AMPICILLIN

POLYPEN

250 mg, 500 mg & 1 g
Sterile Powder for Injection (I.M./I.V.)
ANTIBACTERIAL (PENICILLIN)

FORMULATION
Each vial of Polypen Sterile Powder for Injection contains:
Ampicillin (as sodium) . . . . . 250 mg
Ampicillin (as sodium) . . . . . 500 mg
Ampicillin (as sodium) . . . . . 1 g

PRODUCT DESCRIPTION
Ampicillin (Polypen) 250 mg, 500 mg, and 1 g is presented as fine, white crystalline powder, odorless or practically so, crystalline powder free from balls or irregular lumps

PHARMACOKINETICS
Ampicillin is given by injection as the sodium salt and following the intramuscular administration of 500 mg peak plasma concentrations occur within about 1 hour and are reported to range from 7-14 µg per mL. Ampicillin is widely distributed and therapeutic concentrations can be achieved in ascitic, pleural and joint fluids. It crosses the placenta into the fetal circulation and small amounts are excreted in breast milk. There is little diffusion into the cerebrospinal fluid except when the meninges are inflamed. About 20% is bound to plasma proteins and the plasma half-life is about 1-1.5 hours, but this may be increased in neonates and the elderly; in renal failure half-lives of 7-20 hours have been reported.
Ampicillin is metabolized to some extent to penicilloic acid which is excreted in the urine.
Renal clearance of ampicillin occurs partly by glomerular filtration and partly by tubular secretion; it is retarded by the concomitant administration of probenecid. Ampicillin is the least serum-bound of all penicillins, averaging about 20% compared to approximately 60-90% for other penicillins. Following parenteral administration about 60 to 80% is excreted in the urine within 6 hours. High concentrations are reached in bile; it undergoes enterohepatic recycling and some is excreted in the feces.

PHARMACODYNAMICS
Ampicillin is a beta-lactam antibiotic. It is bactericidal and has a similar mode of action to that of benzylpenicillin but as an amino-penicillin with an amino group side chain attached to the basic penicillin structure, ampicillin is better able to penetrate the outer membrane of some gram negative bacteria and has broader spectrum of activity. It resembles benzylpenicillin in its action against gram positive organisms including Streptococcus pneumoniae and other streptococci but, apart perhaps from Enterococcus faecalis, it is slightly less potent than benzylpenicillin. Listeria monocytogenes is highly sensitive. The gram negative cocci Moraxella (Branhamella) catarrhalis, Neisseria gonorrhea and N. meningitidis are sensitive. Ampicillin is more active than benzylpenicillin against some gram negative bacilli including Haemophilus influenzae and Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp. It is inactive against Pseudomonas aeruginosa. Ampicillin also has activity similar to benzylpenicillin against other organisms including many anaerobes and Actinomyces spp.

INDICATIONS
Ampicillin (Polypen) is used in the treatment of a variety of infections due to susceptible organisms. They include billiary-tract infections, bronchitis, endocarditis, epiglottis, gastroenteritis (including Escherichia coli enteritis, salmonella enteritis and shigellosis), gonorrhea, listeriosis, bacterial meningitis, otitis media, peritonitis, pneumonia, septicemia, typhoid and paratyphoid fever and urinary tract infections.

DOSAGE AND ADMINISTRATION

TREATMENT DOSAGE
A. Infections of the Respiratory Tract and Soft Tissues:

Weight	Dose	Frequency
Patients weighing 40 kg or more	250 mg to 500 mg	Every 6 hours IV or IM
Patients weighing less than 40 kg	25 to 50 mg per kg body weight daily in equally divided doses	Every 6 to 8 hours

B. Infections of Gastrointestinal and Genitourinary Tracts:

Weight	Dose	Frequency
Patients weighing 40 kg or more	500 mg	Every 6 hours IV or IM
Patients weighing less than 40 kg	50 mg per kg body weight daily in equally divided doses	Every 6 to 8 hours

C. Gonorrhea:

Age Group	Dose	Frequency
Adults	500 mg for 2 doses	Every 8 to 12 hours, IV or IM. Treatment may be repeated if necessary.

