FORURI

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
FORURI, 3 g granules for oral solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains fosfomycin trometamol equivalent to fosfomycin 3 g.

Excipient with known effect:
Contains sugar (sucrose). One sachet contains 2,213 g sucrose. See section 4.4.
Contains sweetener (saccharin sodium). One sachet contains 0,016 g.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Granules for oral solution.
White or almost white granules without lumps or particulates.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
FORURI is indicated as a single-dose in the treatment of acute uncomplicated lower urinary tract infections caused by sensitive *E. coli* in women and adolescent women.
FORURI is also indicated for prophylaxis in diagnostic and surgical transurethral procedures in adult men.

4.2 Posology and method of administration
Posology
Women and adolescent women (> 12 years of age):
The recommended dose for uncomplicated urinary tract infections in women, including the elderly up to 75 years, is a single 3 g dose.

Adult men:
The recommended dose for prophylaxis prior to transurethral surgical and diagnostic procedures in adult men, including the elderly, is two doses of 3 g. The first dose should be taken 3 hours before surgery. The second dose should be taken 24 hours after surgery.

Children:
FORURI 3 g is not suitable for children between the ages of 5 and 12 years, as the recommended dose for this age group is a single 2 g dose and the sachet contents cannot be divided.

Method of administration
FORURI is taken orally, immediately after reconstitution in a glass of water. It should be taken at least 2 hours before the next meal, on an empty stomach.

4.3 Contraindications
- hypersensitivity to fosfomycin or to any of the excipients of FORURI (see section 6.1)
- patients with severe renal insufficiency (creatinine clearance < 10 mL/min)
- patients undergoing haemodialysis.

4.4 Special warnings and precautions for use
Hypersensitivity reactions
Hypersensitivity reactions, including anaphylaxis and anaphylactic shock, may occur during treatment with FORURI and may be life-threatening (see section 4.8). If such reaction occurs, FORURI should never be re-administrated and adequate medical treatment is required.

Antibiotic-associated diarrhoea and *Clostridium difficile*-associated disease (CDAD)
Antibiotic-associated diarrhoea has been reported and may range in severity from mild diarrhoea to fatal colitis. Diarrhoea, particularly if severe, persistent and/or bloody, during or after treatment with FORURI (including several weeks after treatment), may be symptomatic of *Clostridium difficile*-associated disease (CDAD). It is therefore important to consider this diagnosis in patients who develop severe diarrhoea during or after treatment with FORURI.
If CDAD is suspected or confirmed, appropriate treatment should be initiated without delay (see section 4.8).
Anti-peristaltic medicines are contraindicated in this clinical situation.

Renal insufficiency
Urinary concentrations of fosfomycin remain effective for 48 hours after a usual dose if creatinine clearance is above 10 mL/min.

Paediatric population
FORURI 3 g is not recommended for children under the age of 12 years (see section 4.2).

Information on the excipients
FORURI contains sucrose and saccharin sodium (see section 2).
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take FORURI.

4.5 Interactions with other medicines and other forms of interaction
Metoclopramide
Concomitant administration of metoclopramide has been shown to lower serum and urinary concentrations of fosfomycin and should be avoided.
Other medicines that increase gastrointestinal motility may produce similar effects.

Alteration in international normalised ratio (INR)
Many cases of increased oral anticoagulant activity have been reported in patients receiving antibiotics, including FORURI. Risk factors include severe infection or inflammation, age and poor general health.

Food
Food may delay the absorption of the active ingredient of FORURI, with consequent slight decrease in peak plasma levels and urinary concentrations. It is therefore preferable to take FORURI on an empty stomach, at least 2 hours before the next meal, or about 2 - 3 hours after meals.

4.6 Fertility, pregnancy and lactation
Pregnancy
No evidence has been found in animals or humans to indicate adverse effects of FORURI in pregnancy. However, the safety and/or efficacy of single-dose therapy has not been established for FORURI in pregnancy.

Breastfeeding
Fosfomycin is excreted into human milk. FORURI should not be given to lactating women.

4.7 Effects on ability to drive and use machines
Patients should be informed that dizziness has been reported. This may influence some patients' ability to drive and use machines.

