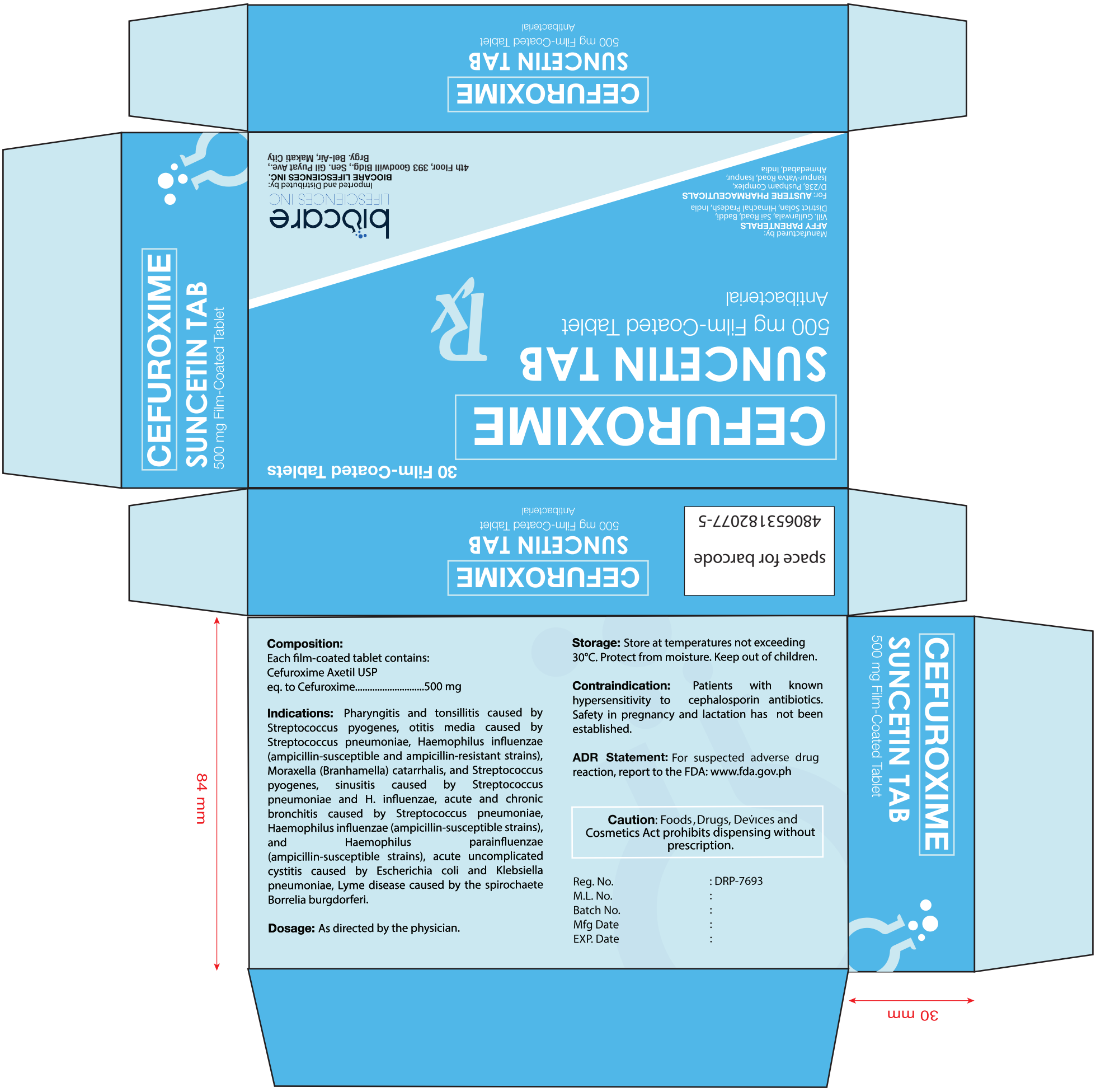
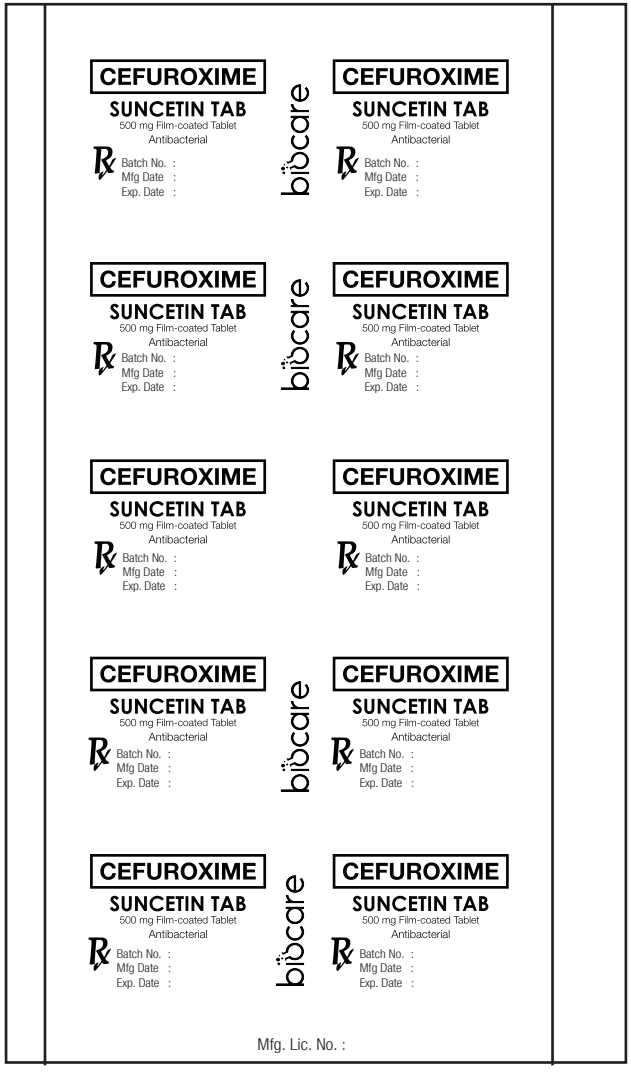
PANTONE PASTELS NEONS	
RGB	84, 184, 233
CMYK	64, 21, 0, 9
HEX	#54b8e9
PANTONE SOLID	
COATED	2915 C
UNCOATED	2915 U
PANTONE PASTELS NEONS	
COATED	915 C

