Clamo Powder for Syrup 457mg/5ml

COMPOSITION: Each 5ml or sachet contains:

Main ingredient:

Amoxicillin (as trihydrate)……400mg(potency)

Clavulanate Potassium, Diluted…….137mg

as potassium clavulanate 57mg

Excipient: with Microcrystalline Cellulose

PHARMACOLOGY:

1.Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in Clamo anticipates this defence mechanism by blocking the β-lactamase enzymes, thus rendering the organisms sensitive to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body.
Clavulanate by itself has little antibacterial activity: however, in association with amoxicillin as Clamo, it produces an antibiotic agent of broad spectrum with wide application in hospital and general practice.
Clamo is bactericidal to a wide range of organisms including:
Gram-positive
Aerobes: Bacillus anthracis*, Corynebacterium species, Enterococcus faecalis*, Enterococcus faecium*, Listeria monocytogenes, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, Streptococcus agalactiae, Streptococcus species, Staphylococcus aureus*, Coagulase negative staphylococci* (including Staphylococcus epidermidis). Anaerobes: Clostridium species, Peptococcus species, Peptostreptococcus.
Gram-negative
Aerobes: Bordetella pertussis, Brucella species, Escherichia coli*, Gardnerella vaginalis, Haemophilus influenzae*, Helicobacter pylori, Klebsiella species*, Legionella species, Moraxella catarrhalis* (Branhamella catarrhalis), Neisseria gonorrhoeae*, Neisseria meningitides*, Pasteurella multocida, multocida, Proteus mirabills*, Proteus vulgaris*, Salmonella species*, Shigella species*, Vibrio cholera, Yersinia enterocolitica*.
Anaerobses: Bacteroides species* (including Bacteroides fragilis), Fusobacterium species*.
*Some members of these species of bacteria produce β-lactamase, rendering them insensitive to amoxicillin alone.
Infections caused by amoxicillin susceptible organisms are amenable to Clamo treatment due to its amoxicillin content.
Mixed infections caused by amoxicillin-susceptible organisms in conjunction with Clamo –susceptible β-lactamass producing organisms may therefore be treated with Clamo.
2.The pharmacokinetics of the two components of Clamo are closely matched both clavulanate and amoxicillin have low levels of serum binding：about 70% remains free in the serum.
Doubling the dosage of Clamo approximately doubles the serum levels achieved.

INDICATIONS:

Short-term treatment of bacterial infections at the following sites：Upper respiratory tract infection (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media.
Lower respiratory tract infections e.g. acute and chronic bronchitis.lobar and bronchopneumonia.
Genito-uninay tract infection e.g. cystitis. urethritis , pyelonephritis.
Skin and soft tissue infection, e.g. boils, abscesses, cellulites, wound infections.
Bone and joint infections e.g. osteomyelitis.

DRUG INTERACTION:

Prolongation of bleeding time and prothrombin time have been reported in some patients receiving Clamo. Clamo should be used with care in patients on anti-coagulation therapy. In common with other broad-spectrum antibiotics, Clamo may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with Clamo may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.
Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reaction. There are no data on the concomitant use of Clamo and allopurinol.

PREGNANCY AND LACTATION:

Use in Pregnancy
Reproduction studies in animals (mice and rats) with orally and parenterally administered Clamo have shown no teratogenic effects. There is limited information on the use of Clamo in human pregnancy. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.
Use in Lactation
Clamo may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there ate no detrimental effects for the infant.

ADBERSE EFFECTS:

Side effects, as with amoxicillin, are uncommon and mainly of a mild of a mild and transitory nature.

Gastrointestinal reactions
Effects include diarrhoea, indigestion, nausea and vomiting, Candidiasis, antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely. Nausea, although uncommon, is more often associated with higher oral dosages. If gastrointestinal side effects occur with oral therapy they may be reduced by taking Clamo at the start of meals. As with other antibiotics the incidence of gastrointestinal side effects may be raised in children under 2 years. In clinical trials, however, only 4% of children under 2 years were withdrawn from treatment.
Hepatic effects
A moderate rise in AST and/or ALT has been noted in patients with semi-synthetic penicillins but the significance of these findings is unknown. Hepatitis and cholestatic jaundice have been reported rarely with Clamo. They may however be severe and continue for several months. They are reported as occurring predominantly in adult or elderly patients and slightly more frequently in males.
Signs and symptoms may occur during treatment but are more frequently reported after cessation of therapy with a delay of up to six weeks. The hepatic events are usually reversible.
However, in extremely rare circumstances, deaths have been reported. Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.
Hypersensitivity reactions
Urticarial and erythematous rashes sometimes occur. Rarely erythema multiforme. Stevens- Johnson syndrome, toxic epidermal necrolysis and exfoliative dermatitis have been reported.
Treatment should be discontinued if one of these types of rash appears.
In common with other β-lactam antibiotics angioedema oedema, anaphylaxis serum sickness-like syndrome and hypersensitivity vasculitis have been reported.
Interstitial nephritis con occur rarely.
Haematological effects.
As with other β-lactams reversible leucopenia (including neutropenia or agranulocytosis)
Reversible thrombocytopenia and heamolytic anaemia have

Dental infections e.g. dentoalveolar abscess.
Other infection e.g. intra-abdominal sepsis.

DOSAGE AND ADMINISTRETION:
It should be used under doctor's prescription.
Dispenesing 12gm equivalent to 3.75gm(potency)of Clamo powder for oral suspension in 60-ml bottle with cold water to make a suspension with the final concentration of 62.5mg (potency)/ml which contains amoxicillin 50mg (potency)/ml and clavulanic acid 12.5mg (potency)/ml.
For children the usual recommended dosage is 50mg/kg/day in divided doses every eight hours, the table below presents guidance for children.
Under 1year: 50mg/kg/day,for example a 7.5kg child would require 2ml of Clamo powder for oral suspension, three times a day.
1～6year(10～18Kg):5ml of Clamo powder for oral suspension, three times a day.
over 6 years (18～40Kg):10ml of Clamo powder for oral suspension, three times a day.
In more serious infections the dosage may be increased up to 50mg/kg/day in divided doses every eight hours.

PRECAUTIONS:
Changes in liver function tests have been observed in some patients receiving Clamo.
The clinical significance of these changes is uncertain but Clamo should be used with caution in patients with evidence of hepatic dysfunction.
Cholestatic jaundice, which may be severe, but is usually reversible.has been reported rarely.
Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.
In patients with moderate or severe renal impairment Clamo dosage should be adjusted as recommend in the Dosage and administration section.
Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy. These reaction are more likely to occur in individuals with a history of penicillin hypersensitivity(see Contra-indications)
Erythematous rashes have been associated with glandular fever in patients following the use of amoxicillin Clamo should be avoided if glandular fever is suspected.
Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.
Clamo Oral suspension contain 2.0mg aspartame per 1ml dose and therefore care should be taken in phenylketonuria.

been reported rarely.
CHS effects
CNS effects have been seen very rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

OVERDOSAGE:
Cases of overdosage with Clamo are usually asymptomatic. If encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically with attention to the water electrolyte balance. Clamo can be removed from the circulation by haemodialysis.

STORAGE:
1. Clamo should be stored in a dry place at 25℃ or below.
2. Clamo should be stored in refrigerator (not in freeze) after dispensing and used within 7 days.

SPECIFICAITON:USP 32-NF 29 page-1544
REG NO.: VH-
PACKAGE: 35ml/bottle, 70ml/bottle, 1g/sachet.

SEE THE INSTRUCTION CAREFULLY BEFORE USE.

KEEP OUT OF REACH OF CHILOREN.

Manufacturer.

GP
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