4.8 Undesirable effects
a. Summary of the safety profile
Frequent adverse reactions following the single-dose administration of fosfomycin trometamol involve the gastrointestinal tract, mainly diarrhoea. These events are usually self-limited in duration and resolve spontaneously.

b. List of adverse events

System Organ Class	Frequency	Side effects
Infections and infestations	*Frequent*	Vulvovaginitis
	Frequency unknown	Antibiotic-associated colitis, pseudomembranous colitis
Blood and the lymphatic system disorders	*Frequency unknown*	Agranulocytosis, aplastic anaemia, eosinophilia, granulocytopenia, leucopenia, pancytopenia, and thrombocytopenia
Immune system disorders	*Frequency unknown*	Angioedema, anaphylactic reactions including anaphylactic shock, hypersensitivity
Nervous system disorders	*Frequent*	Headache, dizziness
	Frequency unknown	Optic neuritis
Respiratory, thoracic and mediastinal disorders	*Frequent*	Pharyngitis, rhinitis
	Frequency unknown	Exacerbation of asthma
Gastrointestinal disorders	*Frequent*	Diarrhoea, nausea, dyspepsia, abdominal pain
	Less frequent	Vomiting
	Frequency unknown	Antibiotic-associated colitis (see section 4.4), toxic megacolon
Hepatobiliary disorders	*Frequency unknown*	Cholestatic jaundice, hepatic necrosis
Skin and subcutaneous tissue disorders	*Less frequent*	Rash, urticaria, pruritus
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Back pain
Reproductive system and breast disorders	*Frequent*	Dysmenorrhoea, vaginitis
General disorders and administration site conditions	*Frequent*	Pain (non-localised), asthenia
Investigations	*Frequency unknown*	Increases in serum concentration of aminotransferases, alkaline phosphatase and bilirubin

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. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product

4.9 Overdose
No information is available on the overdose of oral fosfomycin.
In the event of overdose, side effects can be precipitated and/or be of increased severity (refer section 4.8).
In the event of overdose, treatment should be symptomatic and supportive. Rehydration is recommended to promote urinary elimination of the medicine.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antibacterials for systemic use – other antibacterials.
ATC code: J01XX01
Pharmacological classification: A 20.1.1 Broad and medium spectrum antibiotics

Fosfomycin trometamol is a broad-spectrum bactericidal antibiotic, derived from phosphonic acid with activity in the lower urinary tract. The antibacterial activity of fosfomycin is due to an inhibition of bacterial cell wall synthesis. Its mechanism of action is inhibition of enol pyruvyl transferase.

Resistance:
The main mechanism of resistance is a chromosomal mutation causing an alteration of the bacterial fosfomycin transport systems.

5.2 Pharmacokinetic properties
Absorption:
Fosfomycin trometamol is an orally well-absorbed salt of fosfomycin. It usually provides therapeutic concentrations of the active moiety in the urine for periods of 36 hours or more from a single dose.
Food delays and reduces absorption of fosfomycin trometamol, resulting in reduced blood and urinary concentrations.

Biotransformation and elimination:
Fosfomycin is eliminated mainly unchanged through the kidneys and this results in very high peak urinary concentrations (approximately 3 000 mg/L) within 2 - 4 hours. Therapeutic concentrations in urine are usually maintained for at least 36 hours.

Special populations
In patients with moderately reduced renal function (creatinine clearance < 80 mL/min), including the physiological reduction in the elderly, the half-life of fosfomycin is prolonged but urinary concentration remains therapeutically adequate.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Sucrose
Saccharin sodium
Mandarin flavour
Orange flavour.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months
Reconstituted solution: Administer soon after dissolving.

6.4 Special precautions for storage
Store at or below 25 °C.

6.5 Nature and contents of the container
FORURI is packed in a four layered (surlyn/aluminium/low-density polyethylene/paper) sachet.
Sachets are supplied in cartons containing 1 - 2 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
The dose must be dissolved in a glass of water and administered soon after dissolving. Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town
South Africa

8. REGISTRATION NUMBER
A53/20.1.1/0575

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
16 May 2023

10. DATE OF REVISION OF THE TEXT
26 January 2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FORURI, 3 g granules for oral solution
Fosfomycin trometamol
Contains sugar (sucrose) and sweetener (saccharin sodium)
One sachet contains 2,213 g sucrose and 0,016 g saccharin sodium

Read all of this leaflet carefully before you start taking FORURI
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FORURI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FORURI is and what it is used for
FORURI is a broad-spectrum antibiotic that is used in women and adolescent women to treat urinary tract and bladder infections. It is used in adult men to prevent infection from urinary surgery.

