

255 mm

SCHEDULING STATUS **S4**

PROPRIETARY NAME (AND DOSAGE FORM)
Flucloxacillin 250 mg Oethmaan (Capsule)

COMPOSITION

Each capsule contains flucloxacillin sodium equivalent to 250 mg flucloxacillin.
Sugar free.
Excipients: Colloidal anhydrous silica, gelatin, iron oxide black, iron oxide red, iron oxide yellow, magnesium stearate and titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION

A20.1.2 Penicillins

PHARMACOLOGICAL ACTION

Pharmacodynamic properties: Flucloxacillin is a semi-synthetic isoxazolyl penicillin which is resistant to hydrolysis by staphylococcal penicillinase. Flucloxacillin exhibits bactericidal activity against Gram-positive organisms, particularly penicillinase producing strains of *Staphylococcus aureus*.

Pharmacokinetic properties:

Absorption: Flucloxacillin is rapidly but incompletely absorbed from the gastrointestinal tract. 30 – 50 % is absorbed and a peak serum concentration of 6–10 mcg/ml is attained 1 hour after administration of a 250 mg oral dose. Absorption is more efficient when flucloxacillin is taken on an empty stomach and should preferably be administered one hour before or two hours after meals to ensure better absorption. 84 % of flucloxacillin is plasma protein bound.
Elimination: 50–65 % of flucloxacillin is excreted unchanged by the kidney in the first six hours after a conventional oral dose. The half-life of flucloxacillin is 0,7 – 1,3 hours when creatinine clearance is >50 ml/min.

INDICATIONS

Flucloxacillin 250 mg Oethmaan is indicated for the treatment of infections caused by penicillinase producing staphylococci.

CONTRAINDICATIONS

Flucloxacillin 250 mg Oethmaan is contraindicated in patients with hypersensitivity to penicillins, any other beta-lactam antibiotics, or any of the capsule ingredients.

WARNINGS AND SPECIAL PRECAUTIONS

Before initiating therapy with Flucloxacillin 250 mg Oethmaan, careful enquiry should be made concerning previous hypersensitivity reactions with beta-lactam antibiotics (see "CONTRAINDICATIONS").

Flucloxacillin 250 mg Oethmaan is associated rarely with an increased risk of hepatitis and cholestatic jaundice. In some patients, almost always those with serious underlying hepatic disease, fatalities have occurred. The onset of hepatic adverse effects may be delayed for up to 2 months after stopping treatment, and is not related to the dose or to the route. Older patients and those receiving treatment for more than 2 weeks are at increased risk. Flucloxacillin 250 mg Oethmaan should not be used in patients with a history of hepatic dysfunction related to its use, and should be used only with caution in patients with evidence of other hepatic impairment.

Flucloxacillin 250 mg Oethmaan has been associated with acute attacks of porphyria and is considered unsafe in porphyric patients.

Special precautions:

Flucloxacillin 250 mg Oethmaan should be used with caution in patients with a known history of allergies.
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.

Effects on ability to drive and use machines:

Adverse effects on the ability to drive or operate machinery have not been observed.

INTERACTIONS

Concurrent use of other hepatotoxic medicines with Flucloxacillin 250 mg Oethmaan may increase the potential for hepatotoxicity. Probenecid decreases the renal tubular secretion of penicillins when used concurrently. This effect results in increased and prolonged serum concentrations, prolonged elimination half-life, and increased risk of toxicity.

PREGNANCY AND LACTATION

Pregnancy:

The safety of Flucloxacillin 250 mg Oethmaan for use in human pregnancy has not been established. Flucloxacillin 250 mg Oethmaan should be used in pregnancy only if the potential benefit outweighs the risk to the foetus.

Lactation:

Flucloxacillin 250 mg Oethmaan is distributed into human breast milk. Although significant problems have not been documented, the use of Flucloxacillin 250 mg Oethmaan by nursing mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

INDICATIONS AND DIRECTIONS FOR USE

Usual adult dose:

250 mg every six hours, one hour before meals.

Patients with renal impairment:

Patients with impaired renal function do not generally require a reduction in dose unless the impairment is severe.

SIDE EFFECTS

The following side effects have been reported:

Infections and infestations:

More frequent Oral candidiasis, vaginal candidiasis.

Blood and lymphatic system disorders:

The following side effects have been reported but their frequencies are unknown: Agranulocytosis, leukopenia or neutropenia.

Immune system disorders:

Less frequent: Anaphylaxis, allergic reactions presenting as a pruritic skin rash, an erythematous skin reaction or urticaria, fever, eosinophilia, joint pains, angioneurotic oedema, or exfoliative dermatitis.

Should an allergic or anaphylactic reaction occur, Flucloxacillin 250 mg Oethmaan should be discontinued and the appropriate treatment instituted.

The following side effects have been reported but their frequencies are unknown: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.

