SUMMARY OF PRODUCT CHARACTERISTICS

1.Name of the Medicinal Product

Lasodox DS

2.Qualitative and Quantitative Composition

Each 5 ml of the reconstituted suspension
contains: Cefpodoxime Proxetil USP
Equivalent to Cefpodoxime 100 mg

For the full list of excipients see section 6.1

3.Pharmaceutical Form

Dry Powder For Oral Suspension.
Description: An off-whit colour granular powder filled in opaque white colour bottle. On reconstitution with water it forms off-white colour thick suspension.

4.Clinical Particulars

4.1 Therapeutic indications

Cefpodoxime used for the treatment of acute bacterial sinusitis, tonsillitis, acute otitis media and bacterial pneumonia.

4.2 Posology and method of administration

Route of administration:
oral. Adults and Elderly:
Not applicable .
The following dosage regimen is proposed:-
Infants and Pediatric Patients (age 2 months through 12 years)

Type of Infection	**Total Daily Dose**	**Dose Frequency**	**Duration**
Acute otitis media	10 mg/kg/day (Max 400 mg/day)	5 mg/kg Q 12 h (Max 200 mg/dose)	5 days
Pharyngitis and/or tonsillitis	10 mg/kg/day (Max 200 mg/day)	5 mg/kg/dose Q 12 h (Max 100 mg/dose)	5 to 10 days

Acute maxillary sinusitis	10 mg/kg/day (Max 400 mg/day)	5 mg/kg Q 12 hours (Max 200 mg/dose)	10 days

Cefpodoxime should not be used in infants less than 15 days old, as no experience yet exists in this age group.
The product should be taken during meals for optimal absorption.

Constitution Direction for Oral Suspension:
Add little distilled water and first shake the bottle to loosen granules. Then add the water upto mark with vigorous shaking.

4.3 Contra-indications
Cefpodoxime is contraindicated in patients with known hypersensitivity to cephalosporins or porphyria.

4.4 Special warnings and precautions for use
Do not use this product with any other product containing cefpodoxime.
Prolonged use of cefpodoxime may result in an overgrowth of bacteria that do not respond to the medication.
Should be taken with care in patients with renal failure, known allergy to penicillins.

4.5 Interaction with other medicinal products and other forms of interaction Absorption of cefpodoxime is decreased by antacids or histamine H2-receptor antagonists. Probenecid inhibits the renal excretion of cefpodoxime.
Concomitant administration with nephrotoxic drugs may increase nephrotoxic potential.

4.6 Pregnancy and lactation
There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Cefpodoxime is excreted in human milk. Because of the potential for serious reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines
No harmful effects have been observed

4.8 Undesirable effects

The most commonly seen adverse reactions of cefpodoxime are mild and transient such as diarrhoea, abdominal pain, nausea and vomitting, headaches, itching, skin rashes, urticaria.

Other undersirable effects including anaphylactoid reactions, fever, erythema, transient hepatitis and jaundice, eosinophilia, reversible interstitial nephritis, anxiety, insomnia and dizziness were seen rarely.

Stop use and ask a doctor if: Diarrhoea, nausea and vomiting occur.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PvERS) https://pv.pharmacyboardkenya.org

5.Pharmacological Properties

5.1 Pharmacodynamic properties

Cefpodoxime is a semi-synthetic antibiotic in the third-generation cephalosporins. The bactericidal activity of cefpodoxime results from its inhibition of cell wall synthesis. Cefpodoxime is stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to penicillins and cephalosporins, due to their production of beta-lactamase, may be susceptible to cefpodoxime. Cefpodoxime is inactivated by certain extended spectrum beta-lactamases.

5.2 Pharmacokinetic properties

Cefpodoxime proxetil is absorbed from the gastrointestinal tract and de-esterified in the intestinal epithelium after oral doses, to release active cefpodoxime in the bloodstream.

- Bioavailability is about 50% in fasting subjects and may be increased in the presence of food. Absorption is decreased in conditions of low gastric acidity. The plasma half-life is about 2 to 3 hours and is prolonged in patients with renal impairment.

- After an oral dose of cefpodoxime in healthy subjects with normal renal function, peak plasma concentrations of about 1.5, 2,5, and 4.0 micrograms/mL have been achieved 2 to 3 hours after oral doses of 100, 200, and 400 mg cefpodoxime respectively.Cefpodoxime reaches therapeutic concentrations in the respiratory and genito-urinary tracts and bile. It has been detected in low concentrations in breast milk. About 20 to 30% of

cefpodoxime is bound to plasma proteins.

- Cefpodoxime is excreted unchanged in the urine by glomerular filtration and tubular secretion. Approximately 29 to 33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. Some is removed by dialysis.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6.Pharmaceutical Particulars

6.1 List of excipients

Sodium Benzoate
Sodium carboxy methyl cellulose
Aspartame
Colloidal silicon Dioxide
Sodium citrate
Citric acid monohydrate
Vanilla flavor
Sunset yellow colour
Sugar

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months.

6.4 Special precautions for storage

Store below 30^0C. Protect from light.
For Reconstituted suspension: After mixing, suspension should be stored in a refrigerator, 2° to 8°C (36° to 46°F). Shake well before using. Keep container tightly closed. The mixture may be used for 7days. Discard unused portion after 7 days.

6.5 Nature and contents of container

60 ml white PET bottle packed in a printed carton along with pack insert.

6.6. Instructions for use and handling
No special requirements

7. Marketing Authorisation Holder
Laso Healthcare Pvt Ltd
Old No:1/90, New No:5/92
Pillayar Koil
Street Medavakkam Chennai-
600100, India.

8. Marketing Authorization Number
H2022/CTD8609/18083

9. Date of First Registration / Renewal of the Registration
11-01-2022

10. Date of Revision of the Text
11-01-2022