

Meiact®

Cefditoren Pivoxil

Composition:

Meiact 200: Each tablet contains Cefditoren Pivoxil equivalent to 200 mg Cefditoren.
Meiact 400: Each tablet contains Cefditoren Pivoxil equivalent to 400 mg Cefditoren.
Excipients: Sodium Caseinate, Croscarmellose Sodium, Mannitol, Sodium Tripolyphosphate, Magnesium Stearate, Opadry, Carnuba wax.

Properties:

Cefditoren Pivoxil is a semi-synthetic cephalosporin antibiotic for oral administration, it is metabolized during absorption to Cefditoren, which has antibacterial activity against a wide spectrum of gram-positive and gram-negative bacteria. It also shows strong antibacterial activity against strains that produce β -lactamase.

Cefditoren inhibits the synthesis of bacterial cell wall, and has high affinity to penicillin binding proteins in various bacteria, showing a bactericidal effect.

After absorption, Cefditoren is mainly eliminated by excretion into the urine, with a renal clearance of approximately 4-5 L/h, which is reduced in patients with renal insufficiency.

Indications:

Meiact is indicated in the following infections caused by Cefditoren-susceptible strains of *Staphylococci*, *Streptococci* (including *Streptococcus pneumoniae*), *Peptostreptococcus* sp., *Moraxella catarrhalis*, *Propionibacterium acnes*, *Escherichia coli*, *Citrobacter* sp., *Klebsiella* sp., *Enterobacter* sp., *Serratia* sp., *Proteus* sp. (*Proteus mirabilis*, *Proteus vulgaris*), *Morganella* sp., *Providencia* sp., *Haemophilus influenzae* and *Bacteroides* sp.

- Respiratory tract infections:** Tonsillitis (peritonsillitis, peritonsillar abscess), Pharyngolaryngitis (throat abscess), Otitis media, sinusitis, acute bronchitis, acute bacterial exacerbation of chronic bronchitis, bronchiectasis with infection, secondary infection in chronic respiratory disease, pneumonia, pulmonary suppuration.
- Skin and soft tissue infections:** Folliculitis, furuncle, impetigo, contagiosa, erysipelas, phlegmon, lymphangitis (lymphadenitis), suppurative paronychia (paronychia), felon, subcutaneous abscess, hidradenitis, infectious atheroma, chronic pyoderma.
- Surgical Infections:** Mastitis, perianal abscess, superficial secondary infection in trauma, surgical wound.
- Urinary tract infections:** Pyelonephritis, cystitis.
- Gynecological Infections:** Uterine adnexitis, intrauterine infection, Bartholin's.
- Biliary tract infections:** Cholecystitis, cholangitis.
- Ophthalmological Infections:** Blepharitis, hordeolum, eyelid abscess, dacryocystitis, tarsaladenitis.
- Oral and dental surgical infections:** Periodontal tissue inflammation, pericoronitis, gnathitis.

Contraindications:

Meiact is contraindicated in patients with known hypersensitivity to any of its components, Cephalosporin antibiotics, milk protein, and carnitine deficiency.

Precautions:

- As for other antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms.
- Precautions should be taken in patients with poor intake or who are receiving parenteral alimentation, and patients in poor general health (Patients should be observed carefully because vitamin K deficiency symptoms such as bleeding tendency may develop).
- This drug should be administered to pregnant women, only if the expected therapeutic benefits outweigh the possible risks associated with treatment.
- This drug should be administered with care to patients who have a milk protein allergy.
- It has been reported that this drug decreases serum carnitine.
- Use with caution in patients with a history of penicillin allergy.
- It is not for long term therapy due to the possible development of carnitine deficiency over time.
- Safety and efficacy have not been established in children less than 12 years of age.

Interaction with other drugs:

The Co-administration of Cefditoren Pivoxil with antacids and H_2 -receptor antagonists will decrease the absorption of Cefditoren. The Co-administration of Cefditoren Pivoxil with probenecid will increase the plasma concentration of Cefditoren. Cefditoren Pivoxil has no effect on the pharmacokinetics of ethinyl estradiol (the estrogen component in most contraceptives).

Warnings:

Use cautiously in patients with renal or hepatic impairment. Like nearly all antibacterial agents (including Cefditoren Pivoxil) pseudomembranous colitis has been reported, therefore it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Dosage and Administration:

Cefditoren Pivoxil is administered orally with meals (to enhance GI absorption). The usual dosage of Cefditoren Pivoxil in adults and adolescent 12 years of age or older is 200-400 mg twice daily for 10 days in accordance with the severity of symptoms.

Overdosage:

No overdosage information about Cefditoren Pivoxil has been reported.

Adverse reactions:

Shock or anaphylactoid reaction: Unwell feeling, oral cavity discomfort, stridor, vertigo, defecation desire, tinnitus, diaphoresis.
Serious colitis with bloody stool such as pseudomembranous colitis: Abdominal pain, frequent diarrhea.
Stevens-Johnson syndrome (Muco-cutaneo-ocular syndrome) or Lyell syndrome (toxic epidermal syndrome).
Interstitial pneumonia, PIE syndrome accompanied with fever, cough, dyspnea, abnormal chest x-ray and eosinophilia.
Hepatic function disorder associated with jaundice, markedly increased AST (GOT), ALT (GPT) and A1-P.
Serious renal dysfunction such as acute renal failure.
Agranulocytosis or hemolytic anemia.
Hypersensitivity: Rash, urticaria, erythema, pruritus, fever, lymph node swelling and arthralgia.
Hematologic: Granulocytopenia, eosinophilia and thrombocytopenia.
Hepatic: Increased AST (GOT), ALT (GPT) and A1-P, jaundice.
Renal: Increased BUN, increased serum creatinine, proteinuria and hematuria.
Gastrointestinal: Diarrhea, loose stool, nausea, stomach discomfort, abdominal pain, feeling of enlarged abdomen and vomiting.
Microbial substitution: Stomatitis, candidiasis.
Avitaminosis: Vitamin K deficiency symptoms (hypoprothrombinemia, bleeding tendency), vitamin B complex deficiency symptoms (glossitis, stomatitis, anorexia and neuritis).
Others: Headache, dizziness, edema and numbness.
Consult your Pharmacist or Physician if any side effect is observed.

Pharmaceutical Precautions:

Keep at room temperature (15-30 °C). Do not use beyond the expiry date or if the product shows any sign of deterioration.

Presentation:

Meiact 200 : Pack of 20 Tablets.
Meiact 400 : Pack of 20 Tablets.

Further information is upon your request.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.

Under license from
Meiji Seika Kaisha, Ltd.



Manufactured by:
TABUK PHARMACEUTICAL MANUFACTURING COMPANY,
P.O. Box 3633, TABUK, SAUDI ARABIA.

Sept. 2003
24/05/1981