

PYRIDIUM

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

PYRIDIUM 100mg (tablets)
Phenazopyridine hydrochloride
Contains sugar.
Each tablet contains 64,26 mg lactose monohydrate and 0,158 mg dextrose monohydrate

Read all of this leaflet carefully because it contains important information for you:

- PYRIDIUM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PYRIDIUM carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share PYRIDIUM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

- What PYRIDIUM is and what it is used for
- What you need to know before you take PYRIDIUM
- How to take PYRIDIUM
- Possible side effects
- How to store PYRIDIUM
- Contents of the pack and other information

1. What PYRIDIUM is and what it is used for

PYRIDIUM is used to relieve symptoms caused by irritation of the urinary tract such as pain, burning, and the feeling of needing to urinate urgently or frequently. This medicine does not treat the cause of the urinary irritation, but it can help relieve the symptoms while other treatments take effect. PYRIDIUM is a dye that works as a painkiller to soothe the lining of the urinary tract.

2. What you need to know before you take PYRIDIUM

Do not take PYRIDIUM if:

- you are hypersensitive (allergic) to phenazopyridine hydrochloride or any of the other ingredients of PYRIDIUM (listed in section 6).
- you suffer from inflammation of blood vessels around the kidney (confirmed by urine testing), urea in the blood (progressive weakness and easy fatigue, loss of appetite due to nausea and vomiting)
- you suffer from impaired renal function
- you suffer from severe inflammation of the liver (hepatitis)
- PYRIDIUM should not be used for repeated or prolonged treatment without full diagnostic investigation
- you suffer from glucose-6-phosphate dehydrogenase (G6PD), as deficiency. You are at an increased risk of severe haemolytic anaemia (blood disorder)
- you are pregnant or breastfeeding you baby.
- PYRIDIUM contains lecithin (soya). If you are allergic to peanut or soya, do not use this medicinal product PYRIDIUM.

Warnings and precautions

Take special care with PYRIDIUM:

- PYRIDIUM is for relief of symptoms and you should not delay the process of determining the underlying cause of your disease. Prompt appropriate treatment of the cause of pain must be instituted. Stop using PYRIDIUM if the symptoms are controlled.
- If PYRIDIUM is used concurrently with an antibiotic treatment, the duration of PYRIDIUM therapy should not exceed 2 days.
- If your symptoms persist or recur, a doctor should be consulted.
- PYRIDIUM produces an orange to red colour in the urine and faeces and may stain clothing. Staining of contact lenses has been reported.
- PYRIDIUM may affect the results of tests performed to determine the cause of your disease. Inform you doctor that you are taking PYRIDIUM prior to being tested.
- You should stop taking PYRIDIUM if your eyes and skin becomes discoloured.

Other medicines and PYRIDIUM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
PYRIDIUM may affect the results of tests performed to determine the cause of your disease.
Inform you doctor that you are taking PYRIDIUM prior to being tested.

PYRIDIUM with food and drink

PYRIDIUM should be taken with or after meals.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
The safety and/or efficacy of the use of PYRIDIUM during pregnancy and breastfeeding have not been established (see section 2).
No fertility studies have been conducted in humans.

Driving and using machines

PYRIDIUM does not appear to influence the ability to drive or use machines; however, it is known to cause visual disturbances.
It is not always possible to predict to what extent PYRIDIUM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PYRIDIUM affects them.

PYRIDIUM contains lactose, dextrose, sodium and lecithin (soya)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PYRIDIUM.
PYRIDIUM contains lecithin (soya). If you are allergic to peanut or soya, do not use PYRIDIUM (see section 2).

PYRIDIUM contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take PYRIDIUM

Always take PYRIDIUM exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.
Adults should take two tablets three times per day with or after meals.
If PYRIDIUM is used concurrently with an antibiotic treatment, the duration of PYRIDIUM therapy should not exceed 2 days.
PYRIDIUM is for oral use.
Tablets should not be chewed.

If you take more PYRIDIUM than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

The following can occur with an overdose:

- the presence of a higher than normal level of methemoglobin in your blood.
 - The symptoms include shortness of breath, blue or purple colouration of the skin, mental status changes, headache, fatigue, exercise intolerance, dizziness and loss of hairlines
 - abnormal breakdown of red blood cells characterised by pallor, fatigue, shortness of breath, and potential for heart failure
 - impaired liver function and sometimes kidney failure.
- Treatment of overdose is symptomatic and supportive.

If you forget to take PYRIDIUM

If you forget to use a dose of PYRIDIUM, carry on with the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking PYRIDIUM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- a rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, headache and neck stiffness (meningitis).
- These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- headache
- nausea, vomiting and diarrhoea
- abdominal cramps or stomach pains
- skin discolouration
- tiredness, weakness
- visual disturbances
- crystal deposits in your urinary tract
- discolouration of urine and other body fluids.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found on-line 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 PYRIDIUM.

5. How to store PYRIDIUM

- Store all medicines out of reach of children
- Store at or below 25 °C in a dry place.
- 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 PYRIDIUM contains:

The active substance is phenazopyridine hydrochloride.