2. What you need to know before you take FORURI
Do not take FORURI:
- if you are hypersensitive (allergic) to fosfomycin or any of the other ingredients of FORURI (listed in section 6, What FORURI contains)
- if you suffer from severe kidney problems
- if you are undergoing haemodialysis (a procedure used to clean the blood from wastes and extra fluids, when the kidneys are not working).

Warnings and precautions
Take special care with FORURI:
- if you have an allergic reaction on FORURI. See section 4, Possible side effects, for some signs of an allergic reaction. Contact your doctor immediately if you have such symptoms
- tell your doctor, pharmacist or nurse before taking FORURI if you have previously experienced diarrhoea upon administration of any other antibiotics. FORURI may cause severe diarrhoea and inflammation of the bowel in some patients (see section 4)
- tell your doctor if you have kidney disease. The effects of FORURI may be increased because of slower removal from the body.

Children
FORURI 3 g is not indicated for children between the ages of 5 and 12 years, as the sachets cannot be divided.

Other medicines and FORURI
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you take:
- a medicine called metoclopramide (a medicine to stop you from feeling sick) as this may influence FORURI
- medicines that reduce blood clotting (such as warfarin).

FORURI with food and drink
Food delays and reduces the absorption of FORURI, resulting in reduced blood and urinary concentrations. FORURI should be taken on an empty stomach at least 2 hours before the next meal, or at least 2 - 3 hours after a meal.

Pregnancy and breastfeeding
Safety has not been established for use in pregnancy. Do not take FORURI if you are pregnant or breastfeeding.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice.
Fosfomycin is excreted into human milk. You should not breastfeed your baby if you take FORURI, or you should not take FORURI if you breastfeed your baby.

Driving and using machines
You may experience side effects such as dizziness which may affect your ability to drive or use machines. Do not drive or use machines if you are affected.

FORURI contains sugar (sucrose) and sweetener (saccharin sodium)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FORURI.

3. How to take FORURI
Do not share medicines prescribed for you with any other person.
Always take FORURI exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:
Adult and adolescent women (> 12 years of age):
Only one dose is taken: One 3 g sachet of FORURI as a single dose, at least 2 hours before the next meal, on an empty stomach.

Adult men:
Two doses are usually taken:
- one 3 g sachet 3 hours *before* surgery
- one 3 g sachet 24 hours *after* surgery.

Directions for use:
Dissolve the contents of the sachet in a glass of water and drink all the contents immediately (see section 6, What FORURI contains).
If you have the impression that the effect of FORURI is too strong or too weak, tell your doctor or pharmacist.

If you take more FORURI 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.

If you forget to take FORURI
If you forget to take the dose, take it as soon as you remember.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking FORURI
Women only take a single dose.
For effective prevention of infection, men should take both their doses as directed in section 3, How to take FORURI.

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

If any of the following happens, stop taking FORURI 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
- rash, itching or hives on the skin
- abdominal pain, nausea with yellowing of the skin and eyes, which may be due to jaundice or liver failure
- severe abdominal cramps, bloody stools, rapid heart rate and/or fever. These symptoms may mean that you have an infection of the large intestine (pseudomembranous colitis) or a toxic megacolon (an abnormal dilation of the large intestine).

These are all very serious side effects. If you have them, you may have had a serious reaction to FORURI. 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:
- signs of infections, such as a sore throat, vaginal inflammation, or combined vaginal and vulvar inflammation
- worsening of asthma.

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

Tell your doctor if you notice any of the following:
Frequent side effects
- headache
- dizziness
- runny nose
- diarrhoea
- nausea (feeling sick)
- dyspepsia (heartburn)
- abdominal pain
- back pain
- painful menstruation
- general pain
- abnormal physical weakness.

Less frequent side effects
- vomiting
- pain in the eye, vision loss (inflammation of the optic nerve).

Blood tests may show:
- low white blood cell count
- low numbers of red blood cells
- low blood platelet count
- increase in certain enzymes in the body (aminotransferases, alkaline phosphatase)
- increase in bilirubin (an orange-yellow pigment formed in the liver).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of FORURI. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store FORURI
Store all medicines out of reach of children.
Store at or below 25 °C.
Do not store in a bathroom.
Use entire contents immediately once opened.
Do not use after the expiry date stated on the carton.
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 FORURI contains:
The active substance is fosfomycin. Each sachet contains fosfomycin trometamol equivalent to fosfomycin 3 g.
The other ingredients are sucrose, saccharin sodium, mandarin flavour and orange flavour.

