1.3.1 Summary of product characteristics (SmPC)

Summary of products characteristics (SmPC) of Sulbacin Tablet (Sultamicillin Tablet) is enclosed overleaf.

SUMMARY OF PRODUCTS CHARACTERISTICS

SULBACIN TABLET
(Sultamicillin Tablet)

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. Name of the Medicinal Product

1.1 Product name : SULBACIN TABLET

1.2 Strength : Sultamicillin Tablet

1.3 Pharmaceutical Dosage form : Tablet

2.Label Claim:

Each Film Coated Tablet contains:
Sultamicillin (as Tosylate)
Equivalent to Sulbactam……..147mg
Ampicillin…….220mg

Sr. No.	Ingredients	Qty/Tablet (mg)	Qty/Batch (kg)	Function
1.	Sultamicillin Tosylate	488.890	48.889	O. Spec
2.	Maize Starch*	97.610	10.736	BP
3.	Lactose monohydrate	71.000	7.100	BP
4.	Sodium Starch Glycollate	37.000	3.700	BP
5.	Hydroxypropyl Cellulose	11.500	1.150	BP
6.	Magnesium Stearate	14.000	1.400	BP
Coating **				
7.	Hydroxy Propyl Methyl Cellulose	15.000	1.950	BP
8.	Titanium Dioxide	6.000	0.780	BP
9.	Diethyl Pthalate	2.000	0.260	BP
10.	Methanol	-	7.800	BP
11.	Methylene Chloride	-	86.450	BP

3. Pharmaceutical Form

Capsule shaped, biconvex, white film coated tablet having Sulbacin debossed centrally on one side along the length.

4.1 Therapeutic indications :

SULBACIN is suitable for the treatment of infections by susceptible organisms which may be seen in the following clinical conditions:

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- Intra - Abdominal Infections
- Obstetrics and Gynaecological Infections
- Skin and Soft Tissue Infections
- Bone and Joint Infections
- Upper and Lower Respiratory Tract Infections
- E N T Infections
- Urinary Tract Infections
- Gonorrhoea
- Surgical prophylaxis

4.2 Posology and method of administration:

In adults the usual dose of SULBACIN is 1-2 tablets (375 - 750 mg) twice daily for 5-14 days. For children above 30 kg the dose is same as for adults.

Tablets are to be swallowed whole, with plenty of water.

For patients with impaired renal function (Creatinine clearance below 20 ml/min) the following dosage schedule is recommended:

Creatinine clearance (ml/min)	Dose intervals
Above 20	Normal (1 dose / 12 hrs.)
5 - 19	1 dose/24 hrs.
Below 5	1 dose/48 hrs.

When creatinine clearance is not known it may be calculated from the serum creatinine value, as follows:

Males: $\frac{\text{weight (kg)} \times (140 - \text{Age})}{72 \times \text{serum creatinine}}$

Females: 0.85 × above value.

4.3 Contraindications

SULBACIN is contraindicated in patients with a history of hypersensitivity to penicillins and cephalosporins.

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(Sultamicillin Tablet)

4.4 Special warning and precautions for use

Some patients with infectious mononucleosis may develop skin rash after **SULBACIN** administration. The ampicillin group of antibiotics should not be administered to such patients.

Superinfections with Pseudomonas aeruginosa or fungi may occur during therapy, they should be suitably treated.

As is the case with all drugs, care should be exercised while treating pregnant women and nursing mothers with **SULBACIN**.

4.5 Interaction with other medicinal products and other forms of interactions

SULBACIN should not be combined with bacteriostatic agents. Concomitant therapy with allopurinol has been reported to increase the incidence of skin rash. Co-administration of probenecid increases serum antibiotic levels by reducing excretion.

4.6 Pregnancy and lactation

4.7 Effects on ability to drive and use machine

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4.8 Undesirable effects

Side effects of SULBACIN are similar to other antibiotics of the Penicillin group and they include rash, gastrointestinal disorders like diarrhoea and very rarely, pseudomembranous colitis. Haematological disorders such as hypoprothrombinaemia, eosinophilia have been reported with SULBACIN® use, but their incidence is rare and they are readily reversible. Elevation of liver enzymes may also be noted.

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4.9 Overdose and special antidotes

Neurological adverse reactions including convulsions, may occur with the attainment of high CSF levels of beta lactams. Ampicillin may be removed from circulation by hemodialysis. The molecular weight, degree of protein binding and pharmacokinetics profile of sulbactam suggest that this compound may also be removed by hemodialysis.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Sultamicillin is a double ester of a broad spectrum antibiotic ampicillin with sulbactam, a semisynthetic b-lactamase inhibitor, which extends the antibacterial spectrum of ampicillin to include some b-lactamase producing strains of bacteria that would otherwise be resistant.

5.2 Pharmacokinetic Properties

Upon oral administration, the ester is hydrolysed during absorption, releasing equimolar quantities of ampicillin and sulbactam. The absorption is rapid and peak concentrations of sulbactam and ampicllin occur in approximately one hour. The areas under the plasma concentration vs time curves for both ampicillin and sulbactam are similar indicating a close relationship between the pharmacokinetic handling of the two components.

Distribution of both the drugs after oral administration is seen in sputum, sinus aspirates, bile, purulent ascites, wound exudates, and middle ear effusions, as well as in tissue from various organs, including tonsils, gall bladder, appendix and genital organs. Sulbactam and ampicillin cross the placenta and are present in maternal milk upto 6 hours after a dose of sultamicillin.

Sultamicillin is excreted primarily in the urine as sulbactam and ampicillin.

5.3 Preclinical Safety Data

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SUMMARY OF PRODUCTS CHARACTERISTICS

SULBACIN TABLET
(Sultamicillin Tablet)

6. Pharmaceutical Particulars

6.1 List of excipients : Not applicable

6.2 Incompatibilities :

None

6.3 Shelf life: 24 Months

6.4 Special precautions for storage :

Store below 30°C.

6.5 Nature and contents of container :

Each carton containing amber coloured glass bottle of 10 Tablets along with pack insert.

7. Marketing Authorization Holder

Unichem Laboratories Limited,
Unichem Bhavan
Prabhat Estate, S.V. Road
Jogeshwari (West)
Mumbai - 400 102
INDIA.

8. Manufacturer's Name

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