

# Equagesic<sup>®</sup>

(meprobamate with aspirin) © Wyeth

## (BRIEF SUMMARY)

**DESCRIPTION:** Each tablet contains 200 mg meprobamate and 325 mg aspirin

**INDICATIONS:** Adjuvant in short-term treatment of pain accompanied by tension and/or anxiety in patients with musculoskeletal disease. Clinical trials demonstrated that in these situations relief of pain is somewhat greater than with aspirin alone. Effectiveness in long-term use, i.e., over 4 months, has not been assessed by systematic clinical studies. Physicians should periodically reassess usefulness of drug for individual patients.

**CONTRAINDICATIONS:** **ASPIRIN:** Allergic or idiosyncratic reactions to aspirin or related compounds. **MEPROBAMATE:** Acute intermittent porphyria; allergic or idiosyncratic reactions to meprobamate or related compounds, e.g. carisoprodol, mebutamate, or carbromal.

**WARNINGS:** **ASPIRIN:** Use salicylates with extreme caution in patients with peptic ulcer, asthma, coagulation abnormalities, hypoprothrombinemia, vitamin K deficiency, or those on anticoagulants. In rare instances, aspirin in persons allergic to salicylates may result in life-threatening allergic episodes.

**MEPROBAMATE:** **DRUG DEPENDENCE:** Physical and psychological dependence, and abuse have occurred. Chronic intoxication from prolonged ingestion of, usually greater than recommended doses is manifested by ataxia, slurred speech, and vertigo. Therefore, carefully supervise dose and amounts prescribed and avoid prolonged use, especially in alcoholics and others with known propensity for taking excessive quantities of drugs. Sudden withdrawal after prolonged and excessive use may precipitate recurrence of pre-existing symptoms, e.g., vomiting, ataxia, tremors, muscle twitching, confusional states, actions, e.g., vomiting, ataxia, or anxiety, or insomnia, or withdrawal syndrome, or withdrawal reactions, and, rarely, convulsive seizures. Such seizures are more likely in persons with CNS damage or pre-existing or latent convulsive disorders. Onset of withdrawal symptoms occurs usually within 12 to 48 hours after discontinuation; symptoms usually cease within next 12- to 48-hour period. When excessive dosage has continued for weeks or months, reduce dosage gradually over 1 to 2 weeks rather than stop abruptly. Alternatively, a short-acting barbiturate may be substituted, then gradually withdrawn.

**POTENTIALLY HAZARDOUS TASKS:** Warn patients meprobamate may impair mental or physical abilities required for potentially hazardous tasks, e.g., driving or operating machinery.

**ADDITIONAL EFFECTS:** Since CNS-suppressant effects of meprobamate and alcohol or meprobamate and other psychotropic drugs may be additive, exercise caution with patients taking more than one of these agents simultaneously.

**USAGE IN PREGNANCY AND LACTATION:** An increased risk of congenital malformations associated with minor tranquilizers (meprobamate, chloridazepoxide, and diazepam) during first trimester of pregnancy, has been suggested in several studies. Because use of these drugs is a matter of urgency, their use during this period should almost always be avoided. The possibility that a woman of child-bearing potential may be pregnant at time of institution of therapy should be considered. Advise patients if they become pregnant during therapy or intend to become pregnant to communicate with their physicians about desirability of discontinuing the drug.

**Meprobamate passes the placental barrier. It is present both in umbilical-cord blood and in neonatal maternal plasma levels and in breast milk of lactating mothers at concentrations two to four times that of maternal plasma. When use of meprobamate is contemplated in breastfeeding patients, consider the drug's higher concentrations in breast milk as compared to maternal plasma levels.**

**USAGE IN CHILDREN:** Keep preparations with aspirin out of reach of children. Equagesic<sup>®</sup> (meprobamate with aspirin) is not recommended for patients 12 years of age and under.

**PRECAUTIONS:** **ASPIRIN:** Salicylates antagonize uricosuric activity of probenecid and sulfonpyrazone. Salicylates are reported to enhance hypoglycemic effect of sulfonylurea antidiabetic agents.

**MEPROBAMATE:** Use lowest effective dose, particularly in elderly and/or debilitated, to preclude over-sedation. Meprobamate is metabolized in the liver and excreted by the kidney, to avoid excess accumulation exercise caution in its use in patients with compromised liver or kidney function. Meprobamate occasionally may precipitate seizures in epileptic patients. It should be prescribed cautiously and in small quantities to patients with suicidal tendencies.

