often than in the acute form. Chronic pulmonary reactions occur rarely in patients who have received continuous therapy for six months or longer and are more common in elderly patients. Changes in ECG have occurred, associated with pulmonary reactions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via The '6.04 Adverse Drug Reactions Reporting Form'. Found under SAHPRA's publications: **https://www/sahpra.org.za/Publications/Index/8.**

4.9 Overdose

Treatment is symptomatic and supportive (see section 4.7).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 18.5 Urinary tract antiseptics

Pharmacotherapeutic group: Antimicrobials for systemic use, nitrofurantoin derivative.
ATC code: J01XE01.

Mechanism of action
Nitrofurantoin is an antibacterial medicine for specific urinary tract infections. Nitrofurantoin is a broad spectrum antibacterial medicine, active against the majority of urinary pathogens. The wide range of organisms sensitive to the bactericidal activity include:
Escherichia coli
Enterococcus faecalis
Klebsiella Species
Enterobacter Species
Staphylococcus Species e.g. *S. Aureus, S. Saprophyticus, S. Epidermidis Citrobacter Species*
Clinically most common urinary pathogens are sensitive to nitrofurantoin. Most strains of Proteus and Serratia are resistant. All Pseudomonas strains are resistant.

5.2. Pharmacokinetic properties

The nitrofurantoin macrocrystals are specially formulated. The controlled crystal size is designed to control the speed of absorption and thus reduce the incidence of nausea. Clinical and animal studies indicate that nitrofurantoin therapy decreases the likelihood of nausea in patients who might experience these symptoms on nitrofurantoin therapy. This special formulation of nitrofurantoin had not caused any decrease in antibacterial efficacy.

Absorption

Orally administered nitrofurantoin is rapidly and completely absorbed from the gastrointestinal tract and is rapidly excreted in the urine. Blood concentrations at therapeutic dosages are usually low.

Elimination

Anti-bacterial concentration are not achieved in plasma following ingestion of recommended doses because of rapid elimination, Maximum urinary excretion usually occurs 2 - 4 hours after administration of nitrofurantoin. Urinary medicine dose recoveries of about 40 - 45 % are obtained. It has an elimination half-life of about 30 minutes.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Capsules content:

Nitrofurantoin
Cellulose microcrystalline (Grade 101)
Croscarmellose sodium (Ac-Di-Sol)
Magnesium stearate (Ligamed MF-2-V)

Capsules shell:

Iron oxide yellow (E172)
Titanium dioxide (E171)
Gelatin
Purified water

Composition of the ink:

Shellac
Dehydrated alcohol
Isopropyl alcohol
Butyl alcohol
Propylene glycol
Strong ammonia solution
Black Iron Oxide
Potassium hydroxide
Purified water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

The capsules should be stored in light-resistant and preferably, moisture-proof containers.
Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

1) Blister Pack

a) Clear 250 micron PVC - Aluminium foil blister pack:
Blister pack comprises of clear thermoformable 250 micron PVC film as the forming film and printed 25 micron aluminium foil as the lidding material.
Pack Sizes: 50's: Printed cardboard carton containing 5 blisters of 10 capsules each.

b) White Opaque 250 micron PVC film - Aluminium foil blister pack:
Blister pack comprises of white opaque thermoformable rigid 250 micron PVC film as the forming film and printed 25 micron aluminium foil as the lidding material.
Pack Sizes: 50's: Printed cardboard carton containing 5 blisters of 10 capsules each.

2) HDPE Container Pack:

UNITRO 50

White opaque round 40 mL HDPE container with 33 mm neck finish closed with white opaque 33 mm – 400 polypropylene continuous thread closure with wad having Tekniplex HS 123 induction sealing liner.

Pack size: 50's. Each HDPE container contains 50 capsules.

UNITRO 100

White opaque round 60 mL HDPE container with 33 mm neck finish closed with white opaque 33 mm – 400 polypropylene continuous thread closure with wad having Tekniplex HS 123 induction sealing liner.

