Package Insert

Scheduling status: **S4**

Proprietary names and dosage forms:

SANDOZ FLUCLOXACILLIN 250 (capsules)

Composition:

Each Sandoz Flucloxacillin 250 Capsule contains: Flucloxacillin sodium equivalent to 250 mg flucloxacillin.

Sugar free.

Pharmacological classification:

A 20.1.2 Penicillins

Pharmacological action:

Flucloxacillin is a semi-synthetic, penicillinase-stable penicillin with bactericidal activity against Gram-positive organisms, particularly penicillinase-producing strains of *Staphylococcus aureus*.

Indications:

Infections caused by penicillinase producing staphylococci.

Contra-indications:

Allergy to penicillins.

Warnings and Special Precautions:

The use of this antibiotic may lead to the appearance of resistant strains of organisms, and sensitivity testing should therefore be carried out whenever possible to ensure the appropriateness of the therapy.
Oral administration can cause gastrointestinal symptoms such as diarrhoea, nausea, heartburn and colic, pruritus ani, and disturbances of electrolyte balance, which are dose-related and a result of local irritation.

It should be given with caution to patients with known histories of allergy.

Cholestatic hepatitis has been reported rarely.

Dosage and Directions for Use:

Usual adult dose: 250 mg every six hours, one hour before meals.

Side Effects:

Allergic reactions may occur, presenting as a pruritic skin rash, an erythematous skin reaction or urticaria, fever, eosinophilia, joint pains, angioneurotic oedema, or exfoliative dermatitis. Should a serious anaphylactic reaction occur, flucloxacillin should be discontinued and the patient treated with the usual agents: adrenalin, corticosteroids and antihistamines.

Known symptoms of overdosage and particulars of its treatment:

See “Side effects and special precautions”.

Treatment is symptomatic and supportive.

Identification:

Black and yellow opaque, size 2, hard gelatin capsules.

Presentations:

Amber glass bottles or securitainers with 20, 40 or 100 capsules.

Storage instructions:

Store tightly closed in a dry place at or below 25 °C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

Registration numbers:

T/20.1.2/33

Name and business address of the holder of the certificates of registration:

Sandoz SA (Pty) Ltd.[1]
72 Steel Road
Spartan
Kempton Park
1619
South Africa

Date of publication of this package insert:

16 May 1989

[1]Company Reg. No.: 1990/001979/07
Marketed by Cipla Medpro (Pty) Ltd

Additional countries registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Botswana	Sandoz Flucloxacillin 250	S2	B9309015
Namibia	Sandoz Flucloxacillin 250	NS2	90/20.1.2/001471

ATC Code: J01CF05 – Beta-lactamase resistant penicillins

Name and address of manufacturer:

Medreich Sterilab Limited
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