PANTONE PASTELS NEONS	
RGB	203, 232, 239
CMYK	15, 3, 0, 6
HEX	#cbe8ef
PANTONE SOLID	
COATED	7457 C
UNCOATED	7457 U
PANTONE PASTELS NEONS	
COATED	9460 C



82 mm x 140 mm


CEFUROXIME
SUNCETIN TAB
500 mg Film-coated Tablet
Antibacterial
Batch No. :
Mfg Date :
Exp. Date :
bibcare
Mfg. Lic. No. :

PRINT
145 mm x 260 mm

CEFUROXIME

SUNCETIN TAB

500 mg Film-Coated Tablet
Antibacterial

FORMULATION:
Each film coated tablet contains:
Cefuroxime axetil USP Eq. to Cefuroxime.....500 mg

DESCRIPTION:
White to off white oval shaped film-coated tablets.

PHARMACOLOGICAL CLASSIFICATION
A 20.1.1. Broad and medium spectrum antibiotics.

PHARMACOLOGICAL ACTION
Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime.
The bacterial action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

PHARMACOKINETICS
After oral administration, cefuroxime axetil is absorbed from the gastro-intestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation. Optimum absorption occurs when it is administered after a meal. Peak serum levels (2-3 mg/mL for a 125 mg dose, 4-5 mg/mL for a 250 mg dose, 5-7 mg/mL for a 500 mg dose) occur approximately two to three hours after dosing when taken after food. The serum half-life is between 1 and 1.5 hours. Protein binding has been variously stated as 33-50% depending on the methodology used. Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50%. Serum levels of cefuroxime are reduced by dialysis.

INDICATIONS
Cefuroxime axetil is indicated for the treatment of patients with infections caused by susceptible strains of the designated organisms in the following diseases:
Pharyngitis and tonsillitis caused by Streptococcus pyogenes, Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefuroxime axetil is generally effective in the eradication of streptococci from the oral pharynx. Cefuroxime axetil is not indicated for the prophylaxis of subsequent rheumatic fever because data to support such use is not yet available.
Otitis media caused by Streptococcus pneumoniae. Haemophilus influenzae (ampicillin-susceptible and ampicillin-resistant strains), Moraxella (Branhamella) catarrhalis, and Streptococcus pyogenes.
Sinusitis caused by Streptococcus pneumoniae and H. influenzae.
Acute and chronic bronchitis caused by Streptococcus pneumoniae Haemophilus influenzae (ampicillin-susceptible strains), and Haemophilus parainfluenzae (ampicillin-susceptible strains).
Acute uncomplicated cystitis caused by Escherichia coli and Klebsiella pneumoniae.
Lyme disease caused by the spirochaete Borrelia burgdorferi. Cefuroxime is indicated for the treatment of early Lyme disease and subsequent prevention of late Lyme disease in adults and children over 12 years old.