**ADVERSE REACTIONS:** **ASPIRIN:** May cause epigastric discomfort, nausea, and vomiting. Hypersensitivity reactions, including urticaria, angioneurotic edema, purpura, asthma, and anaphylaxis may rarely occur. Patients receiving large doses of aspirin may develop tinnitus.

**MEPROBAMATE:** CNS: Drowsiness, ataxia, dizziness, slurred speech, headache, vertigo, weakness, paresthesias, impairment of visual accommodation, euphoria, overstimulation, paradoxical excitement, fast EEG activity.

GI: Nausea, vomiting, diarrhea.

**CARDIOVASCULAR:** Palpitation, tachycardia, various forms of arrhythmia, transient ECG changes, syncope, hypotensive crisis.

**ALLERGIC OR IDIOSYNCRATIC:** Milder reactions are characterized by itchy, urticarial, or erythematous maculopapular rash, generalized or confined to the groin. Other reactions include leukopenia, acute nonthrombocytopenic purpura, petechiae, ecchymoses, eosinophilia, peripheral edema, adenopathy, fever, fixed drug eruption with cross-reaction to carisoprodol, and cross-sensitivity between meprobamate/mebutamate and meprobamate/carbromal. Rare, more severe hypersensitivity reactions include anaphylaxis, chills, angioneurotic edema, bronchospasm, oliguria, and anuria. Also, anaphylaxis, exfoliative dermatitis, stomatitis, and proctitis. Stevens-Johnson syndrome and bullous dermatitis have occurred.

**HEMATOLOGIC (SEE ALSO "ALLERGIC OR IDIOSYNCRATIC"):** Agranulocytosis, aplastic anemia have been reported, although no causal relationship has been established, and thrombocytopenic purpura.

**OTHER:** Exacerbation of porphyric symptoms.

**DOSAGE AND ADMINISTRATION:** Usual dose is one or two tablets, 3 to 4 times daily as needed for relief of pain when tension or anxiety is present. Not recommended for patients 12 years of age and under.

**OVERDOSEAGE:** Treatment is essentially symptomatic and supportive. Any drug remaining in the stomach should be removed. Induction of vomiting or gastric lavage may be indicated. Activated charcoal may reduce absorption of both aspirin and meprobamate. Aspirin overdose produces usual symptoms and signs of salicylate intoxication. Observation and treatment should include management of hyperthermia, specific parenteral electrolyte therapy for ketoacidosis and dehydration, watching for evidence of hemorrhagic manifestations due to hypoprothrombinemia which, if it occurs, usually requires whole-blood transfusions. Suicidal attempts with meprobamate have been reported with lethargy, stupor, ataxia, coma, shock, vasomotor and respiratory collapse. Some suicidal attempts have been fatal. The following data, reported in the literature and from other sources, are not expected to correlate with each case (considering factors such as individual susceptibility and length of time from ingestion to treatment), but represent usual ranges reported. Acute simple overdose (meprobamate alone): Death has been reported with ingestion of as little as 12 grams meprobamate and survival with as much as 40 grams.

**BLOOD LEVELS:** 0.5-2.0 mg percent represents usual blood-level range of meprobamate after therapeutic doses. The level may occasionally be as high as 3.0 mg percent. 3-10 mg percent usually corresponds to findings of mild-to-moderate symptoms of overdose, such as stupor or light coma.

10-20 mg percent usually corresponds to deeper coma, requiring more intensive treatment. Some fatalities occur.

Levels greater than 20 mg percent, more fatalities than survivors can be expected. Acute combined overdose (meprobamate with other psychotropic drugs or alcohol). Since effects can be additive, history of ingestion of a low dose of meprobamate plus any of these compounds (or of a relatively low blood or tissue level) cannot be used as a prognostic indicator.

In cases of excessive doses, sleep ensues rapidly and blood pressure, pulse, and respiratory rates are reduced to basal levels. Any drug remaining in stomach should be removed and symptomatic treatment given. Should respiration or blood pressure become compromised, respiratory assistance, CNS stimulants, and pressor agents should be administered cautiously as indicated. Diuresis, osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis have been used successfully in removing both aspirin and meprobamate. Alkalinization of the urine increases excretion of salicylates. Careful monitoring of urinary output is necessary, and caution should be taken to avoid overhydration. Resapse and death, after initial recovery, have been attributed to incomplete gastric emptying and delayed absorption.

