DAWA-FLOX®
INJECTION / CAPSULES / SYRUP

Composition:
Dawa-flox capsules: Each capsule contains flucloxacillin (as sodium) BP 250mg or 500mg.
Dawa-flox powder for oral syrup: Each 5 ml after reconstitution contains flucloxacillin (as sodium) BP 125mg or 250mg.
Dawa-flox powder for injection: Each vial contains flucloxacillin (as sodium) BP 250mg or 500mg.

Pharmacology:
Pharmacodynamics:
Flucloxacillin is a narrow spectrum antibiotic of the group of isoxazolylpenicillins. Its action on the synthesis of the bacterial wall exerts a bactericidal effect on streptococci, staphylococci, including the beta-lactamase-producing strains, clostridia and neisseria.

Pharmacokinetics:
Flucloxacillin is incompletely absorbed from the gastrointestinal tract. Absorption is reduced by the presence of food in the stomach. After an oral dose of 0.25 to 1 g, in fasting subjects, peak plasma concentrations in about 1 hour are usually in the range of 5 to 15 micrograms/mL. Plasma concentrations following the intramuscular injection of flucloxacillin sodium are similar, but peak concentrations are achieved in about 30 minutes. Doubling the dose can double the plasma concentration. About 95% of flucloxacillin in the circulation is bound to plasma proteins. It has a plasma half-life of approximately 1 hour. The half-life is prolonged in neonates. Flucloxacillin crosses the placenta and is distributed into breast milk. There is little diffusion into the CSF except when the meninges are inflamed. It is metabolised to a limited extent and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion. About 66% of a dose by mouth and 76% of a parenteral dose is excreted in the urine within 8 hours. Only small amounts are excreted in the bile.

Therapeutic indications:
Flucloxacillin is indicated for the treatment of infections due to Gram-positive organisms, including infections caused by β-lactamase producing staphylococci. It is also indicated in skin and soft tissue infections e.g. boils abscesses, carbuncles, furunculosis, cellulitis, infected wounds, infected burns, protection of skin grafts, and impetigo. Infected Skin Conditions: e.g. ulcer, eczema and acne.
Respiratory tract infections: Pneumonia, lung abscess, emphysema, sinusitis, pharyngitis, tonsillitis, quinsy, otitis media and externa.

Dosage and directions for use: Recommended dose is as shown below:-
Oral: To be taken at least 30 minutes before food.
Adults: 250–500 mg every 6 hours.
2–10 years: 125 – 250mg every 6 hours.
Children under 2 years: 62.5mg – 125mg every 6 hours.
Intramuscularly: Adults: 250–500 mg every 6 hours.
2–10 years: 125 – 250mg every 6 hours.
Children under 2 years: 62.5mg – 125mg every 6 hours.
By slow intravenous injection or by intravenous infusion:
Adults: 0.25–2 g every 6 hours
2–10 years: 0.125g – 1g.
Children under 2 years: 62.5mg – 500mg.
Endocarditis (in combination with another antibacterial):
Body-weight over 85 kg, 12 g daily in 6 divided doses.
Body-weight under 85 kg, 8 g daily in 4 divided doses.
Osteomyelitis: Up to 8 g daily in 3 – 4 divided doses.
Surgical prophylaxis: by slow intravenous injection or by intravenous infusion, 1-2 g at induction; up to 4 further doses of 500 mg may be given every 6 hours by mouth, or by intramuscular injection, or by slow intravenous injection or by intravenous infusion for high risk procedures.

Contra-indications:
Contraindicated in patients with a history of hypersensitivity to beta-lactam antibiotics (e.g. penicillins, cephalosporin) or any of the excipients. Also contra-indicated in patients with a previous history of flucloxacillin associated jaundice / hepatic dysfunction.

Pregnancy and Lactation:
Flucloxacillin can be used if the benefit outweighs the risks however not known to be harmful.

Special precautions & warnings:
Should not be used in hypersensitivity reactions to beta-lactams. Flucloxacillin should be used with caution in patients with evidence of hepatic dysfunction. Special caution is essential in the newborn because of the risk of hyperbilirubinemia, as there is a potential for high serum levels of flucloxacillin due to a reduced rate of renal excretion. Serious and less frequently, fatal anaphylactic reactions have been reported. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy.
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:
Hypersensitivity reactions: Rash, urticaria, purpura, fever, eosinophilia; sometimes angioneurotic oedema, and less frequently anaphylactic shock. Gastrointestinal reactions: Minor gastrointestinal disturbances may occur during treatment e.g. nausea, diarrhoea. Pseudomembranous colitis has been reported less frequently. Hepatic effects: Hepatitis and cholestatic jaundice have been reported. Renal effects: Interstitial nephritis may occur but is reversible when treatment is discontinued. Haematological effects: Neutropenia (including agranulocytosis) and thrombocytopenia may occur but are reversible when treatment is discontinued.

Drug interactions:
Flucloxacillin should not be administered simultaneously with bacteriostatic medications. Combination with aminoglycosides may result in a synergistic effect. Concurrent use with probenicid may result in increased and prolonged blood levels of flucloxacillin.

Over-dosage:
If encountered, gastro-intestinal symptoms and disturbances of the fluid and electrolyte balance may be evident. Oral administration can cause gastrointestinal symptoms such as transient diarrhoea, nausea and colic which are dose-related. Should be treated symptomatically with attention to the water / electrolyte balance.

Distribution Category: POM

Presentation:
Capsules: Blister pack of 3 x 10's in unit cartons, Blister pack of 5 x 10's in unit cartons, Blister pack of 10 x 10's in unit cartons, HDPE jars with 1000 and 500 capsules,
Oral syrup: Dry powder for reconstitution in 60ml or 100ml bottles.
Injection: Dry powder for reconstitution in 10ml vials

Storage conditions:
Store in a cool dry place, below 30^{0}C, protected from direct sunlight. *Dry syrup:* Once reconstituted, store preferably in a refrigerator, Do not freeze. To be used within 7 days after reconstitution. Keep all medicines out of reach of children.

Manufactured by:

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Ref: DWF/LL/05/19 Date of issue: May 2019