Monuril® fosfomycin (as trometamol) 3g per sachet granules for oral solution

Link to SmPC: Can’t find EMA version so using the UK version

[Monuril 3g granules for oral solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)](https://www.medicines.org.uk/emc/product/7329/smpc#gref)

[Fosfomycin «Infectopharm» - Felleskatalogen](https://www.felleskatalogen.no/medisin/fosfomycin-infectopharm-642767)

[DailyMed - FOSFOMYCIN TROMETHAMINE powder (nih.gov)](https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ca668546-c8ba-af0a-e053-2995a90a2300&audience=consumer)

Link to FHIR R5 [(4.6.0) resources](http://hl7.org/fhir/2021May/resourcelist.html)

Link to Skilarence template: [gravitate-health/input/fsh/Suliqua-instances-en at master · hl7-eu/gravitate-health (github.com)](https://github.com/hl7-eu/gravitate-health/tree/master/input/fsh/Suliqua-instances-en)

# Bundle

Package leaflet Monuril 3 g granules (would be two but we’re focusing on patients so only need the leaflet))

# Composition

Package leaflet Monuril 3 g granules

For patient safety reasons I recommend that going forward we use dummy text in the composition. Don’t want these test ePIs to get mixed up with the real thing. Can just use Lorum ipsum text:

*Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.*

# Organization

Market Authorization Holder

ZAMBON S.p.A.

Via Lillo Del Duca, 10

20091 Bresso (Milan) – Italy

Tel: +39 02 665 241

Fax: +39 02 665 01 492

Regulator

ORG-99999999

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

Can reuse the same EMA Organization resource from Skilarence

# Regulated Authorization

PL 31654/0006-1 x1 sachets

PL 31654/0006-2 x2 sachets

PL 31654/0006 -5 x5 sachets

Can’t find the EMA authorization so made up these from the MHRA numbers for now.

# Medicinal product definition

PL 31654/0006-1 x1 sachets

PL 31654/0006-2 x2 sachets

PL 31654/0006 -5 x5 sachets

Can’t find the EMA authorization so made up these from the MHRA numbers for now.

# Packaged product definition

Three pack presentations

Box with 1 sachet PL 31654/0006-1

Box with 2 sachets PL 31654/0006-2

Box with 5 sachets PL 31654/0006-5

Shelf life

Three years

Storage conditions

After reconstitution in water, the solution is stable at room temperature for 24 hours.

Special precautions for storage

Store away from direct sunlight.

# Administrable product definition

PhPID = from Malin/UMC

Monuril 3 g granules

# Manufactured item definition

MPID = PL 31654/0006

Monuril 3 g granules

# Ingredient

|  |  |  |  |
| --- | --- | --- | --- |
| **Ingredient** | **G-SRS code** | **Role** | **Strength** |
| fosfomycin trometamol | 7FXW6U30GY | active | 5.631 g  Basis = ACTIM  Reference strength   * Substance = fosfomycin (2N81MY12TE) * Strength = 3 g |
| Mandarin flavour | KH3E3096OO | excipient | n/a |
| Orange flavour | 5EVU04N5QU | excipient | n/a |
| Saccharin | FST467XS7D | excipient | n/a |
| Sucrose | C151H8M554 | excipient | n/a |

# Substance

Don’t need substance resource anymore

# Clinical use issue

Indications

|  |  |  |
| --- | --- | --- |
| **Term** | **MedDRA Code** | **System** |
| CYSTITIS | 10011781 | INFECTIONS AND INFESTATIONS |
| BIOPSY PROSTATE | 10004857 | INVESTIGATIONS |

Contraindication

|  |  |  |
| --- | --- | --- |
| **Term** | **MedDRA Code** | **System** |
| DRUG HYPERSENSITIVITY | 10013700 | IMMUNE SYSTEM DISORDERS |

Interactions

|  |  |  |
| --- | --- | --- |
| **Substance or Class** | **Code** | **System** |
| Metoclopramide | L4YEB44I46 | G-SRS |
| Fluoroquinolone Antibacterial [EPC] | N0000193223 | MED-RT |
| Macrolides [Chemical/Ingredient] | N0000175431 | MED-RT |
| Cephalosporin Antibacterial [EPC] | N0000175488 | MED-RT |
| Tetracycline-class Antibacterial [EPC] | N0000175938 | MED-RT |

Undesirable effects

|  |  |  |
| --- | --- | --- |
| **System organ class** | **Adverse drug reactions** | **Frequency** |
| Infections and infestations | Vulvovaginitis | Common |
| Immune system disorders | Anaphylactic reactions including anaphylactic shock, hypersensitivity (see section 4.4) | Not known |
| Nervous system disorders | Headache, dizziness | Common |
| Gastrointestinal disorders | Diarrhoea, nausea, dyspepsia, abdominal pain | Common |
| Gastrointestinal disorders | Vomiting | Uncommon |
| Gastrointestinal disorders | Antibiotic- associated colitis (see section 4.4) | Not known |
| Skin and subcutaneous tissue disorders | Rash, urticaria, pruritus | Uncommon |
| Skin and subcutaneous tissue disorders | Angioedema | Not known |

# Binary

n/a – no images of the granules. Only images of the packaging

# Document Reference