CONTRA-INDICATIONS
Patients with known hypersensitivity to cephalosporin antibiotics.
Safety in pregnancy and lactation has not been established.

INTERACTIONS
Probenecid delays the excretion of cefuroxime by decreasing its renal tubular secretion.
Concomitant use of a nephrotoxic medicine such as the aminoglycoside gentamicin may increase the risk of kidney damage with cefuroxime. There may be antagonism between cefuroxime and bacteriostatic antibacterials.

DOSAGE AND DIRECTIONS FOR USE
Adults:

Sinusitis	250 mg twice daily
Acute and chronic bronchitis	250 mg twice daily
Acute uncomplicated cystitis	125 mg twice daily
Lyme disease	500 mg twice daily for 20 days

Or as directed by the physician.

Children:

Usual dose	125 mg twice daily

For otitis media in children less than 2 years of age the usual dose is 125 mg twice daily and in children over 2 years of age 250 mg twice daily. For Lyme disease in children over the age of 12 years the usual dose is 500 mg twice daily for 20 days. There is no experience in children under the age of 3 months. Because of the bitter taste of cefuroxime axetil, tablets should not be crushed. The usual course of therapy is seven days (range 5 —10 days). Or as directed by the physician. Note: Cefuroxime axetil should be taken half an hour after food for optimum absorption.

ADVERSE EFFECTS AND SPECIAL PRECAUTIONS
There have been few reports of erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis) and sensitivity reactions including skin rashes, urticaria, pruritis, drug fever, serum sickness and anaphylaxis.
Gastrointestinal disturbances, including diarrhoea, nausea and vomiting may occur. Headache has also been reported. Eosinophilia and transient increase of hepatic enzyme level, alanine aminotransferase (serum glutamic pyruvic acid transaminase), aspartate aminotransferase (serum glutamic oxaloacetic transaminase) and LDH levels have been noted during cefuroxime axetil therapy. A positive Coombs' test has been reported during treatment with cefuroxime axetil - this phenomenon can interfere with cross-matching of blood. Patients who experience anaphylactoid reactions to penicillins may experience a similar reaction when cephalosporins (such as cefuroxime) are administered. Should anaphylaxis occur, cefuroxime axetil should be discontinued and the patient treated with the usual agents (adrenaline, corticosteroids and antihistamines).
Neutropenia and thrombocytopenia have been less frequently reported. Nephrotoxicity, hepatitis and cholestatic jaundice have occurred less frequently.
Prolonged use of cefuroxime axetil may result in the overgrowth of non-susceptible organisms (eg. Candida, Enterococci, Clostridium difficile), which may require discontinuation of treatment.
Pseudomembranous colitis has been reported with the use of broad spectrum antibiotics, therefore, it is important to consider its diagnosis in patients who develop serious diarrhoea during or after antibiotic use.
Some patients with syphilis and other spirochaete infections may experience a Jarisch-Herxheimer reaction shortly after starting treatment with cefuroxime. Symptoms include fever, chills, headache, and reactions at the site of lesions. This reaction can be dangerous in cardiovascular syphilis or where there is a serious risk of increased local damage such as with optic atrophy. The Jarisch-Herxheimer reaction has been seen following cefuroxime axetil treatment of Lyme disease. It results directly from the bactericidal activity of cefuroxime axetil on the causative organism of Lyme disease, the spirochaete Borrelia burgdolferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.
It is recommended that either glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil. This antibiotic does not interfere in the alkaline picrate assay for creatinine.
Serum levels of cefuroxime are reduced by dialysis.
Should be given with caution to patients with renal impairment and a dosage reduction may be necessary. Renal and haematological status should be monitored especially during prolonged and high dose therapy.

Laboratory value alterations
A positive Coombs' reaction may occur in patients who receive cephalosporins. Cefuroxime axetil may produce false-positive results for glucose with copper reduction tests (Benedict's, Fehling's, or Clinitest tablets). Glucose enzymatic tests, such as Clinistix and Tes-Tape, are not affected.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See "Adverse effects and Special Precautions". Treatment is symptomatic and supportive.
Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

PACKAGING: Alu/Alu blister pack of 10 tablets, box of 10 film-coated tablets.
Alu/Alu blister pack of 10 tablets, box of 30 film-coated tablets.

STORAGE INSTRUCTIONS
Store at temperatures not exceeding 30°C. Protect from moisture.
KEEP OUT OF REACH OF CHILDREN.

Registration No: DRP-7693

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