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Darvocet-N® 100

propoxyphene napsylate with acetaminophen

Description: Each tablet of Darvocet N 50 contains 50 mg propoxyphene napsylate and 325 mg acetaminophen Each tablet of Darvocet N 100 contains 100 mg propoxyphene napsylate and 650 mg acetaminophen

Indication: These products are indicated for the relief of mild to moderate pain, either when pain is present alone or when it is accompanied by fever

Contraindications: Hypersensitivity to propoxyphene or to acetaminophen

Warnings: C N S Additive Effects and Overdosage -- Propoxyphene in combination with alcohol, tranquilizers, sedative hypnotics, and other central-nervous system depressants has additive depressant effects, and the patient should be so advised Patients taking this drug should be warned not to exceed the dosage recommended by their physician Toxic effects and fatalities have occurred following overdoses of propoxyphene alone and in combination with other central nervous-system depressants The majority of these patients have had previous histories of emotional disturbances or suicidal ideation or attempts as well as histories of misuse of tranquilizers, alcohol, or other C N S active drugs Caution should be exercised in prescribing unnecessarily large amounts of propoxyphene for such patients

Drug Dependence – Propoxyphene can produce drug dependence characterized by psychic dependence and, less frequently, physical dependence and tolerance Propoxyphene will only partially suppress the withdrawal syndrome in individuals physically dependent on morphine or other narcotics The abuse liability of propoxyphene is qualitatively similar to that of codeine although quantitatively less, and propoxyphene should be prescribed with the same degree of caution appropriate to the use of codeine

Usage in Ambulatory Patients – Propoxyphene may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery The patient should be cautioned accordingly.

Usage in Pregnancy – Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Instances of withdrawal symptoms in the neonate have been reported following usage during pregnancy Therefore, propoxyphene should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards

Usage in Children – Propoxyphene is not recommended for use in children, because documented clinical experience has been insufficient to establish safety and a suitable dosage regimen in the pediatric age group.

Precautions: Confusion, anxiety, and tremors have been reported in a few patients receiving propoxyphene concomitantly with orphenadrine The central-nervous-system depressant effect of propoxyphene may be additive with that of other C.N.S depressants, including alcohol.

Adverse Reactions: The most frequent adverse reactions are dizziness. sedation, nausea, and vomiting These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down

Other adverse reactions include constipation, abdominal pain, skin rashes, lightheadedness, headache, weakness, euphoria, dysphoria, and minor visual disturbances

The chronic ingestion of propoxyphene in doses exceeding 800 mg per day has caused toxic psychoses and convulsions

Cases of liver dysfunction have been reported.

Administration and Dosage: A narcotic prescription is not required

These products are given orally The usual dose is 100 mg propoxyphene napsylate and 650 mg acetaminophen every four hours as needed for pain

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Additional information available to the profession on request from Eli Lilly and Company,

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