

**SCHEDULING STATUS:**

**S4**

**PROPRIETARY NAME (and dosage form):**

**INDO FLUCLOXACILLIN - 250 (CAPSULES)**

**COMPOSITION:**

Each INDO FLUCLOXACILLIN - 250 capsule contains flucloxacillin sodium equivalent to 250 mg flucloxacillin.

**PHARMACOLOGICAL CLASSIFICATION:**

A 20.1.2 Penicillins

**PHARMACOLOGICAL ACTION:**

*Pharmacodynamic properties:*

Flucloxacillin is a semi-synthetic penicillin derived from 6-amino-penicillanic acid and is a penicillinase stable penicillin. Flucloxacillin exhibits bactericidal activity against all Gram-positive organisms (with the exception of *Streptococcal faecalis*), including organisms sensitive to penicillin e.g. Haemolytic Streptococci, Staphylococci, *Streptococcus pneumoniae* and *N. gonorrhoea*. *In vitro* efficacy does not imply *in vivo* efficacy.

Flucloxacillin's anti-staphylococcal activity is not affected by penicillinase.

*Pharmacokinetic properties:*

Flucloxacillin is well absorbed orally. A single dose of 250 mg achieves an average peak serum concentration virtually equal to that achieved by an equivalent intramuscular (IM) injection. Peak serum concentration is achieved half to one hour after administration.

Approximately 60 % of an oral dose is excreted unchanged in the active form into the urine within 6 hours.

**INDICATIONS:**

INDO FLUCLOXACILLIN - 250 is indicated in the treatment of infections caused by susceptible Gram-positive organisms, including beta-lactamase producing staphylococci and streptococci:

- Skin and soft tissue infections
- Infected wounds and burns
- Otitis media
- Urinary tract infections
- Respiratory tract infections caused by penicillinase producing organisms
- Orthopaedic infections
- Septicaemia
- Meningitis
- Endocarditis
- Enterocolitis

**CONTRA-INDICATIONS:**

Flucloxacillin is contra-indicated in the following conditions:

Known hypersensitivity to penicillin or cephalosporins. Cases of cross-sensitivity have been reported.

**WARNINGS:**

Anaphylactic reactions can occur which may be fatal at times. Neutropenia has been reported in patients receiving high doses of the medicine. The warning signs include fever, rash and eosinophilia.

**INTERACTIONS:**

Interacts with bacteriostatic antibacterials such as chloramphenicol, and tetracycline.

**PREGNANCY AND LACTATION:**

Safety in pregnancy has not yet been established. INDO FLUCLOXACILLIN - 250 is excreted in breast milk.

**DOSAGE AND DIRECTIONS FOR USE:**

The oral dose should be taken 1 hour before meals, to ensure that maximum absorption is achieved.

*Adults:*

The usual adult dose by mouth is 250 mg four times daily. Doses may be doubled in severe infections; up to 8 g daily in three or four divided doses may be given for endocarditis and osteomyelitis.

*Renal impairment:*

For patients with a creatinine clearance value < 10 ml/min, consider a dose reduction or extension of dose interval. For patients with a creatinine clearance value > 10 ml/min, no dose adjustment is necessary.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Frequent:	<i>Gastrointestinal disorders:</i>	Nausea, vomiting and diarrhoea.
	<i>Skin and subcutaneous tissue disorders:</i>	Hypersensitivity reactions such as skin rashes.

<b>SIDE-EFFECTS AND SPECIAL PRECAUTIONS:</b>		
Less frequent:	<i>Gastrointestinal disorders:</i>	Pseudomembranous colitis.
	<i>Skin and subcutaneous tissue disorders:</i>	Hypersensitivity reactions such as anaphylaxis, angioedema, urticaria and maculopapular rashes, and late reactions which may include serum-sickness like reactions and haemolytic anaemia.
	<i>Blood and lymphatic system disorders</i>	Haemolytic anaemia, neutropenia, prolongation of bleeding time, defective platelet function, convulsions.
	<i>Hepatobiliary disorders:</i>	Hepatitis and cholestatic jaundice.
	<i>Miscellaneous:</i>	Signs of central nervous system toxicity and electrolyte disturbances have been observed.
		Patients with syphilis and other spirochaete infections may experience a Jarish Herxheimer reaction, the symptoms include fever, chills, headache and reactions at the site of the lesion. The reaction can be dangerous in cardiovascular syphilis or where there is a serious risk of increased local damage such as with optic atrophy.
		A sore mouth or black hairy tongue has been occasionally reported.

*Special precautions:*

INDO FLUCLOXACILLIN - 250 should be given with caution to patients with a history of hypersensitivity, especially to medicines.

Care is necessary in patients with poor renal function because of the risk of neurotoxicity. Hence, renal and haematological status should be monitored during prolonged and high dose therapy.

Care should be taken when treating patients with spirochaete infections, particularly syphilis because of the Jarish Herxheimer reaction.

Contact with skin should be avoided since skin sensitisation may occur.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Problems with overdosage are unlikely to occur. If encountered, gastrointestinal symptoms and disturbances of the fluid and electrolyte balance may be evident. They may be treated symptomatically with attention to water/electrolyte balance. INDO FLUCLOXACILLIN - 250 cannot be removed from circulation by haemodialysis.

As with all penicillins, oral administration can cause gastrointestinal symptoms such as transient diarrhoea, nausea, and colic which are dose related and as a result of local irritation and not toxicity.

**IDENTIFICATION:**

INDO FLUCLOXACILLIN - 250 is a grey/caramel coloured hard gelatine size '2' capsule. The capsule contains an off-white granular powder.

**PRESENTATION:**

INDO FLUCLOXACILLIN - 250:

Capsules are packed in an aluminium foil blister strip containing ten capsules. Two, four or ten blister strips are packed in an outer carton.

Capsules are packed in patient ready pack pouches containing 20 or 40 capsules.

Capsules are also packed in a polyethylene bag in a white HDPE container, sealed with an aluminium foil seal and a HDPE cap, containing 100 or 1000 capsules.

**STORAGE INSTRUCTIONS:**

The containers should be kept tightly closed in a cool (below 25°C), dry place. Keep the blisters in the outer carton until required for use.

Keep out of reach of children.

**REGISTRATION NUMBERS:**

INDO FLUCLOXACILLIN - 250: A40/20.1.2/0286

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Unimed Healthcare (Pty) Ltd

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