The other ingredients are:

Tablet cores: Lactose monohydrate, maize starch, sodium starch glycolate, hydrogenated vegetable oil, magnesium stearate.

Film-coating: Opadry 20A565046 Brown: consisting of hypromellose, hydroxypropyl cellulose, talc, FD&C Red #40/Allura red AC aluminium lake, titanium dioxide, FD&C Blue #2 Indigo carmine aluminium lake.

Polishing: Opaglos 2 High Gloss film-coating system 97W19206 clear: consisting of sodium carboxymethylcellulose, maltodextrin, dextrose monohydrate, lecithin (soya).

What PYRIDIUM looks like and contents of the pack

Shiny, smooth, round, maroon film-coated tablet without capping or chipping.
Amber PVC bottle with black polyethylene screw cap and pressure sensitive seal, grey sponge and desiccant.

Holder of Certificate of Registration

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BOTSWANA: Reg. No. BOT2003660	S2

PYRIDIUM

PASIËNT INLIGTINGSBLAD

SKEDULERING STATUS:

S2

PYRIDIUM 100mg (tablette)
 Fenasopiridien hidrochloried
 Bevat suiker.
 Elke tablet bevat 64,26 mg laktosemonohidraat en 0,158 mg dekstrosemonohidraat

Lees die hele inligtingsblad noukeurig deur, want dit bevat belangrike inligting vir jou:

- PYRIDIUM is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n te behandel. Nietemin moet jy steeds PYRIDIUM versigtig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie inligtingsblad. Jy sal dit dalk weer moet lees.
 - Moenie PYRIDIUM met enige ander persoon deel nie.
 - Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
 - Jy moet 'n dokter sien as jou simptome vererger of nie verbeter nie.

Wat hierdie inligtingsblad bevat

1. Wat PYRIDIUM is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy PYRIDIUM neem
3. Hoe om PYRIDIUM te neem
4. Moontlike nuwe-effekte
5. Hoe om PYRIDIUM te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat PYRIDIUM is en waarvoor dit gebruik word

PYRIDIUM word gebruik om simptome te verlig wat veroorsaak word deur irritasie van die urienweg soos pyn, brand, en die gevoel dat jy dringend of gereeld moet urineer. Hierdie medisyne behandel nie die oorsaak van die urinêre irritasie nie, maar dit kan help om die simptome te verlig terwyl ander behandelings in werking tree. PYRIDIUM is 'n kleurstof wat as 'n pynstiller werk om die voering van die urienweg te streef.

2. Wat jy moet weet voordat jy PYRIDIUM neem

Moenie PYRIDIUM neem as:

- jy hipersensitief (allergies) vir fenasopiridienhidrochloried of enige van die ander bestanddele van PYRIDIUM is nie (gelys in afdeling 6).
- jy ly aan inflammasie van bloedvate rondom die nier (bevestig deur urinetoetsing), ureum in die bloed (progressiewe swakheid en maklike moegheid, verlies aan eetlus as gevolg van naarheid en braking)
- jy aan verswakte nierfunksie ly
- jy ly aan ernstige ontsteking van die lewer (hepatitis)
- PYRIDIUM moet nie gebruik word vir herhaalde of langdurige behandeling sonder volledige diagnostiese ondersoek nie
- jy ly aan glukose-6-fosfaatdehidrogenase (G6PD), as tekort. Jy het 'n verhoogde risiko van ernstige hemolitiese anemie (bloedversteuring)
- jy swanger is of jou baba borsvoed.
- PYRIDIUM bevat lesities (soja). As jy allergies is vir grondboontjies of soja, moenie PYRIDIUM gebruik nie.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met PYRIDIUM:

- PYRIDIUM is vir verligting van simptome en jy moet nie die proses van die bepaling van die onderliggende oorsaak van jou siekte vertraag nie. Spoedige toepaslike behandeling van die oorsaak van pyn moet ingestel word. Hou op om PYRIDIUM te gebruik as die simptome onder beheer is.
- Indien PYRIDIUM gelyktydig met 'n antibiotiese behandeling gebruik word, moet die duur van PYRIDIUM terapie nie 2 dae oorskry nie.
- Indien u simptome voortduur of herhaal, moet 'n dokter geraadpleeg word.
- PYRIDIUM produseer 'n oranje tot rooi kleur in die urine en ontlasting en kan klere vlek. Verkleuring van kontaklense is aangemeld.
- PYRIDIUM kan die resultate van toetse wat uitgevoer word om die oorsaak van jou siekte te bepaal, beïnvloed. Stel u dokter in kennis dat u PYRIDIUM neem voordat u getoets word.
- Jy moet ophou om PYRIDIUM te neem as jou oë en vel verkleur.

Ander medisyne en PYRIDIUM

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in). PYRIDIUM kan die resultate van toetse wat uitgevoer word om die oorsaak van jou siekte te bepaal, beïnvloed. Stel u dokter in kennis dat u PYRIDIUM neem voordat u getoets word.