D. Bacterial Meningitis:

Age Group	Dose	Frequency
Adults and Children	150 to 300 mg per kg body weight daily in equally divided doses	Every 3 to 4 hours

THE CATHAY YSS DISTRIBUTORS CO., INC. — PACKAGE DESIGN DEPARTMENT

GENERIC NAME	AMPICILLIN SODIUM		PACK SIZE				Pantone Process Black C			SOFTWARE	CORELDRAW X4	DATE	Feb. 26, 2021
BRAND NAME	POLYPEN	DIMENSIONS(mm)	(H) 255 x (L) 102		COLORS					ITEM CODE			
DOSAGE STR		LAYOUT TYPE								DESIGN CODE	PI-PLP-1012-P-P-14		
DOSAGE FORM	Sterile Powder for Injection		REV NO.:	11	REASON	1. Inclusion of ADR Reporting 2. Inclusion of YSS Logo 3. Inclusion of item Code 4. Itemized Reg Nos & Date/Renewal of Authorization; Increased insert height to 255 mm 5. Relocate CYDC and YSS Logo 6. Revised text information 7. Item Code: PI-LP-P-6 8. Inclusion of Rx symbol.				FILE NAME	Polypen Insert.cdr		

E. Septicemia:

Age Group	Dose	Frequency
Adults and Children	150 to 200 mg per kg body weight daily	Start with IV administration for at least 3 days and continue with the IM route every 3 to 4 hours

PREPARATION
Intramuscular use: To prepare initial dilution for intramuscular use and add 0.9 to 1.9 mL of Sterile Water for Injection or Bacteriostatic Water for Injection to each 250 mg vial ; 1.2 to 1.8 mL of diluent to each 500 mg vial and 1.5 mL of diluent to each 1 g vial.
Intravenous use: To prepare initial dilution for direct intermittent intravenous use, add 5 mL of Sterile Water for Injection or Bacteriostatic Water for Injection to each 250 mg, 500 mg and 1 g vial. The resulting solution should be administered slowly over 3 to 5 minutes period. More rapid administration may result in convulsive seizures.
For Administration by IV Drip: Reconstitute as directed previously (For Intravenous use) prior to diluting with IV Solution. Ampicillin is stable with commonly used intravenous fluids at 23°C if infused over a period of 6 hours. Solutions should be changed after 1 hour if Ampicillin is administered in fluids containing dextrose or other carbohydrates. Ampicillin should not be mixed with blood products or proteinaceous fluids such as protein hydrolysates nor with lipid emulsions. The drug concentration and the rate and volume of the infusion should be adjusted so that the total dose of ampicillin is administered before the drug loses its stability in use.
Directions for use: After reconstitution for intramuscular or direct intravenous use, solutions retain their potency for 1 hour. Use freshly prepared solutions only. Administer intramuscularly or intravenously within 1 hour after preparation since the potency may decrease significantly after this period.

CONTRAINDICATIONS
This product is contraindicated to those who have shown hypersensitivity to the drug, to any penicillin and cephalosporin.

PRECAUTIONS
Ampicillin should be discontinued if a skin rash occurs. It should preferably not be given to patients with infectious mononucleosis since they are specially susceptible to ampicillin induced skin rashes; patients with lymphatic leukemia or HIV infection may also be at increased risk of developing skin rashes.

PREGNANCY
Anaphylaxis is a fairly uncommon event in pregnancy that can have serious implications for both mother and fetus. Several central nervous system damage in the preterm fetus and death in infancy have been attributed to maternal hypotensive anaphylaxis whereas at term the fetus has been regarded as protected. Severe fatal complication after intravenous application of ampicillin to a woman at term has been reported. This case demonstrates that the fetus near term may not be protected against severe damage caused by anaphylaxis. Therefore, drugs with the potential to produce anaphylactic reactions should be given with caution in pregnancies at term. Intensive fetal monitoring in anaphylactic reaction is necessary to allow rapid delivery of the infant.

DRUG INTERACTIONS
Ampicillin may decrease the efficacy of estrogen-containing oral contraceptives. It may also affect the absorption of other drugs due to its effect on the gastrointestinal flora. The possibility of a prolonged bleeding time following oral treatment with a broad spectrum antibiotic like ampicillin should be borne in mind in patients receiving coagulants. There may be antagonism between ampicillin, a bactericidal agent and bacteriostatic agents such as chloramphenicol. Incompatibility in vitro with other drugs may occur. An increased frequency of skin rashes has been reported in patients receiving ampicillin with allopurinol, compared with those receiving antibiotic alone.