Pack size: 50's. Each HDPE container contains 50 capsules.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SOUTH AFRICA (PTY) LTD
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

8. REGISTRATION NUMBER

UNITRO 50 55/18.5/0207
UNITRO 100 55/18.5/0208

9. DATE OF FIRST AUTHORISATION

01 February 2022

P1537692

DETACH BEFORE DISPENSING

SKEDULERINGSTATUS

S4

PASIËNTINLIGTINGSPAMFLET

UNITRO 50 (harde gelatienkapsule)
UNITRO 100 (harde gelatienkapsule)
Nitrofurantoïen
Suikervry

Lees die hele pamflet sorgvuldig deur voordat u begin om UNITRO te gebruik.
- Hou hierdie pamflet. U moet dit dalk weer lees.
- **UNITRO** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan skadelik virhulle wees, selfs al het hulle dieselfde simptome as u
- Indien u verdere vrae het, vra asseblief u dokter of u apteker

Wat is in hierdie pamflet:

1. Wat **UNITRO** is en waarvoor dit gebruik word
2. Wat u moet weet voor u **UNITRO** gebruik
3. Hoe om **UNITRO** te gebruik
4. Moontlike newe-effekte
5. Hoe om **UNITRO** te berg
6. Inhoud van die verpakking en ander inligting

1. Wat UNITRO is en Waarvoor dit gebruik word

UNITRO bevat 'n medisyne genaamd nitrofurantoïen. Dit behoort aan 'n groep antibakteriese medisyne. **UNITRO** word gebruik om die herhaling van spesifieke ongekompliseerde lae urienweginfeksies (ontsteking van die nier en/bekken of die deel daarvan as gevolg van bakteriële infeksie) en sistitis (ontsteking van die urienblaas) te behandel en te voorkom.

2. Wat u moet weet voor u UNITRO gebruik

Moenie URITRO neem nie:
- Indien u allergies of sensitief is vir **UNITRO** of enige van die bestanddele van **UNITRO.**
- Indien u nier heeltemal misluk om urine te produseer of om 'n klein hoeveelheid urine te produseer.
- Indien u swanger is.
- Moenie toedien indien u baba jonger as een jaar is nie.
- Indien u 'n tekort aan glukose-6-fosfaatdehidrogenase het of 'n baba met hierdie tekort borsvoed (Dit is 'n oorerflike toestand waarin rooibloedselle afbreek (hemolise) wanneer die liggaam aan sekere voedsel, dwelms, infeksies of stres blootgestel word. Dit kom voor wanneer 'n persoon lae vlakke van die ensiem glukose-6-fosfaatdehidrogenase het of vermis).

Neem spesiale sorg met UNITRO:
- 'n Terapie kursus moet nie 14 dae oorskry nie.
- Indien u dokter voorstel om herhaalde dosisse te neem, moet dit met rusperiodes geskied.
- Indien u 'n ouer pasiënt is.
- Indien u 'n asma pasiënt is ('n respiratoriese toestand wat gekenmerk word deur aanvalle van die longe, wat moeilike asemhaling veroorsaak), omdat monitering van longfunksie nodig is vir langdurige terapie.
- Indien u enige abnormale bleekheid of gebrek aan kleur van die vel, gelerige vel, oë, en mond (geelsig), donkerkleurige urine, koors, swakheid, duiseligheid of verwarring waarneem, vertel u dokter. Dit is simptome van hemolise (vernietiging van rooibloedselle), die **UNITRO** moet gestaak word.
- Indien u 'n pulmonêre (long) siekte pasiënt is of enige longverwante toestand ervaar wat erger word, en moet u dokter onmiddellik geraadpleeg word.
- Indien u 'n pasiënt met lewergestremdheid is.
- Indien u 'n pasiënt met neurologiese versteuring is (afwyking wat verband hou met die senuweestelsel).

Vertel u dokter indien u enige van die volgende toestande het:
- Indien u aan bloedarmoede ly (tekort aan rooibloedselle) .
- Indien u aan diabetes mellitis ly (verhoogde bloedglukosevlakke in die bloed).
- Indien u 'n pasiënt met elektroliet wanbalans is.
- Indien u 'n pasiënt met vitamien B-tekort is.

Die neem van ander medisyne saam met UNITRO:

Vertel altyd u gesondheidsorgkundige indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).

