SCHEDULING STATUS:
S4

PROPRIETARY NAME (and dosage form):
SEPTAPEN 250 (capsules)

COMPOSITON:
SEPTAPEN 250
Hard gelatin capsules containing flucloxacillin sodium equivalent to 250 mg flucloxacillin per capsule.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.2 Penicillin

PHARMACOLOGICAL ACTION:
SEPTAPEN 250 is a semi-synthetic, penicillinase-stable penicillin derived from 6-amino-penicillanic acid.

Bacteriology
SEPTAPEN 250 exhibits bacterial activity against all Gram-positive organisms (with the exception of Strep. faecalis) e.g. haemolytic streptococci, staphylococci, Streptococcus pneumoniae and N. gonorrhoeae.

SEPTAPEN 250 anti-staphylococcal activity is not affected by penicillinase and as **SEPTAPEN 250** is active against virtually all strains of Staph. aureus (methicillin-resistant strains being the only exception), it is primarily indicated in the treatment of staphylococcal infections.
The minimum inhibitory concentrations of benzylpenicillin against staphylococci are lower than those of flucloxacillin except in the case of the penicillinase producing staphylococci.

Absorption
SEPTAPEN 250 is very well absorbed orally. A single 250 mg oral dose achieves an average peak serum level virtually equal to that achieved by an equivalent IM injection. The peak serum level is achieved half to one hour after administration.

SEPTAPEN 250 should be taken 1 hour before meals to ensure that maximum absorption is achieved.

Excretion
Approximately 60 % of an oral dose and 90 % of an intramuscular and intravenous dose of **SEPTAPEN 250** is excreted unchanged in the active form into the urine within 6 hours.

Probenecid
Even higher **SEPTAPEN 250** serum levels may be achieved after oral administration in patients with normal renal function by the simultaneous administration of a renal blocking agent such as probenecid. Probenecid should not be given in the presence of abnormal renal function.

INDICATIONS:
Infections caused by susceptible organisms, including:
- Skin and soft tissue infections, infected wounds and burns and otitis media
- Urinary tract infections
- Respiratory tract infections caused by penicillinase-producing organisms
- Orthopaedic iinfections-septicaemia
- Meningitis, endocarditis and enterocolitis

CONTRA INDICATIONS:
Allergy to penicillins is an absolute contra indication to the use of **SEPTAPEN 250.** Not to be used topically in the eye.

DOSAGE AND DIRECTIONS FOR USE:
Should be taken one hour before meals.

Adults 250 mg
1 capsule 4 times a day preferably 1 hour before meals.
Skin and soft tissue infections
Up to 8 g daily in divided doses, six to eight hourly, one hour before meals.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
- Attention should be paid to possible cross-sensitivity with other p-lactam antibiotics, e.g. Cephalosporins.
- Allergic reactions may occur. These may present as a pruritic skin rash, an erythematous skin reaction or urticaria. If a skin rash occurs, treatment should be discontinued and administration of an antihistamine considered. An anaphylactic reaction after administration of a penicillin can occur.
  If this happens, treatment should be stopped and appropriate treatment with adrenaline, corticosteroids and antihistamines commenced immediately.
- Prolonged use may result in the overgrowth of non-susceptibleorganisms. Gastro-intestinal upsets (e.g. nausea, colic, diarrhoea) have been reported. As with other penicillins, pseudomembranous colitis has been reported.
- Hepatitis and cholestatic jaundice have been reported.
- Use in pregnancy: Safety in pregnancy has not yet been established.
- **Use in lactation:**
  SEPTAPEN 250 is excreted in the breast milk.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
If encountered, gastro-intestinal symptoms and disturbances of the fluid and electrolyte balance may be evident. They may be treated symptomatically with attention to the water/electrolyte balance. Flucloxacillin cannot be removed from the circulation by haemodialysis.

IDENTIFICATION:
SEPTAPEN 250: Black/Red hard Gelatin capsule.

PRESENTATION:
20's and 40's printed Alu/LDPE patient ready packs.
Securitainers containing 100 capsules.

STORAGE:
SEPTAPEN 250: Store in a cool dry place at or below 25 ^{0}C
Protect from light and moisture.

REGISTRATION NUMBER
SEPTAPEN 250: A29/20.1.2/0550

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Innovata Pharmaceuticals (Pty) Ltd
Crownwood Office Park,
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2091
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22/09/2021

SKEDUIERINGSTATUS:
S4

EIENDOMSNAAM (en doseervorm)
SEPTAPEN 250 (kapsules)

SAMESTELUNG:
SEPTAPEN 250
Harde gelatienkapsules wat natriumflukloksasillien bevat gelykstaande aan 250 mg flukloksasillien per kapsule.

FARMAKOLOGIESE KIASSIFIKASIE
A 20.1.2 Penisillien

FARMAKOLOGIESE WERKING
SEPTAPEN 250 is 'n semi-sintetiese, penisillinase-stabiele penisillien wat 'n derivaat is van 6-amino-penisillaansuur.