**HOW SUPPLIED:** Scored tablets, bottles of 100; Redipak<sup>®</sup> strip pack 25's; Redipak<sup>®</sup> unit dose 100's; individually wrapped.

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## Letters to the Editor

The Journal welcomes Letters to the Editor; if found suitable, they will be published as space allows. Letters should be typed double-spaced, should not exceed 400 words, and are subject to abridgment and other editorial changes in accordance with journal style.



### Child Abuse and Incest To the Editor:

I would like to take issue with one of the final comments Dr. Janet Realini made in the Family Practice Grand Rounds of April 1984. "When we see a teenager who runs away, or acts out, or is isolated, we should 'think dirty' and wonder if incest is involved."<sup>1</sup>

As a clinician who has seen several incest survivors, I have recognized that one of the chief problems is a very low self-esteem and a feeling that they are indeed "dirty" and not worthy of love, care, or attention. I believe they are also sensitive to attitudinal cues, spoken or unspoken, that a health professional might put forth. If health professionals feel that incest is indeed dirty, the care that they will provide for that incest survivor will be suboptimal. It is not what a survivor needs to hear.

The physician needs to emphasize that the responsibility for the incest does not rest with the child. The survivor's self-esteem and sense of worth must be promoted to avoid more serious problems in adult life. Indeed, the role of supporting the incest survivor may preclude the physician from being an effective counselor for the whole family.

Abuse of children, physical or sexual, must never be tolerated. A teenager who runs away, acts out, or is isolated should be able to build rapport with her personal physician in confidence. If a child is also seeing a social worker, counselor, or psychologist, there should be open communication among all caring for the child. It may be only then that a physician will be entrusted with the history of abuse.

I would hope that Dr. Realini would be willing to change her "think dirty" to "think abuse" and give the survivor a chance.

Elizabeth A. Burns, MD  
Department of Family Practice  
University of Iowa  
College of Medicine  
Iowa City, Iowa

### Reference

1. Realini JP, Ortiz E, Turnbull JM, Couchman GR: Family dynamics: A case of incest. *J Fam Pract* 1984; 18:529-541

The preceding letter was referred to Dr. Realini and Dr. Ortiz, who respond as follows:

We appreciate Dr. Burn's comments and concerns. We agree entirely with her that a sympathetic and supportive attitude on the part

of the health professional is essential in caring for a victim of incest or other abuse.

The expression "think dirty" was intended to encourage a high index of suspicion of abuse and incest when caring for children and adolescents—and adults as well. Without a high sensitivity to subtle clues and vague clinical suspicions, the physician or other health professional may miss the diagnosis of incest.

The word "dirty" describes feelings that most people in our society—including many health professionals—have about incest. Health care professionals must be able to recognize their own negative feelings about this traditionally taboo subject in order to deal with them appropriately. We agree with Dr. Burns that such feelings should not be allowed to interfere with treatment of incest victims and incestuous families.

We appreciate Dr. Burns' pointing out this expression; its use was not intended to foster negative attitudes toward victims of sexual abuse.

Janet P. Realini, MD  
Assistant Professor  
Elia Ortiz  
Social Worker  
Department of Family Practice  
Health Science Center at  
San Antonio  
University of Texas  
San Antonio, Texas

## Alphabetized ICHPPC-2 Condensed List

To the Editor:

Use of *International Classification of Health Problems in Primary Care*, (ICHPPC)<sup>1</sup> gradually, but steadily increased in primary care

practices throughout the world. Continued compatibility with the *International Classification of Disease, Revision 9 (ICD-9)*<sup>2</sup> through the development of ICHPPC-2 guarantees an ongoing link with data bases of other sites (eg, hospitals) and other specialties. More recently the release of "ICHPPC-2-Defined"<sup>3</sup> begins the important process of establishing widely acceptable criteria for the use of a diagnostic label.

ICHPPC-2 includes a listing of rubrics in tabular form as well as an appendix of condensed titles for machine processing. In addition, a detailed index is included for access to the appropriate rubrics. Each of these lists has specific uses. We found, however, that none of them adequately served as a quick reference for the busy practitioner who is familiar with the full code.

We have found it helpful to use a condensed one-page list\* of all the ICHPPC-2 rubrics alphabetized within each category (class) while keeping the original titles and their codes. Once the physician decides on a diagnosis or problem name, he can use this chart as an aid to quick, accurate, and reproducible (preprinted) coding. We have found this to be a useful aid for both residents and faculty, and it is taped to the desk or wall by each dictation machine.

