

Summary of product characteristics

Flumox Dry Mix (Oral Suspension)

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1. Name of the medicinal product:

Flumox 250mg Dry Mix (Oral Suspension)

2. Qualitative and quantitative composition:

Each 5ml contains: Amoxicillin (as trihydrate) 125mg and Flucloxacillin (as monohydrate) 125mg

For inactive ingredients see section 6.1

3. Pharmaceutical form:

Powder for oral suspension

4. Clinical particulars:**4.1 Therapeutic indications:**

FLUMOX is indicated in the treatment of a wide range of infections including:

- Respiratory tract infections: Bronchitis, pneumonia and emphysema.
- Ear, nose and throat infections: Otitis media, sinusitis, tonsillitis and pharyngitis
- Gastro-intestinal tract infections: Enteritis, cholecystitis, typhoid and paratyphoid fever.
- Genito- urinary tract infections: Cystitis, pyelonephritis, prostatitis, gonorrhea, and puerperal sepsis.
- Skin and soft-tissue infections: Boils, carbuncles, abscesses, cellulitis, post-operative wound infections, and intra- abdominal sepsis.
- Bone infections: Osteomyelitis and septic arthritis.
- Other infections: Septicaemia, endocarditis, peritonitis , biliary tract infections, and meningitis.

4.2 Posology and method of administration:

Oral administration:

Adults: 250 mg - 1 g every 6 - 8 hours.

Children up to 2 years: 125 - 250 mg (1/2 - 1 teaspoonful) every 6-8 hours.

Children 2 to 12 years: 250 - 500 mg (1 - 2 teaspoonful) every 6-8 hours.

Reconstitution of **FLUMOX®** Dry Mix: To make up , first shake the bottle to loosen powder, then add about 50 ml of water to the content of bottle and shake well. Fill to the mark on the bottle and keep for about 5 minutes. Once reconstituted, **FLUMOX®** must be stored in refrigerator and used within 10 days. Shake well before use.

4.3 Contraindications:

A Known hypersensitivity to penicillin.

4.4 Special warnings and precautions for use:

Doses should be reduced in severe renal impairment.

4.5 Interaction with other medicinal products:

None.

4.6 Pregnancy and lactation:

None.

4.7 Effects on ability to drive and use machines:

None.

4.8 Undesirable effects:

As with other penicillins, side-effects are usually mild and transient including diarrhoea, indigestion and skin rashes.

4.9 Overdose:

None.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

FLUMOX is a combination of two bactericidal penicillins: amoxicillin (broad-spectrum penicillin) and flucloxacillin (penicillinase-resistant penicillin), to produce a wider spectrum of activity. Flucloxacillin exerts a bactericidal action on penicillinase-producing microorganism including most staphylococci. This combination exhibits bactericidal activity against a wide range of Gram-positive and Gram-negative microorganisms including penicillinase and non penicillinase-producing Staphylococci, *Streptococcus pyogenes*, *pneumoniae*, and *faecalis*, *Corynebacterium diphtheriae*, *Clostridium* spp., *Bacillus anthracis*; *H. influenzae*, *Moraxella (Branhamella) catarrhalis*, *N. gonorrhoeae* and meningitidis, *E. coli*, *Proteus mirabilis*, *Salmonella*, *Bordetella pertussis*. and *Bacteroides melaninogenicus*.

5.2 Pharmacokinetic properties:

Both amoxicillin and flucloxacillin are acid-stable and are well absorbed after oral administration. Amoxicillin is more rapidly absorbed than ampicillin producing higher plasma concentrations than those obtained with the same dose of ampicillin. Peak plasma concentrations of amoxicillin and flucloxacillin are achieved in about 1 to 2 hours after oral administration; and in about 30 minutes after parenteral administration. **FLUMOX** is widely distributed in body tissues and fluids. Amoxicillin and flucloxacillin are metabolized to a limited extent, and the unchanged drugs and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion and also in bile.

6. Pharmaceutical particulars:

6.1 List of inactive ingredients:

Maize starch, microcrystalline cellulose PH 101, Talc, purified, colloidal silicon dioxide (Aerosil 200), magnesium stearate, gelatin, titanium dioxide, brilliant blue, carmosine, quinolone, sunset yellow, Erythrosine.

6.2 Incompatibilities:

None known

6.3 Shelf life:

2 years.

6.4 Special precautions for storage:

Store at temperature not exceeding 25°C.

6.5 Nature and contents of container:

FLUMOX Dry Mix, bottles of 60 or 100 ml after reconstitution.

6.6 Special precautions for disposal and other handling:

Any unused medicine or waste material should be disposed of by taking to your local pharmacy.

7. Marketing authorization holder:

EIPICO

8. Date of revision of the text:

March 2021.