Suflaxes (celecoxib) Tablets USP, 400 mg
Suflaxes (celecoxib) Capsules, 100, 150, and 200 mg
Suflaxes (celecoxib) for Oral Suspension USP, 150 mg/ml
Suflaxes (celecoxib) Tablets USP, 600 mg

For oral administration

Indications and Usage

Suflaxes (celecoxib) is a cyclo-oxygenase-2 (COX-2) inhibitor indicated for:

Indications

1. Management of Postoperative Pain

Administration and Dosage

Adults

Dosage: 400 mg daily (2) or
800 mg daily (1)

Children: 8-16 years-

Dosage Forms and Strengths

- Film-coated, scored tablets: 400 mg (3)
- Capsules: 400 mg (3)
- Chewable tablets: 100, 150, and 200 mg (2)
- Oral Suspension: 100 mg/ml, 150 mg/ml, and 300 mg/ml

Full prescribing information contains:

1. INDICATIONS AND USAGE

1.1 Unlabeled Pediatric Trunc Infections

2. DOSAGE AND ADMINISTRATION

2.1 Adults

2.2 Pediatrics (6 months or older)

2.3 Renal Impairment

2.4 Renal Impairment for Oral Suspension

3. DOSAGE FORMS AND STRENGTHS

4. CONTRAINDICATIONS

5. WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

5.2 Serious Additive Adverse Drug

5.3 Drug-Drug Interactions

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5.5 Development of Drug-Resistant Bacteria

6. ADVERSE REACTIONS

6.1 Clinical Global Experience

6.2 Pediatric Marketing Experience

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7.1 Carcinogenesis

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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8.5 Use in Specific Patient Populations

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10. OVERDOSAGE

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13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14. CLINICAL TRIALS

15. REFERENCES

16. HOW SUPPLIED/STORAGE AND HANDLING

17.1 Information for Patients

* Asterisks or subscripts omitted from the full prescribing information are not listed.

For oral administration

Indications and Usage

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Contraindications

- Concomianted in patients with known allergy to celecoxib or other cyclo-oxygenase inhibitors

Hypersensitivity reactions including shock and fatalities have been reported with celecoxib. Discontinue use if a reaction occurs. (1.1)

Clonidine difficult associated diuresis: Evaluate if diuresis occurs. (5.2)

Most common adverse reactions are gastrointestinal such as diarrhea, nausea, flatulence, abdominal pain, bloating, cough, and vomiting. (6.1)

To report suspected adverse reactions, contact Lofaxin Physicians 1-800-229-3053 or 1-800-424-1100 or your local Fda for emergency care.

Drug Interactions

- Elevated carbamyplaz levels have been reported in patients taking benzodiazepines when celecoxib is administered concomitantly. (7.1)

- Increased prednisolone blood levels, with or without clinical bleeding, has been reported when celecoxib is administered concomitantly with warfarin and anticoagulants. (7.2)

Drug Interactions and Use in Specific Populations

- Pregnancy: Celecoxib should be used during pregnancy only if clearly needed. (8.1)

- Nursing Mothers: Celecoxib should be given to breastfeeding women only if the potential benefit justifies the potential risk to the infant. (8.2)

- Pediatric Use: See Table 1. (8.3)

- Use in Specific Patient Populations: See Table 2. (8.5)

- Renal Impairment: Celecoxib may be administered in the presence of impaired renal function. Dose adjustment is required in patients with creatinine clearance less than 60 ml/min. (8.6)

See 17 for patient counseling information.

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11.1.2.2 Clinical Laboratory Tests

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