Bakteriologie
SEPTAPEN 250 toon bakteriese aktiwiteit teen alle Gram-positiewe organismes (met die uitsondering van Strep. faecalis), soos byvoorbeeld:
Hemolitiese streptokokke, stafilokokke, Streptococcus pneumoniae en N. gonorrhoeae.
SEPTAPEN 250 se aktiwiteit teen stafilokokke word geensins deur penisillinase beïnvloed nie en aangesien **SEPTAPEN 250** teen bykans alle stamme van Staph. aureus aktief is (met nie-vatbare metisillienstamme die enigste uitsondering), word dit veral vir die behandeling van stafilokok-infeksies aanbeveel.
Die minimum inhiberende konsentrasies van bensielpenisillien is laer teen stafilokokke as die van flukloksasillien behalwe in die geval van penisillinase produserende stafilokokke.

Absorpsie
SEPTAPEN 250 word besonder goed mondelik geabsorbeer. Na 'n mondelike toediening van 'n enkele 250 mg dosis is die gemiddelde kruinserumpeil feitlik dieselfde as die wat deur 'n ekwivalente binnespierse inspuiting bereik word.
Die kruinserumpeil word 'n half- tot een uur na toediening bereik.
Om te verseker dat maksimum absorpsie na mondelike toediening verkry word, moet **SEPTAPEN 250** 1 uur voor etes geneem word.

Uitskeiding
Ongeveer 60 % van 'n mondelike dosis en 90 % van 'n binnespierse en binneaarse dosis van **SEPTAPEN 250** word binne 6 uur onveranderd in die aktiewe vorm in die urien uitgeskei.

Probenesied
Selfs hoër **SEPTAPEN 250** -serumvlakke kan bereik word na orale toediening by pasiënte met normale nierfunksie deur die gelyktydige toediening van 'n nierblokkerende middel, soos probenesied. Probeneied moet nie in die teenwoordigheid van abnormale nierfunksie toegedien word nie.

INDIKASIES
Infeksies veroorsaak deur vatbare organismes, met inbegrip van:
- Infeksies van die vel en sagteweefsel, besmette wonde en brandwonde en otitis media
- Urienweginfeksies
- Lugweginfeksies veroorsaak deur penisillinase-produserende organismes
- Ortopediese infeksies-Septisemie
- Meningitis, endokarditis en enterokolitis

KONTRA-INDIKASIES
Allergie vir penisilliene is 'n absolute kontra-indikasie vir die gebruik van **SEPTAPEN 250**.
Moet nie plaaslik in die oog gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS
Elke dosis moet een uur voor etes geneem word.
Volwassenes 250 mg
1 kapsule 4 maal per dag, verkieslik 1 uur voor etes.
Vel- en sagteweefseiinfeksies
Tot 8 g daagliks in verdeelde dosisse, ses- tot agtuurliks, een uur voor etes.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAA TREELS
- Aandag moet geskenk word aan moontlike kruisgevoeligheid vir ander β-laktamantibiotika bv. kefalosporiene.
- Allergiese reaksies kan voorkom. Hierdie kan as 'n pruritiese veluitslag, 'n eriteemagtige velreaksie of urtikaria manifesteer. Indien 'n veluitslag voorkom, moet behandeling gestaak word en die toediening van 'n antihistamien oorweeg word.
  'n Anafilaktiese reaksie kan voorkom na die toediening van 'n penisillien. Indien dit voorkom, moet behandeling gestaak word en toepaslike behandeling met adrenalien, kortikostero'iede en antihistamiene onmiddellik begin word.
- Verlengde gebruik kan die oorgroei van nie-vatbare organismes tot gevolg he,
  Gastro'intestinale ongesteldhede (bv. naarheid, koliek, diaree) is aangemeld.
  Soos met ander penisilliene is pseudomembraneuse kolitis aangemeld,
- Hepatitis en cholestatiese geelsug is aangemeld,
- Gebruik tydens swangerskap: Veiligheid gedurende swangerskap is nog nie vasgestel nie.
- **Gebruik tydens laktasie:**
  SEPTAPEN 250 word in moedersmelk uitgeskei.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Indien dit voorkom, kan dit die vorm aanneem van gastroïntestinale simptome en versteurings van die vloeistof- en elektrolietbalans. Dit kan simptomaties behandelword met aandag aan die water- /elektrolietbalans, Flukloksasillien kan nie deur hemodialise uit die bloedsomloopstelsel verwyder word nie.

IDENTIFIKASIE
SEPTAPEN 250: Swart/Rooi harde gelatien kapsules

AANBIEDING
20's en 40's Alu/LDPE gedrukte pasiënt-gereed pakkette.
Sekuritainers bevat 100 kapsules.

BERGINGSAANWYSINGS
Berg by of benede 25 °C in 'n droë plek.
Beskerm teen lig en vog.

REGISTRASIENOMMER
SEPTAPEN 250: A29/20.1.2/0550

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT
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