Metabolism and nutrition disorders:

The following side effects have been reported but their frequencies are unknown: Disturbances of electrolyte balance. Acute attacks of porphyria (see "WARNINGS AND SPECIAL PRECAUTIONS").

Nervous system disorders:

More frequent Headache.

The following side effect has been reported but its frequency is unknown: Seizures.

Gastrointestinal disorders:

More frequent Diarrhoea, nausea, vomiting.

The following side effects have been reported but their frequencies are unknown: Heartburn, colic, pruritus ani, *Clostridium difficile* colitis.

Hepato-biliary disorders:

The following side effects have been reported but their frequencies are unknown: Hepatotoxicity, hepatitis and cholestatic jaundice (see "WARNINGS AND SPECIAL PRECAUTIONS").

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is symptomatic and supportive. Flucloxacillin 250 mg Oethmaan is not removed from the circulation to a significant degree by hemodialysis.

IDENTIFICATION

Size 2, caramel and black coloured hard gelatin capsule filled with white to almost white granular powder.

PRESENTATION

20, 28, 40 and 100 capsules packed in opaque white PVC/silver aluminium foil blister strips packed in cardboard cartons.

20, 40 and 100 capsules packed in aluminium laminated Patient-Ready-Packs (PRP) pouch.

100 capsules packed in securitainers.

STORAGE INSTRUCTIONS

Store in a dry place, at or below 25 °C.

Do not remove the blister from the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

44/20.1.2/0816

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

Oethmaan Biosims (Pty) Ltd

14 Komatjie Road

Emmarentia

Johannesburg, 2195

DATE OF PUBLICATION OF THE PACKAGE INSERT

Date of registration: 06 March 2014

Date of revision: 15 November 2017

SKEDULERINGSSTATUS **S4**

EIENDOMSNAAM (EN DOSEERVORM)
Flucloxacillin 250 mg Oethmaan (Kapsule)

SAMESTELLING

Elke kapsule bevat natriumflukloksasiliën ekwivalent aan 250 mg flukloksasiliën.

Suikervry.

Ander bestanddele is: Kolloïdale anhidiese silika, gelatien, swart ysteroksied, rooi ysteroksied, geel ysteroksied, magnesiumstearaat en titaniumdioxide.

FARMAKOLOGIESE KLASSIFIKASIE

A20.1.2 Penisilliene

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe:

Flukloksasiliën is 'n semi-sintetiese isoksazoliel penisilliën wat weerstandig is teen hidrolise van staflokokkale penisilliëne. Flukloksasiliën openbaar bakteriedodende aktiwiteit teenoor Gram-positiewe organismes, veral penisilliëne produseerende stamme van *Staphylococcus aureus*.

Farmakokinetiese eienskappe:

Absorpsie: Flukloksasiliën word vinnig, maar onvolledig uit die gastro-intestinale kanaal geabsorbeer. 30 – 50 % word geabsorbeer en piek serumkonsentrasies van 6–10 mcg/ml word 1 uur na toediening van 'n 250 mg mondelike dosis bereik. Absorpsie is meer effektief wanneer flukloksasiliën op 'n leë maag geneem word en moet verkieslik 1 uur voor of twee ure na 'n maaltyd geneem word om beter absorpsie te verseker. 84 % van flukloksasiliën is plasmaproteïengebond.

Eliminasie: 50–65 % flukloksasiliën word onveranderd in die eerste ses ure na in konvensionele mondelike dosis deur die niere uitgeskei. Die halfleefyd van flukloksasiliën is 0,7 – 1,3 uur wanneer kreatienopruiming > 50 ml/min is.

INDIKASIES

Flucloxacillin 250 mg Oethmaan word aangedui vir die behandeling van infeksies wat veroorsaak word deur penisilliëne produseerende staflokokki.

KONTRA-INDIKASIES

Flucloxacillin 250 mg Oethmaan is teenaangedui by pasiënte met 'n hipersensitiewe vir penisilliëne, enige ander beta-laktaam antibiotika, of enige van die kapsule bestanddele.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Alvorens terapie met Flucloxacillin 250 mg Oethmaan geïnisieer word, moet versigtig ondersoek ingestel word rakende vorige hipersensitiewe reaksies met beta-laktaam antibiotika (sien "KONTRA-INDIKASIES").

Flucloxacillin 250 mg Oethmaan word seld met 'n verhoogde risiko van hepatitis en cholestatiese geelsg geassosieer. In sommige pasiënte, amper altyd die met ernstige onderliggende hepatiese siektes, het sterftes voorgekom. Die begin van hepatiese newe-effekte mag tot 2 maande nadat behandeling gestaak is, vertraag wees en dit is verwant aan die dosis of die toedieningsroete nie. Ouer pasiënte en die wat behandeling vir langer as twee weke ontvang, is 'n verhoogde risiko. Flucloxacillin 250 mg Oethmaan moet nie by pasiënte met 'n geskiedenis van hepatiese disfunksie gebruik word wat verband hou met die gebruik daarvan nie, en moet slegs met versigtigheid gebruik word by pasiënte met bewys van ander hepatiese inkorting.

