

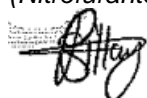
Applicant: Aurogen South Africa (Pty) Ltd
Product Name: [UNITRO]
Dosage form and strength: HARD GELATIN CAPSULE, each capsule contains 50 mg and 100 mg Nitrofurantoin

MODULE 1
 1.3.2
Date: 2020.09.08
Submitted: 2022.02.01

APPROVED PATIENT INFORMATION LEAFLET CLEANED AMENDED COPY

1.3.2 Patient Information Leaflet

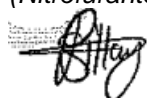
Line No.		Reference
	<p>SCHEDULE STATUS</p> <p>S4</p>	
	<p>PATIENT INFORMATION LEAFLET</p>	
	<p>[UNITRO] 50 mg (hard gelatin capsule)</p> <p>[UNITRO] 100 mg (hard gelatin capsule)</p> <p>Nitrofurantoin</p>	
	<p>Read all of this leaflet carefully before you start taking [UNITRO].</p> <ul style="list-style-type: none"> - Keep this leaflet. You may need to read it again. - If you have further questions, please ask your doctor or your pharmacist. - [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. 	
	<p>What is in this leaflet?</p> <ol style="list-style-type: none"> 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] 	



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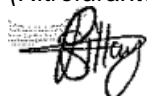
	6. Contents of the pack and other information	
	<p>1. What [UNITRO] is and What it is used for</p> <p>[UNITRO] contain a medicine called nitrofurantoin. This belongs to a group of antibacterial medicine.</p> <p>[UNITRO] is used to treat and prevent the recurrence of specific uncomplicated lower urinary 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).</p>	
	2. What you need to know before you take [UNITRO]	
	<p>Do not take [UNITRO]:</p> <ul style="list-style-type: none"> • 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 a 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) 	



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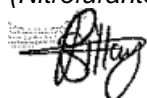
	<p>Take special care with [UNITRO]:</p> <ul style="list-style-type: none"> - A course of therapy should not exceed 14 days. - If your doctor suggest to take repeated doses, it should be separated by rest periods. - If you are older age patient. - If you are asthma patient (a respiratory condition marked 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), the [UNITRO] should be discontinued. - If you are a pulmonary (lung) disease patient or experience any lung related condition, treatment should be discontinued and your doctor should be consulted immediately. - If you are liver impairment patient. - If you are neurological disorder (disorder pertaining to the nervous system) patient. <p>Tell your doctor, if you have any of the following conditions:</p> <ul style="list-style-type: none"> - 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. 	
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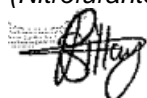
	- If you are vitamin B deficient patient.	
	Taking other medicines with [UNITRO]	
	Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines)	
	Other medicines and [UNITRO]	
	[UNITRO] may have an effect on other medicines or other medicines may have an effect on [UNITRO].	
	<ul style="list-style-type: none"> - 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 sulfipyrazone (anti gout medicines) reduces the [UNITRO] excretion. - Antacid medicine i.e., magnesium trisilicate reduces the absorption of [UNITRO]. - Antibacterial medicines, like Nitrofurantoin, 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). 	
	<ul style="list-style-type: none"> - Pregnancy and breastfeeding: - If you are pregnant or breast-feeding, think you may be 	



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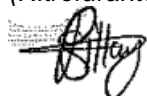
	<p>pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. As far as it is known Nitrofurantoin Capsules may be used in pregnancy.</p> <ul style="list-style-type: none"> - However, it should not be used during labour or delivery because there is a possibility that use at this stage may affect the baby. If you want to breast feed, please consult your doctor first. 	
	<p>If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking [UNITRO].</p>	
	<p>Driving and using machinery:</p> <p>Nitrofurantoin can cause dizziness and drowsiness. In that case, the patient is not allowed to drive or operate machines until the symptoms disappear.</p>	
	<p>Important information about some of the ingredients of [UNITRO]</p> <p>Tell your doctor if you are allergic to any one of the [PRODUCT NAME} ingredients.</p>	
	<p>3. How to take [UNITRO]</p>	



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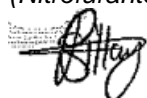
	<p>Do not share medicines prescribed for you with any other person.</p> <div style="border: 1px solid black; padding: 10px;"> <p>Always take [UNITRO] exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment 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.</p> </div>	
	<p>Taking [UNITRO] with food and drink: [UNITRO] can be taken with food or milk.</p>	
	<p><u>Adult dose:</u> <i>For acute urinary tract infection:</i> 50 to 100 mg four times a day. <i>For prevent recurrences:</i> 50 to 100 mg per day. <u>Children dose:</u> 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. <i>For prevent recurrences:</i> 1 mg/kg/day for long-term therapy.</p>	
	<div style="border: 1px solid black; padding: 10px;"> <p>Your doctor will tell you how long your treatment with [UNITRO] will last. Do not stop treatment early because this may 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.</p> </div>	



