ANALGESIC ACTIVITY

**INDICATIONS:** For relief of mild to moderate pain, fever and inflammation as in influenza, common cold, low back and neck pain, headache, trauma, following dental and surgical procedures.

**DOSEAGE:** 222 Adults - 1 to 2 tablets once to three times daily. Children's dosage, when recommended by a physician: 10 to 14 years, one tablet, one to three times daily; 5 to 10 years, one-half tablet, one to three times daily; 222 Adults - 1 tablet two to three times daily.

**CONTRAINICATIONS:** Gastrointestinal ulceration and sensitivity to any of the components.

**WARNINGS:** Salicylates increase the effects of anticoagulants. Caution is necessary when salicylates and anticoagulants are prescribed concurrently. Also, salicylates may depress the concentration of prothrombin in the plasma. Large doses of salicylates may affect insulin requirements of diabetics. Salicylates may potentiate sulfonlurea hypoglycemic agents. Analgesic abuse (excessive and prolonged therapy) has been associated with nephropathy. TO AVOID ACCIDENTAL POISONING ACETYL-SALICYLIC ACID PREPARATIONS MUST BE Kept Well Out OF reach OF children.

**PRECAUTIONS:** Give with caution to patients with asthma, other allergic conditions, bleeding tendencies, or hypoprothrombinemia. Salicylates can produce changes in thyroid function tests.

Observe care in use of codeine, although tolerance and addiction are rare. Give codeine with caution to patients with severe respiratory depression. Its depressant effect may be enhanced by concurrent administration of sedatives and tranquilizers.


**Codeline:** Average or large doses may cause various gastrointestinal symptoms such as nausea, vomiting and constipation.

**Caffeine:** May cause nausea, nervousness, insomnia, headache, vomiting, palpitation, vertigo, muscle tremor, sensory disturbances, excessive diuresis in sensitive patients. Large doses may cause gastric ulceration.

FULL INFORMATION AVAILABLE ON REQUEST

**HAWn SUPPLIED**

- **222 Tablets** - Peach, O marked, scored, engrafted 222 on one side. Each tablet contains: acetylsalicylic acid 375 mg, caffeine citrate 30 mg, codeine phosphate 30 mg. Available in bottles of 50 and 500.
- **223 Tablets** - White, scored, engrafted 223 on one side. Each tablet contains: acetylsalicylic acid 375 mg, caffeine citrate 30 mg, codeine phosphate 30 mg. Available in tubes of 12; bottles of 40 and 100; also bottles of 50 with safety cap.

**References**


Bendectin: The Manufacturers Reply

CANADIAN FAMILY PHYSICIAN recently published a letter1 from a Sorrento, B.C. physician asking the College of Family Physicians' members to consider: "Is Bendectin a minor teratogen?" A similar letter from the same author also appeared in the Canadian Medical Association Journal2 one month previously.

There is, in fact, a large body of published data showing that Bendectin and its ingredients are not teratogenic. Studies in humans3-11 have been uniformly negative and consistent with animal studies.12-13

Bendectin has already been the subject of extensive epidemiologic studies, both prospective and retrospective, comparing the outcome of pregnancies of women who received the product or its ingredients with those who did not. All of these studies, as well as recent epidemiologic surveillance, show no association of Bendectin with birth defects.

In the face of these data, sporadic individual case reports of relatively common birth defects are not a reasonable basis for Dr. Paterson's suggestion that there is a need for research to determine the "ultimate safety" of Bendectin or for his recent unfounded suggestion3 that Bendectin "may not safely be used" in pregnancy.

Since the spontaneous incidence of congenital defects is rather high, sporadic reports of birth defects in children born to women who used any drug during pregnancy are to be expected. These reports can serve as an alert only if an unusually large percent of a certain type of defect or an unexpected number of a very rare defect are reported. The isolated reports specifically sent to the manufacturer for Bendectin over a 21-year period (during which time over 20,000,000 pregnant women have been treated worldwide) represent a miniscule sample of the hundreds of thousands of defects which were destined to occur in the offspring of treated women - purely from the expected incidence of such defects. The distribution of defects by type in the Bendectin sample is consistent with the distribution observed by review of birth certificates of the general population.11,14

For the record, Merrell discussed the Bendectin safety data with Dr. Paterson on June 1, 1977, and then sent him the relevant documentation, suggesting that he contact certain Canadian experts in the field of teratology for an independent opinion about the safety of the product.

Few drugs, foods or environmental chemicals have been studied as thoroughly as Bendectin for evidence of teratologic potential with such consistently negative results. The family physician deserves a proper presentation of facts rather than conjecture in relation to a preparation like Bendectin, which is of proven value in helping avoid the consequences of uncontrolled nausea and vomiting of pregnancy.

Murray Weiner, MD
Vice-president, Wm. S. Merrell Co., Weston, Ont.
FLAVIL* 75 mg Tablets

(amitriptyline hydrochloride, MSD Std.)

Indications: In the drug management of depressive illness including that accompanied by anxiety. May also be used for the treatment of enuresis and for the treatment of secondary nocturnal enuresis when organic causes have been excluded.