Flucloxacillin 250 mg Oethmaan is geassosieer met akute aanvalle van porfirie en word as onveilig geag in pasiënte met porfirie.

Spesiale voorsorgmaatreëls:

Flucloxacillin 250 mg Oethmaan moet met versigtigheid by pasiënte met 'n geskiedenis van allergieë gebruik word.

Die gebruik van hierdie antibiotika mag tot die verskyning van weerstandige stamme van organismes lei, en sensitiwiteitstoets moet dus uitgevoer word wanneer nodig om die toepaslikheid van die behandeling te verseker.

Uitwerking op vermom op motors te bestuur of masjinerie te gebruik:

Nadelige uitwerking op die vermoë om te bestuur of masjinerie te gebruik is nog nie waargeneem nie.

INTERAKSIES

Die potensiaal vir hepatotoksiteit mag verhoog met die gelyktydige gebruik van ander hepatotoksiese medisyne saam met Flucloxacillin 250 mg Oethmaan.

Probenesid verminder die renale tubulêre sekresie van penisilliëne met gelyktydige gebruik. Hierdie effek lei tot verhoogde en verlengde serumkonsentrasies, verlengde eliminasië halfleefyd, en verhoogde toksisiteitsrisiko.

SWANGERSKAP EN LAKTASIE

Swangerskap:

Veiligheid van Flucloxacillin 250 mg Oethmaan in menslike swangerskap is nog nie bevestig nie. Flucloxacillin 250 mg Oethmaan moet net tydens swangerskap gebruik word indien die potensiele voordele die risiko aan die fetus oortref.

Laktasie:

Flucloxacillin 250 mg Oethmaan word in menslike borsmelk uitgeskei. Alhoewel beduidende probleme nog nie gedokumenteer is nie, mag die gebruik van Flucloxacillin 250 mg Oethmaan deur vroue wat borsvoed, tot sensitisasie, diaree, kandidiasis en veluitslag in die baba lei.

DOOS EN GEBRUIKSAANWYSINGS

Gewone volwasse dosis:

250 mg elke ses ure, een uur voor maaltye.

Pasiënte met nierinkorting:

Pasiënte met ingekorte nierfunksie benodig nie gewoonlik 'n verlaagde dosis nie, tensy die inkorting ernstig is.

NEWE-EFFEKTE

Die volgende newe-effekte is aangemeld:

Infeksies en infestaties:

Meer dikwels: Orale kandidiasis, vaginale kandidiasis.

Bloed- en limfasieestelsel versteurings:

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Agranulose, leukopenie of neutropenie.

Immuunstelselversteurings:

Minder dikwels: Anafilakse, allergiese reaksies in die vorm van 'n pruritiëse veluitslag, 'n eritemateuse vrelaksie of urtikarie, koors, eosinofilie, gewrigspyne, angioneurootiese oedeem of eksfoliatiewe dermatitis.

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Flucloxacillin 250 mg Oethmaan dadelik gestaak word en die nodige behandeling toegepas word.

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Erythema multiforme, Stevens-Johnson sindroom, toksiese epidermale nekrolise.

Metabolisme en voedselversteurings:

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Elektrolietbalans versteurings. Akute aanvalle van porfirie (sien "WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS").

Meer dikwels: Hoofpyn.

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Sluip.

Gastro-Intestinale versteurings:

Meer dikwels: Diaree, naarheid, braking.

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Soorbrand, koliek, pruritus ani, *Clostridium difficile* kolitis.

Hepatoese- en bilêre versteurings:

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend: Hepatotoksiteit, hepatitis en cholestatiese geelsg (sien "WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS").

Behandeling is simptomaties en ondersteunend. Flucloxacillin 250 mg Oethmaan word nie tot 'n beduidende mate deur hemodialise uit die sirkulasie verwyder nie.

IDENTIFIKASIE

Grootte 2, karamel en swart gekleurde harde gelatienkapsule, gevul met wit tot amper wit granulêre poeier.

AANBIEDING

20, 28, 40 en 100 kapsules verpak in ondeursigtige wit PVC/silwer aluminium-foelie-stuipstrokke in kartonhouers.

20, 40 en 100 kapsules verpak in aluminium-gelamineerde Pasiënt-Gereed-Pakke-sakke.

100 kapsules verpak in securitainers.

BERGINGSAAWYSINGS

Bewaar in 'n droë plek, by of benede 25 °C.

Maens- die stuijerpakkings uit die karton verwyder voordat dit vir gebruik benodig word nie.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIE-NOMMER

44/20.1.2/0816

NAAM EN BESIGHEIDSAADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Oethmaan Biosims (Pty) Ltd

Komatieweg 14 Emmarentia, 2195 Johannesburg

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBLIJET

Datum van registrasie: 06 Maart 2014

Datum van hersiening: 15 November 2017

IP142002

120 mm

120 mm