PYRIDIUM saam met kos en drank

PYRIDIUM moet met of na etes geneem word.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik. Die veiligheid en/of doeltreffendheid van die gebruik van PYRIDIUM tydens swangerskap en borsvoeding is nie vasgestel nie (sien afdeling 2). Geen vrugbaarheidstudies is by mense uitgevoer nie.

Bestuur en gebruik van masjiene

PYRIDIUM blyk nie die vermoë om te bestuur of masjiene te gebruik beïnvloed nie; dit is egter bekend dat dit visuele versteurings kan veroorsaak. Dit is nie altyd moontlik om te voorspel tot watter mate PYRIDIUM met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak voordat hulle bewus is van die mate waarin PYRIDIUM hulle affekteer nie.

PYRIDIUM bevat laktose, dekstrose, natrium en lesities (soja)

As jy deur jou dokter gesê is dat jy 'n onverdraagsaamheid vir sommige suikers het, kontak jou dokter voordat jy PYRIDIUM neem. PYRIDIUM bevat lesities (soja). As jy allergies is vir grondboontjies of soja, moenie PYRIDIUM gebruik nie (sien afdeling 2). PYRIDIUM bevat minder as 1 mmol natrium (23 mg) per tablet, dit wil sê in wese 'natriumvry'.

3. Hoe om PYRIDIUM te neem

Neem altyd PYRIDIUM presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster vir jou gesê het. Gaan na jou dokter, apteker of verpleegster as jy nie seker is nie. Volwassenes moet twee tablette drie keer per dag met of na etes neem. As PYRIDIUM gelyktydig met 'n antibiotiese behandeling gebruik word, moet die duur van PYRIDIUM-terapie nie 2 dae oorskry nie. PYRIDIUM is vir orale gebruik. Tablette moet nie gekou word nie.

As jy meer PYRIDIUM neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Die volgende kan met 'n oordosis voorkom:

- die teenwoordigheid van 'n hoër as normale vlak van methemoglobien in jou bloed. Die simptome sluit in kortasem, blou of pers kleur van die vel, veranderinge in geestelike status, hoofpyn, moegheid, oefenintoleransie, duiseligheid en verlies van haarlyn.
- abnormale afbreek van rooibloedselle wat gekenmerk word deur bleekheid, moegheid, kortasem en potensiaal vir hartversaking
- verswakte lewerfunksie en soms nierversaking.

Behandeling van oordosis is simptomaties en ondersteunend.

As jy vergeet om PYRIDIUM te neem

As jy vergeet om 'n dosis PYRIDIUM te gebruik, gaan voort met die volgende dosis op die gewone tyd. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

4. Moontlike nuwe-effekte

PYRIDIUM kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir PYRIDIUM aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u PYRIDIUM neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om PYRIDIUM te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme kan veroorsaak om te sluk of asem te haal,
 - 'n uitslag of jeuk,
 - floute,
 - vergeling van die vel en oë, ook genoem geelsug.
- Dit is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op PYRIDIUM gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende probleme:

- koors, hoofpyn en nekstyfheid (meningitis).
- Dit is alles ernstige nuwe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:

- hoofpyn
- naarheid, braking en diarree
- abdominale krampe of maagpyn
- velverkleuring
- moegheid, swakheid
- visuele versteurings
- kristalvorming in jou urienweg
- verkleuring van urine en ander liggaamsvloeistowwe.

Aanmelding van nuwe-effekte

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van PYRIDIUM te verskaf.

5. Hoe om PYRIDIUM te bewaar

- Berg alle medisyne buite bereik van kinders
- Berg by of benede 25 °C in 'n droë plek.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6.Inhoud van die pakkie en ander inligting

Wat PYRIDIUM bevat:

Die aktiewe bestanddeel is fenasopiridienhidrochloried.

Die ander bestanddele is:

Tabletkern: Laktosemonohidraat, meliëstysel, natriumstyselglikolaat, gehidrogeneerde plantaaridige olie, magnesiumstearaat.
Filmbedekking: Opadry 20A565046 Bruin: bestaande uit hipromellose, hidroksiopropielsellulose, talk, FD&C Red #40/Allura rooi AC aluminiummeer, titaandioksied, FD&C Blue #2 Indigo karmyn-aluminiummeer.
Poleer: Opaglos 2 Hoëglans filmbedekkingstelsel 97W19206 helder: bestaande uit natriumkarboksietielsellulose, maltodekstriene, dekstrosemonohidraat, lesities (soja).

Hoe PYRIDIUM lyk en die inhoud van die verpakking

Blink, gladde, ronde, maroen filmbedekte tablet sonder omhulsel of skeuring. Amber PVC-bottel met swart poliëtileen-skroefdop en drukgevoelige seël, grys spons en droogmiddel.

Houer van Registrasiesertifikaat

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Hierdie pamflet is laas hersien in

5 Maart 2024

Registrasienumer

H/18/1728

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BOTSWANA: Reg. Nr. BOT2003660	S2