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	<p>If you take more [UNITRO] than you should:</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control Centre.</p> </div> <p><u>Symptoms of Overdose</u></p> <p>Symptoms and signs of overdose include gastric irritation, nausea and vomiting.</p> <p>In over dose, treatment is symptomatic and supportive.</p>	
	<p>If you forget to take [UNITRO]:</p> <p>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.</p>	
	<p>4. POSSIBLE SIDE EFFECTS</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>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 this medicine, please consult your doctor, pharmacist or other health care professional for advice.</p> </div>	
	<p>[UNITRO] can have side effects:</p> <p>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 Nitrofurantoin Capsules.</p> <p>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</p>	



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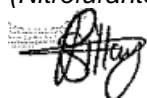
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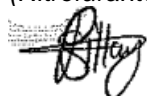
	<p>[UNITRO] and go to a doctor immediately if you experience the following:</p> <ul style="list-style-type: none"> • If you notice any sudden wheeziness, • difficulty in breathing, • swelling of the eyelids, face or lips, • rash or itching (especially affecting your whole body) <p>If you experience any of the side effects detailed below stop taking Nitrofurantoin Capsules and consult your doctor.</p> <ul style="list-style-type: none"> • Your lungs may react to Nitrofurantoin Capsules. 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 coloration 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 	
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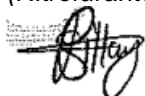
	<p>known as cutaneous vasculitis.</p> <ul style="list-style-type: none"> • Symptoms of jaundice, fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as autoimmune hepatitis. <p>Please note that while taking Nitrofurantoin Capsules your urine may become dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.</p> <p>Other less frequent side effects include:</p> <ul style="list-style-type: none"> • Aplastic anemia (Blood stops producing enough blood cells), • Cyanosis(a bluish discoloration of the skin), • Loss of consciousness (collapse) <p>Frequency unknown:</p> <ul style="list-style-type: none"> • Superinfections (Fungi or resistant organisms caused infections), • Granulocytopenia (loss of neutrophils in circulating blood), • Leukopenia (lowered white blood cell count), • Megaloblastic anemia (many large immature and dysfunctional red blood cells), • Thrombocytopenia (deficiency of platelets in the blood), • Aplastic anemia (deficiency of all types of blood cells in blood), • Haemolytic anemia (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, 	
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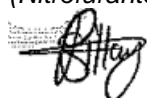
	<ul style="list-style-type: none"> • Severe rash with blistering. • Feeling sick (nausea) • Depression, • Confusion, • Psychiatric reactions, • Headache • Loose stools • Loss of appetite, • Stomach ache, • Vomiting, • Dizziness, • Drowsiness • Blood cells have been affected in some patients. This may 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 Nitrofurantoin Capsules. • Inflammation of small blood vessel walls, 	
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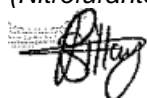
	<ul style="list-style-type: none"> • Skin lesions • Liver inflammation due to turn of immune system against liver cells, • Inflammation of kidney tissue surrounding tubules, • Renal impairment, • Stevens - Johnson syndrome (a serious systemic (body-wide) allergic reaction with a characteristic rash involving 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). 	
	<p>Reporting of side effects</p> <p>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 via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf.</p> <p>By reporting side effects, you can help provide more information on the safety of this medicine.</p>	
	<p>5. How to store [UNITRO]</p> <p>Store at or below 25 °C.</p> <p>Keep the blisters in the carton until required for use.</p> <p>Keep HDPE containers tightly closed.</p> <p>STORE ALL MEDICINES OUT OF REACH OF CHILDREN.</p>	



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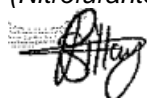
	<p>Return all unused medicine to your pharmacist.</p> <p>Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).</p>	
	<p>6. Contents of the pack and other information</p>	
	<p>What [UNITRO] contains</p> <p>The active substance is Nitrofurantoin</p> <p>The other ingredients of [UNITRO] are:</p> <p>cellulose microcrystalline, croscarmellose sodium and Magnesium stearate.</p>	
	<p>What [UNITRO] looks like and contents of the pack</p> <p>[UNITRO] 50 mg: 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.</p> <p>[UNITRO] 100 mg: 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.</p>	
	<p>[UNITRO] 50 mg and 100 mg:</p> <p>1) Blister pack:</p> <p><i>(clear thermo form film - aluminium foil):</i></p> <p>Capsules are packed in thermo form clear 250 micron PVC film</p>	



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	<p>as the forming film and 25 micron aluminium foil with 7 g/m² heat seal lacquer as the lidding material.</p> <p>Pack size: 50's – Each carton contains 5 blisters of 10 capsules each.</p> <p>(white opaque thermo form film - aluminium foil):</p> <p>Capsules are packed in white thermo form rigid 250 micron PVC film as the forming film and 25 micron aluminium foil with 7 g/m² heat seal lacquer as the lidding material.</p> <p>Pack size: 50's – Each carton contains 5 blisters of 10 capsules each.</p> <p>2. HDPE Container Pack:</p> <p>[UNITRO] 50 mg:</p> <p>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.</p> <p>Pack size: 50's – One HDPE container contains 50 capsules.</p> <p>[UNITRO] 100 mg:</p> <p>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.</p> <p>Pack size: 50's – One HDPE container contains 50 capsules.</p>	
	<p>Holder of Certificate of Registration</p>	



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