

## Summary of product characteristics

# Flumox Capsules

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## **1. Name of the medicinal product:**

Flumox 500mg Capsules

## **2. Qualitative and quantitative composition:**

Each capsule contains: Amoxicillin (as trihydrate) 250mg and Flucloxacillin (as monohydrate) 250mg

For inactive ingredients see section 6.1

## **3. Pharmaceutical form:**

Capsules

## **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:**

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

### **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* s pp., *Bacillus anthracis*; *H. influenzae*, *Moraxella (Branhamella) catarrhalis*, *N. gonorrhoeae* and meningitidis, *E. coli*, *Proteus mirabilis*, *Salmonella*, *Bordetella pertussis*. and *Bacteroides melaninogenicus*.

#### **5.2 Pharmacokinetics 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, talc purified, magnesium stearate, colloidal silicon dioxide (Aerosil 200), gelatin, methyl paraben, propyl paraben, sodium lauryl sulfate, aerosol, titanium dioxide, quinalone yellow, carmoisine red, brilliant blue, sunset yellow.

#### **6.2 Incompatibilities:**

None known

#### **6.3 Shelf life:**

3 years.

#### **6.4 Special precautions for storage:**

Store at temperature not exceeding 25°C.

#### **6.5 Nature and contents of container:**

**FLUMOX 500 mg capsule, -Blisters of 8 capsules each.**  
-Boxes of 8,16 capsules.

**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.