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Cyclobenzaprine Hcl (Flexeril)

??? ??????: 30 ??????/?????? 2017

Incidence of most common adverse reactions in the 2 double-blind, placebo-controlled 5 mg studies (incidence of > 3% on FLEXERIL 5 mg):

Placebo N=469	FLEXERIL 10 mg N=249	FLEXERIL 5 mg N=464	
10%	38%	29%	Drowsiness
7%	32%	21%	Dry Mouth
3%	6%	6%	Fatigue
8%	5%	5%	Headache

Adverse reactions which were reported in 1% to 3% of the patients were: abdominal pain, acid regurgitation, constipation, diarrhea, dizziness, nausea, irritability, mental acuity decreased, nervousness, upper respiratory infection, and pharyngitis.

The following list of adverse reactions is based on the experience in 473 patients treated with FLEXERIL 10 mg in additional controlled clinical studies, 7607 patients in the postmarketing surveillance program, and reports received since the drug was marketed. The overall incidence of adverse reactions among patients in the surveillance program was less than the incidence in the controlled clinical studies.

The adverse reactions reported most frequently with FLEXERIL were drowsiness, dry mouth and dizziness. The incidence of these common adverse reactions was lower in the surveillance program than in the controlled clinical studies:

Surveillance Program With FLEXERIL 10 mg	Clinical Studies With FLEXERIL 10 mg	
16%	39%	Drowsiness
7%	27%	Dry Mouth
3%	11%	Dizziness

Among the less frequent adverse reactions, there was no appreciable difference in incidence in controlled clinical studies or in the surveillance program. Adverse reactions which were reported in 1% to 3% of the patients were: fatigue/tiredness, asthenia, nausea, constipation, dyspepsia, unpleasant taste, blurred vision, headache, nervousness, and confusion. The following adverse reactions have been reported in post-marketing experience or with an incidence of less than 1% of patients in clinical trials with the 10 mg tablet:

Syncope; malaise. **Body as a Whole:**

Tachycardia; arrhythmia; vasodilatation; palpitation; hypotension. **Cardiovascular:**

Vomiting; anorexia; diarrhea; gastrointestinal pain; gastritis; thirst; flatulence; edema of the tongue; abnormal liver function and rare reports of hepatitis, **Digestive:** jaundice and cholestasis.

Anaphylaxis; angioedema; pruritus; facial edema; urticaria; rash. **Hypersensitivity:**

Local weakness. **Musculoskeletal:**

Seizures, ataxia; vertigo; dysarthria; tremors; hypertonia; convulsions; muscle twitching; disorientation; insomnia; depressed **Nervous System and Psychiatric:** mood; abnormal sensations; anxiety; agitation; psychosis, abnormal thinking and dreaming; hallucinations; excitement; paresthesia; diplopia, serotonin syndrome.

Sweating. **Skin:**

Ageusia; tinnitus. **Special Senses:**

Urinary frequency and/or retention. **Urogenital:**

Causal Relationship Unknown

Other reactions, reported rarely for FLEXERIL under circumstances where a causal relationship could not be established or reported for other tricyclic drugs, are listed to serve as alerting information to physicians:

Chest pain; edema. **Body as a whole:**

Hypertension; myocardial infarction; heart block; stroke. **Cardiovascular:**

Paralytic ileus, tongue discoloration; stomatitis; parotid swelling. **Digestive:**

Inappropriate ADH syndrome. **Endocrine:**

Purpura; bone marrow depression; leukopenia; eosinophilia; thrombocytopenia. **Hematic and Lymphatic:**

Elevation and lowering of blood sugar levels; weight gain or loss. **Metabolic, Nutritional and Immune:**

Myalgia. **Musculoskeletal:**

Decreased or increased libido; abnormal gait; delusions; aggressive behavior; paranoia; peripheral neuropathy; Bell's palsy; **Nervous System and Psychiatric:** alteration in EEG patterns; extrapyramidal symptoms.

Dyspnea. **Respiratory:**

Photosensitization; alopecia. **Skin:**

Impaired urination; dilatation of urinary tract; impotence; testicular swelling; gynecomastia; breast enlargement; galactorrhea. **Urogenital:**

Drug Abuse And Dependence

Pharmacologic similarities among the tricyclic drugs require that certain withdrawal symptoms be considered when FLEXERIL is administered, even though they have not been reported to occur with this drug. Abrupt cessation of treatment after prolonged administration rarely may produce nausea, headache, and malaise. These are not indicative of addiction.