What FORURI looks like and contents of the pack
The granules for oral solution are white or almost white, without lumps or foreign particles.
FORURI is packed in a four layered (surlyn/aluminium/low-density polyethylene/paper) sachet.
1 - 2 sachets are packed into printed cardboard boxes.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town
South Africa

This leaflet was last revised in
26 January 2024

Registration number
A53/20.1.1/0575

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

FORURI, 3 g granules vir mondelike oplossing
Fosfomisientrometamol
Bevat suiker (sukrose) en versoeter (natriumsakkarien)
Een sakkie bevat 2,213 g sukrose en 0,016 g natriumsakkarien

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om FORURI te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- FORURI is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad

1. Wat FORURI is en waarvoor dit gebruik word
FORURI is 'n breëspektrum antibiotikum, wat deur vroue en adolessente vroue gebruik word, om urienweg- en blaasinfeksies, te behandel. Dit word gebruik deur volwasse mans, om infeksie na urinêre chirurgie, te voorkom.

2. Wat u nodig het om te weet, voordat u FORURI gebruik
Moet nie FORURI neem:
- indien u hipersensitief (allergies) is vir fosfomisien, of vir enige van die ander bestanddele van FORURI nie (gelys in afdeling 6, Wat FORURI bevat)
- indien u aan erge nierprobleme ly nie
- indien u hemodialise ondergaan nie ('n prosedure wat gebruik word om bloed van afvalstowwe en oortollige vloeistowwe te suiwer, indien die niere nie funksioneer nie).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met FORURI:
- indien u 'n allergiese reaksie met FORURI ervaar het. Sien afdeling 4, Moontlike newe-effekte, vir sommige tekens van 'n allergiese reaksie. Raadpleeg u dokter onmiddellik, indien u sulke simptome ervaar
- vertel u dokter, apteker, of verpleegkundige, voordat u FORURI gebruik, indien u voorheen diarree met die gebruik van enige ander antibiotika ervaar het. FORURI mag erge diarree en inflammasie van die derms, by sommige pasiënte veroorsaak (sien afdeling 4)
- vertel u dokter, indien u niersiekte het. Die effekte van FORURI mag versterk word, vanweë die stadiger verwydering daarvan, vanuit die liggaam.

Kinders
FORURI 3 g word nie aangedui vir kinders tussen die ouderdomme van 5 en 12 jaar oud nie, aangesien die sakkies nie verdeel kan word nie.

Ander medisyne en FORURI
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem. (Dit sluit alle aanvullende, of tradisionele medisyne in).

Vertel u dokter indien u die volgende neem:
- 'n medisyne wat metoklopramied genoem word ('n medisyne om te verhoed dat u naar voel), aangesien dit FORURI mag beïnvloed
- medisyne wat bloedstolling verminder (soos warfarien).

FORURI saam met kos en drinkgoed
Voedsel vertraag en verminder die absorpsie van FORURI en lei tot verlaagde bloed- en urinêre konsentrasies. FORURI moet op 'n leë maag geneem word, ten minste 2 uur voor die volgende maaltyd, of ten minste 2 - 3 uur na 'n maaltyd.

Swangerskap en borsvoeding
Veiligheid vir gebruik tydens swangerskap, is nie vasgestel nie. Moet nie FORURI neem indien u swanger is, of borsvoed nie.
Indien u swanger is, of borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies.
Fosfomisien word in mensmelk uitgeskei. U moet nie u baba borsvoed, indien u FORURI neem nie, of u moet nie FORURI neem, indien u u baba borsvoed nie.

Bestuur en die hantering van masjiene
U mag newe-effekte soos duiseligheid ervaar, wat u vermoë om te bestuur, of masjiene te hanteer, mag beïnvloed. Moet nie bestuur of masjiene hanteer, indien u aangetas word nie.

FORURI bevat suiker (sukrose) en versoeter (natriumsakkarien)
Indien u dokter aangedui het, dat u 'n onverdraagsaamheid teenoor sekere suikers toon, kontak u dokter, voordat u FORURI gebruik.