ADVERSE DRUG REACTIONS
Skin rashes are among the most common side effects and are generally either urticarial or maculopapular; the urticarial reactions are typical of penicillin hypersensitivity while the erythematous maculopapular eruptions are characteristics of ampicillin and often appear more than 7 days after commencing treatment. There has been controversy over whether the maculopapular rash is an allergic or toxic response, but since in practice it may be difficult to distinguish between them, skin testing for hypersensitivity may be advisable before another penicillin is used in patients who have had ampicillin rashes.
Most patients with infectious mononucleosis develop a maculopapular rash when treated with ampicillin and patients with other lymphoid disorders such as lymphatic leukemia also appear to be at higher risk.

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

ADR REPORTING
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

AVAILABILITY
Ampicillin (Polypen) 250 mg: Colorless glass vial with rubber stopper and aluminium flip off (Box of 10's)
Ampicillin (Polypen) 500 mg: Clear glass vial with rubber stopper and gold aluminium seal (Box of 10's)
Ampicillin (Polypen) 1 g: Type III Clear glass vial with rubber stopper and green aluminum seal (Box of 10's)

STORAGE
Store at temperatures not exceeding 30°C. Use immediately after preparation.

	REG. NO.	DATE OF FIRST AUTHORIZATION	DATE OF REVISION OF PACKAGE INSERT
Polypen 250 mg SPFI	DRP-588	Dec. 6, 2010	July 16, 2019
Polypen 500 mg SPFI	DRP-403	Apr. 19, 2007	July 16, 2019
Polypen 1 g SPFI	DRP-1862	Jan. 29, 2010	July 16, 2019

Marketing Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
2/F Vernida I Condo., 120 Amorsolo St.,
Legaspi Village, Makati City

Manufacturer
YSS LABORATORIES CO., INC.
1133 United Nations Ave., Paco, Manila

Here you go, Here's the data i've collected

Notification for Minor Variation Polypen DRP-403 MiV-PH-N1-Letter/Request (General)

Log Date	Remarks
2021-05-03 13:13:20	MiV-PH-N1_Acknowledged and updated in Notification database. Remarks by: amsora
2021-04-22 13:45:07	Actual received MiV Notification from FDAC (April 22, 2021), Forwarded to and Received by Evaluator, w/ Soft copy Remarks by: CDRRCentral Releasing
2021-04-21 08:21:12	Submission of proof of payment. With Soft Copy. Referred to CDRR. Remarks by: fapdelacruz
2021-03-26 16:10:32	Date of Payment: 03-25-2021 / Amount Paid: PHP 510.00 / Sequence Number: 32521257593 Remarks by: pesalmazan
2021-03-19 15:51:15	Received by:dcpong-pong
2021-03-19 15:51:15	received from e-mail

FDA-20184BBOJ1YHRVN93W9ITGBW

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number	:	**DRP-403**
Generic Name	:	Ampicillin (as sodium)
Brand Name	:	Polypen
Dosage Strength & Form	:	500 mg Sterile Powder for Injection (IM/IV)
Pharmacologic Category	:	Antibacterial (Penicillin)
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	60 months
Storage Condition	:	Store at temperatures not exceeding 30°C
Packaging	:	Clear glass vial with rubber stopper and gold aluminum seal (Box of 10's)
Manufacturer	:	YSS Laboratories Company, Inc. 1133 United Nations Ave., Paco, Manila
Distributor	:	The Cathay YSS Distributors Company, Incorporated 2/F Vernida 1 Condominum, 120 Amorsolo St., Legaspi Village, Makati City

The marketing authorization shall be valid until **27 July 2023** subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **29 October 2018**.

NELA CHARADE G. PUNO, RPh
Director General

REG. STATUS : **Automatic Renewal**
AMOUNT : **Php 10,100**
OR NUMBER : **1025119**
DATE : **18 July 2018**
CODE : **434-151-235**
BAR CODE / DOC TRACK : **2 0 1 8 0 7 0 3 1 2 3 4 3 4**

ISO 9001:2008 Management System
www.tuv.com ID 9105072396

FDA-0304018

Registration Number : DRP-403

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

X	A	This is subject to batch notification.
	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
X	D	Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.
	E	Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.
	F	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a personalized ordinary prescription form. It is a habit-forming drug.
	H	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
	I	Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular No. 2014-016.
	J	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.
	K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:
Exhaustion up to retail level of all existing inventory of the previous labelling materials is allowed only until **29 October 2019**. No further extension shall be granted.