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## Skelaxin (metaxalone) - Drug Summary

Pfizer Laboratories Div Pfizer Inc

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#### Skelaxin (metaxalone)

#### THERAPEUTIC CLASS

Muscular analgesic (centrally acting)

#### DEA CLASS

RX

#### ADULT DOSAGE & INDICATIONS

Musculoskeletal Pain

**Relief of Discomforts Associated w/ Acute Conditions:**  
800mg tid-qid

#### PEDIATRIC DOSAGE & INDICATIONS

Musculoskeletal Pain

**Relief of Discomforts Associated w/ Acute Conditions:**  
**>12 Years:**  
800mg tid-qid

#### ADMINISTRATION

Oral route

Taking w/ food may enhance general CNS depression.

#### HOW SUPPLIED

**Tab:** 800mg\* \*scored

#### CONTRAINDICATIONS

Known tendency to drug-induced, hemolytic, and other anemias. Significantly impaired renal/hepatic function.

#### WARNINGS/PRECAUTIONS

Serotonin syndrome (SS) reported; reports generally occurred when used concomitantly w/ serotonergic drugs or when used at doses higher than the recommended dose. Caution w/ preexisting liver damage; perform serial liver function studies in these patients. False (+) Benedict's tests reported; glucose-specific test will differentiate findings. Taking w/ food may enhance general CNS depression; elderly patients may be especially susceptible to this CNS effect.

#### ADVERSE REACTIONS

Drowsiness, dizziness, headache, nervousness, irritability, N/V, GI upset.

#### DRUG INTERACTIONS

Additive sedative effects may occur w/ other CNS depressants (eg, alcohol, benzodiazepines, opioids, TCAs); use w/ caution if taking >1 CNS depressant simultaneously. Caution w/ drugs that may affect the serotonergic neurotransmitter systems (eg, tramadol, SSRIs).

#### PREGNANCY AND LACTATION

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**Pregnancy:** Should not be used in women who are or may become pregnant and particularly during early pregnancy unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.  
**Lactation:** It is not known whether metaxalone is secreted in human milk; not for use in nursing.

## MECHANISM OF ACTION

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Muscular analgesic (central-acting); has not been established. Activity may be due to general depression of CNS.

## PHARMACOKINETICS

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**Absorption:** (400mg)  $C_{max}$ =983ng/mL,  $T_{max}$ =3.3 hrs; AUC=7479ng•hr/mL. (800mg)  $C_{max}$ =1816ng/mL,  $T_{max}$ =3 hrs; AUC=15,044ng•hr/mL. **Distribution:**  $V_d$ =800L. **Metabolism:** Liver; via CYP1A2, 2D6, 2E1, 3A4, and to a lesser extent CYP2C8, 2C9, C19. **Elimination:** Urine (metabolites);  $T_{1/2}$ =9 hrs (400mg), 8 hrs (800mg).

## ASSESSMENT

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Assess for known tendency to drug-induced, hemolytic, or other anemias, significant renal/hepatic impairment, hypersensitivity to the drug, pregnancy/nursing status, and possible drug interactions.

## MONITORING

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Monitor for signs/symptoms of SS, CNS depression, and any other adverse reaction. Perform serial liver function studies in patients w/ preexisting liver damage.

## PATIENT COUNSELING

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Inform that drug may impair mental and/or physical abilities required to perform hazardous tasks, especially when used w/ alcohol or other CNS depressants.

## STORAGE

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15-30°C (59-86°F).

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