3. Hoe om FORURI te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem FORURI altyd presies soos deur u dokter of apteker aanbeveel word. Raadpleeg u dokter of apteker, indien u onseker is.

Die gewone dosis is:
Volwasse en adolessente vroue (> 12 jaar oud):
Slegs een dosis word geneem: Een 3 g sakkie FORURI as 'n enkeldosis, ten minste 2 uur voor die volgende maaltyd, op 'n leë maag.

Volwasse mans:
Twee doserings word gewoonlik geneem:
- een 3 g sakkie 3 uur *voor* 'n operasie
- een 3 g sakkie 24 uur *na* 'n operasie.

Gebruiksaanwysings:
Los die inhoud van die sakkie in 'n glas water op en drink die hele inhoud dadelik (sien afdeling 6, Wat FORURI bevat).
Indien u onder die indruk is dat die effek van FORURI té sterk of té swak is, raadpleeg u dokter, of apteker.

Indien u meer FORURI neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.

Indien u vergeet om FORURI te neem
Indien u vergeet om die dosis te neem, neem dit so gou as wat u onthou.
Moet nie 'n dubbeldosis neem, om op te maak vir die vergete, individuele doserings nie.

Indien u die gebruik van FORURI staak
Vroue neem slegs 'n enkeldosis.
Om doeltreffende voorkoming van infeksie te bewerkstellig, moet mans beide doserings neem, soos aangedui in afdeling 3, Hoe om FORURI te neem.

4. Moontlike newe-effekte
FORURI kan newe-effekte hê.
Nie alle newe-effekte wat vir FORURI aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar, terwyl u FORURI neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van FORURI en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel, wat sluk en asemhaling mag bemoeilik
- uitslag, gejeuk, of galbulte op die vel
- buikpyn, naarheid met vergeling van die vel en oë, wat aan geelsug of lewerversaking te wyte mag wees
- erge buikkrampe, bloederige stoelgang, vinnige harttempo en/of koors. Hierdie simptome mag beteken dat u 'n infeksie van die dikderm (pseudomembraneuse kolitis) of 'n toksiese megakolon ('n abnormale verwyding van die dikderm) het.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, kon u 'n ernstige allergiese reaksie teenoor FORURI ondervind het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- tekens van infeksies, soos 'n seer keel, vaginale inflammasie, of gekombineerde vaginale en vulvêre inflammasie
- lae van asma.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter, indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom
- hoofpyn
- duiseligheid
- loopneus
- diarree
- naarheid (voel mislik)
- dispepsie (sooibrand)
- buikpyn
- rugpyn
- pynlike menstruasie
- algemene pyn
- abnormale fisiese swakheid.

Minder algemene newe-effekte
- braking
- oogpyn, sigverlies (inflammasie van die optiese senuwee).

Bloedtoetse mag die volgende toon:
- lae witbloedseltelling
- lae aantal roobloedselle
- lae bloedplaatjietelling
- toename in sommige ensieme in die liggaam (aminotransferase, alkaliese fosfatase)
- toename in bilirubien ('n oranje-geel pigment wat in die lewer gevorm word).

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter, of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van FORURI in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om FORURI te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 25 °C.
Moet nie in 'n badkamer bewaar nie.
Gebruik die hele inhoud onmiddellik, sodra dit oopgemaak is.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat FORURI bevat:
Die aktiewe bestanddeel is fosfomisien. Elke sakkie bevat fosfomisientrometamol, gelykstaande aan 3 g fosfomisien.
Die ander bestanddele is sukrose, natriumsakkarien, nartjiegeur en lemoengeur.
Los die inhoud van die sakkie op in 'n glas water.

Hoe FORURI lyk en die verpakkingsinhoud
Die korrels vir mondelike oplossing is wit, tot naaswit, sonder klonte, of vreemde deeltjies.
FORURI word verpak in 'n vierlaag-sakkie (surlyn/aluminium/lae-digtheid poli-etileen/papier).
1 - 2 sakkies word in gedrukte kartonhouers verpak.
Nie alle verpakkingshoeveelhede word noodwendig bemark nie.

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
1ste Vloer Grapevine House
Steenberg Office Park
Silverwood Close
Westlake, 7945
Kaapstad
Suid-Afrika

Hierdie inligtingsblad was voorheen hersien
26 Januarie 2024

Registrasie nommer
A53/20.1.1/0575