

# Cynfo<sup>®</sup> Suspension / Capsules

(Fosfomycin Calcium)

## DESCRIPTION:

Fosfomycin is a synthetic, broad spectrum, bactericidal antibiotic. Fosfomycin, a phosphonic acid derivative, is available in calcium salt form. Its molecular formula is  $C_3H_5CaO_4P \cdot H_2O$  and its molecular weight is 194.1

## COMPOSITION:

### Cynfo<sup>®</sup> 250mg/5ml Suspension

Each 5ml of reconstituted suspension contains:

Fosfomycin Calcium Ph.Eur.

equivalent to Fosfomycin .....250mg

### Cynfo<sup>®</sup> 500mg Capsules

Each capsule contains:

Fosfomycin Calcium Ph.Eur.

equivalent to Fosfomycin.....500mg

## CLINICAL PHARMACOLOGY:

### Mode of action

The bactericidal action of fosfomycin is due to its inactivation of the enzyme enolpyruvyl transferase, thereby irreversibly blocking the condensation of uridine diphosphate-N-acetylglucosamine with p-enolpyruvate, one of the first steps in bacterial cell wall synthesis. It also reduces adherence of bacteria to uroepithelial cells

### Pharmacokinetics

Peak plasma concentrations 4 hours after a 1g dose of fosfomycin calcium are about 7 micrograms/mL, and bioavailability has been calculated at about 30 to 40%

The plasma half-life is about 2 hours. Fosfomycin does not appear to be bound to plasma proteins. It crosses the placenta and is widely distributed in body fluids including the CSF; small amounts have been found in breast milk and bile. The majority of a parenteral dose is excreted unchanged in the urine, by glomerular filtration, within 24 hours

Fosfomycin is excreted unchanged in both urine and faeces

### Microbiology

Fosfomycin is a bactericidal antibiotic. It is active *in vitro* against a range of gram-positive and gram-negative bacteria including *Staphylococcus aureus*, some Streptococci, ESBL positive *Escherichia coli*, most Enterobacteriaceae, *Haemophilus influenzae*, *Neisseria* spp., and some strains of *Pseudomonas aeruginosa* although some are resistant. *Bacteroides* spp. are not sensitive

Fosfomycin has been reported to show antimicrobial synergy with a wide range of antibacterial agents against organisms such as Enterococci, methicillin-resistant *Staph. aureus*, and the Enterobacteria. Such synergistic effects have been reported particularly with the beta-lactams, but also with aminoglycosides, macrolides, tetracyclines, chloramphenicol, rifamycin and lincomycin

Antimicrobial antagonism with a beta-lactam has also been reported. There is some suggestion that use of fosfomycin with an aminoglycoside may also reduce the nephrotoxicity of the latter *in vivo*

## INDICATIONS:

Urinary tract infections (± catheter) caused by multiple resistant *E. coli* & *Klebsiella* organisms with proven resistance to all other antibiotics where no other appropriate agent is available. Other conditions as advised by Microbiology or ID consultant (Ref. NHS: ADTC Approved Sept.2011)

## CONTRAINDICATIONS:

Fosfomycin is contraindicated in patients with known hypersensitivity to the drug

## DOSAGE & ADMINISTRATION:

### Susceptible infections

The usual oral dose is 0.5 to 1g every 6 to 8 hours

### Acute uncomplicated urinary tract infections

3g as a single dose

Should be taken on an empty stomach (1 hour before or 2 hours after meals)

OR

As directed by the physician

## PRECAUTIONS:

### Pregnancy

Pregnancy category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women

## Nursing mothers

It is not known whether fosfomycin is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to not administer the drug, taking into account the importance of the drug to the mother

## DIRECTION FOR RECONSTITUTION OF SUSPENSION:

Shake bottle to loosen the mass. Add one time completely filled provided cup (50ml) with freshly boiled cool water into bottle. Shake well to form uniform suspension

## STABILITY:

See expiry on the pack

## PRESENTATIONS:

Cynfo<sup>®</sup> 250mg/5ml suspension in pack of 60ml

Cynfo<sup>®</sup> 500mg capsules in pack of 10's

## INSTRUCTIONS:

Keep out of reach of children

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine

The reconstituted suspension should be kept in a cool place, so the potency remain stable and be used within 7 days

سینفو<sup>®</sup> اسپینشن / کیپسول  
(فاسفو مائیسین کیلشیم)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں  
ہدایت: بچوں کی پہنچ سے دور رکھیں  
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ  
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی  
تیار شدہ اسپینشن کو خستہ نہ کیجئے تاکہ دوا کی  
تاثیر برقرار رہے اور سات یوم کے اندر استعمال کر لیں



Manufactured by:  
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