Ander medisyne en UNITRO:

UNITRO kan 'n effek hê op ander medisyne of ander medisyne kan 'n effek hê op **UNITRO.**
- Kombinasie van **UNITRO** en kinoloon antibiotika produseer teenoorgestelde meganismes, so hierdie gelyktydige toediening word nie aanbeveel nie (levofloksasien, sprofloksasien, moflloksasien), ook fluorokinolone verhoog die natiuklsensiteur.
- Die antibakteriële aktiwiteit van **UNITRO** word verminder deur koolsuuranhidrase-inhibeerders (aetasoolamied, metasoolamied ens.).
- Probenesied of sulfinpirasoon (medisyne teen jig) verminder die **UNITRO**-uitskeiding.
- Teensuurmedisyne d.w.s., magnesiumtrisilikaat verminder die absorpsie van **UNITRO.**
- Antibakteriese medisyne, soos nitrofurantoïen, maak die mondelinge tifuskoors-entstof oneffektief.
- Vals positiewe resultate of verkeerde hoë lesing kan voorkom met urinê glukosetoetse gebaseer op die vermindering van kopersulfaat, soos Benedict se reagens en Clinitest (Ames).

Swangerskap en borsvoeding:
- Sover dit bekend is, kan **UNITRO** tydens swangerskap gebruik word.
- Dit moet egter nie tydens kraam of bevalling gebruik word nie, want daar is 'n moontlikheid dat gebruik in hierdie stadium die baba kan beïnvloed. Indien u wil borsvoed, raadpleeg asseblief eers u dokter.

Bestuur en gebruik van masjinerie:

UNITRO kan duiseligheid en lomerigheid veroorsaak. In daardie geval, mag die pasiënt nie toegelaat word om te bestuur of masjiene te gebruik totdat die simptome verdwyn het nie.

3. Hoe om UNITRO te gebruik

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem **UNITRO** altyd presies soos u dokter u voorgeskryf het. Raadpleeg u dokter of apteker indien u onseker is. U dokter sal u vertel hoe lank u behandeling met **UNITRO** sal duur. Indien u die indruk het dat die effek van **UNITRO** te sterk of te swak is, raadpleeg u dokter of apteker.

Die neem van UNITRO met voedsel en drank:

UNITRO kan met voedsel of melk geneem word.

Volwasse dosis:

Vir akute urieneweginfeksie: 50 tot 100 mg vier keer per dag.

Om herhalings te voorkom: 50 tot 100 mg per dag.

Kinder dosis:

Die dosis hang af van die gewig van die kind en sal deur u dokter voorsien word. Volg u dokter se instruksies presies.

Vir akute urieneweginfeksie: Moet bereken word op die basis van 5 tot 7 mg/kg liggaamsmassa per 24 uur wat in verdeelde dosisse vier keer per dag gegee moet word.

Om herhalings te voorkom: 1 mg/kg/dag vir langtermyn-terapie.

U dokter sal u vertel hoe lank u behandeling met **UNITRO** sal duur. Moenie die behandeling vroegtydig stop nie, want u toestand kan weer voorkom. Indien u die indruk het dat die effek van **UNITRO** te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer UNITRO neem as wat u moet:

In die geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of giftbeheersentrum.

Simptome van oordosis:
Simptome en tekens van oordosis sluit maagirritasie, naarheid en braking in.
In oordosering, is behandeling simptomaties en ondersteunend.

Indien u vergeet om UNITRO te neem:
Indien u vergeet om 'n dosis te neem, neem dit so gou as wat u onthou, tensy dit amper tyd vir u volgende dosis. Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

Nie alle newe-effekte aangemeld vir **UNITRO** is in hierdie pamflet ingesluit nie. Indien u enige skielike agteruitgaan of indien u enige ongewensde effekte ervaar terwyl u **UNITRO** neem, raadpleeg asseblief u dokter of gesondheidsorgkundige vir advies.

UNITRO kan newe-effekte hê.
Soos alle medisyne, kan hierdie medisyne newe-effekte veroorsaak, hoewel nie almal dit kry nie. Die meeste van hulle is lig en verdwyn wanneer u ophou om **UNITRO** te neem.
Alle medisyne kan allergiese reaksies veroorsaak, hoewel ernstige allergiese reaksies skaars is. Indien u allergiese reaksies soos hyging, asemhalingsprobleme, swelling van die ooglede, gesig of lippe, uitslag of jeuk (wat veral u hele liggaam affekteer) opmerk, **HOU OP OM UNITRO** te neem en gaan na u dokter indien u die volgende ervaar:
Indien u enige
- skielike hyging opmerk,
- moeilike asemhaling,
- swelling van die ooglede, gesig of lippe.
- uitslag of jeuk (wat veral u hele liggaam affekteer).