Dosage Summary: Oral: Dosage should be initiated in adults at a small and increased gradually, notoring carefully the clinical response and any evidence of intolerance. Initial dose for adults: 25 mg three times a day. If necessary, increase doses preferably in the late afternoon or evening to a total of 75 mg a day. Hospitalized patients may require 10 mg a day initially; increased gradually to 200 mg a day if necessary. A small number need as much as 300 mg a day.

Adaptations for Elderly Patients: In general, lower dosages recommended: 10 mg three times a day with 20 mg at bedtime or less, may be satisfactory. Manufacturers’ remarks: Dosage may be adjusted according to individual response.

Intramuscular Dosage: Initially, 20 to 30 mg four times a day. FLAVIL Tablets should replace the injection as soon as possible.

Usage in Children: Not recommended for treatment of enuresis of less than 12 years of age. In Enuresis: Children 5 to 11 years, 10 to 20 mg one hour before bedtime. In older children 25 to 50 mg may be required.

Contraindications: Known hypersensitivity. Should not be given concomitantly with, nor within 14 days of, a MAO inhibitor. MAO inhibitors should be discontinued 14 days prior to initiating therapy. Concurrent use of monoamine oxidase inhibitors and tricyclic antidepressants may result in potentially fatal hypertensive crisis. Patients with a history of cardiovascular diseases such as myocardial infarction and congestive heart failure. Patients with a history of seizures or urinary retention, or with a history of prostatic hypertrophy. Patients with a history of increased intracranial pressure. Patients with a history of arrhythmias, sinus tachycardia, and prolongation of the conduction time have been reported, particularly with high doses. A few instances of unexplained death have been reported in patients with a history of cardiovascular diseases. Myocardial infarction and stroke have also been reported with drugs of this class. Therefore, these drugs should be used with caution in patients with a history of cardiovascular diseases such as myocardial infarction and congestive heart failure. Close supervision is required for hypertrophic patients or those receiving thyroid medication. May impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

Usage in Pregnancy: FLAVIL Tablets are not indicated for use in pregnancy. Close supervision is required for hypertrophic patients or those receiving thyroid medication. May impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

Adverse Reactions: Behavioural: Activation of latent schizophrenia; high doses may cause temporary or permanent confusion, depression, or a transient visual hallucinations; hypomimic reactions; drowsiness which usually disappears with continuation of therapy; insomnia, loneliness, restlessness, agitation, fatigue, nightmares, disorientation, delusions, excitation, and pseudotyphoid. Neurological: Epileptic seizures; numbness, tingling, paresthesias of the limbs including peripheral neuropathy; dizziness, fine tremor, headache, ataxia, alteration in EEG patterns, extrapyramidal symptoms, tinnitus and incoordination; severe tremor only observed with high doses. Autonomic: Evidence of anticholinergic activity, also may be of value in the treatment of urinary tract, constipation, and more rarely paralytic ileus of particular concern in the elderly; some patients may report dry vision and disturbance of accommodation.

Cardiovascular: A quinidine like effect and other reversible effects include: prolongation of the interval of T waves, and bundle branch block; orthostatic hypotension, hypertension, palpitation, arrhythmias, heart block and, in children, ventricular tachycardia and fibrillation; myocardial infarction and stroke. A few instances of unexplained death have been reported in patients with cardiovascular disorders.

Toxic and Allergic Effects: Bone marrow depression including agranulocytosis, leucopenia, eosinophilia, purpura and thrombocytopenia; jaundice, hepatitis, and pancreatitis. Local reactions manifested by skin rash, urticaria, photosensitization or swelling of the face and tongue which occurred rarely. Gastrointestinal: Nausea, epigastric distress, heartburn, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, gastrointestinal bleeding or ulceration rarely. Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement and galactorrhoea in the female, increased intraocular pressure and increased intraocular tension, delusions, drowsiness which usually disappears with continuation of therapy; insomnia, loneliness, resistent to therapy; insomnia, loneliness, restlessness, agitation, fatigue, nightmares, disorientation, delusions, excitation, and pseudotyphoid. Neurological: Epileptic seizures; numbness, tingling, paresthesias of the limbs including peripheral neuropathy; dizziness, fine tremor, headache, ataxia, alteration in EEG patterns, extrapyramidal symptoms, tinnitus and incoordination; severe tremor only observed with high doses. Autonomic: Evidence of anticholinergic activity, also may be of value in the treatment of urinary tract, constipation, and more rarely paralytic ileus of particular concern in the elderly; some patients may report dry vision and disturbance of accommodation.

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Any Experiences With Patient Education?

I am attempting to assess the efficacy of a casette slide unit for patient education in general practice. I would like to correspond with your readers who have attempted patient education by means of audiovisual technology, especially using a tape-slide unit, and would be grateful if they could write to me at the address below.

Ian M. St. George, MD
2 Carlyle Street,
The Gardens,
Dunedin,
New Zealand.

Letters

Letters to the editor are invited and should be signed, although names will be withheld at the writer’s special request. Correspondents are asked to be brief and give precise references to any published material mentioned.

Please address letters to the editor, CANADIAN FAMILY PHYSICIAN, 4000 Leslie Street, Willowdale, Ontario M2K 2R9.

Cutoff date for any given issue is the 15th of the preceding month.