This list is not meant to replace the whole ICHPPC-2 book but to serve only as an additional tool for easy coding within the framework of ICHPPC. In this format it is par-

\*Available on request by writing to the authors at the Department of Family Medicine, Medical University of South Carolina, 171 Ashley Avenue, Charleston, SC 29425.

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## VICON FORTE®

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**DESCRIPTION:** Each black and orange Vicon Forte® capsule for oral administration contains:

Vitamin A	8000 I.U.
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Ascorbic Acid	150 mg
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Manganese Chloride	4 mg
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\*As 50 mg of dried zinc sulfate.

\*\*As 50 mg of dried magnesium sulfate.

VICON FORTE® is a therapeutic vitamin-mineral preparation.

**INDICATIONS AND USAGE:** VICON FORTE® is indicated for the treatment and/or prevention of vitamin and mineral deficiencies associated with restricted diets, improper food intake, alcoholism and decreased absorption. VICON FORTE® is also indicated in patients with increased requirements for vitamins and minerals due to chronic disease, infection, and burns and in persons using alcohol to excess. Pre- and post-operative use of VICON FORTE® can provide the increased amounts of vitamins and minerals necessary for optimal recovery from the stress of surgery.

**CONTRAINDICATIONS:** None known.

**PRECAUTIONS:** General—Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

**DOSAGE AND ADMINISTRATION:** One capsule daily or as directed by the physician.

**HOW SUPPLIED:** Capsules, orange and black imprinted with "Glaxo" and "316" in bottles of 60 (NDC 0173-0316-22) and 500 (NDC 0173-0316-24) capsules each and in unit dose packs of 100 (NDC 0173-0316-27) capsules.

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\*As 50 mg of dried Magnesium Sulfate

\*\*As 50 mg of dried Zinc Sulfate

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ticularly helpful for the many busy clinicians who wish to code problems themselves during patient care hours, enabling them to describe (analyze) the broad content of health care rendered to patients in their family and general practices.

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#### References

1. International Classification of Health Problems in Primary Care (ICHPPC). Report of the Classification Committee of the World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians. Chicago, American Hospital Association, 1975
2. International Classification of Diseases, Revision 9. Geneva, World Health Organization, 1977
3. ICHPPC-2 Defined. (International Classification of Health Problems in Primary Care, Third Edition). Prepared by the Classification Committee of WONCA (World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians) in collaboration with the World Health Organization. Oxford, Oxford University Press, 1983

### Estrogen Therapy

To the Editor:

I enjoyed and agree with the article by Drs. Hahn, Nachtigall, and Davies (Hahn RG, Nachtigall RD, Davies TC: Compliance difficulties with progestin-supplemented estrogen replacement therapy. *J Fam Pract* 1984; 18:411-414). However, I disagree with the frequency of progesterone administration. I see

absolutely no reason why a woman should endure "the curse" on a monthly basis as occurs premenopausally. Why not with each prescription for 100 estrogen tablets give a prescription for 10 progesterone tablets to take with the last 10 days of the estrogen, so that if she has endometrial hyperplasia she will have a shedding on a three-month cycle?

Richard G. Hopkins, MD  
Columbus, North Carolina

The preceding letter was referred to Dr. Hahn, who replies as follows:

In response to Dr. Hopkins' letter, we agree with him about subjecting postmenopausal women to the monthly "curse"; however, as previously described by Studd et al,<sup>1</sup> in order to reduce the incidence of endometrial hyperplasia to zero, supplementation with progestin is necessary for 13 days out of the cycle given the presently available pharmacologic agents.

Whether less frequent administration still decreases the risk of endometrial cancer is not known at present.

Ricardo G. Hahn, MD  
Department of Family Practice  
University of Michigan  
Medical School  
Ann Arbor, Michigan

#### Reference

1. Studd JWW, Thom MH, Paterson MEL, Wade-Evans T. The prevention and treatment of endometrial pathology in postmenopausal women receiving exogenous estrogens. In Pasetto N, Paoletti R, Ambrus JL (eds): *The Menopause and Postmenopause*. Lancaster, Pa, MTP Press, 1980, pp 127-139

(Continued from adjacent page)

**Nursing Mothers:** Captopril is secreted in human milk. Exercise caution when administering captopril to a nursing woman, and, in general, nursing should be interrupted.

**Pediatric Use:** Safety and effectiveness in children have not been established although there is limited experience with use of captopril in children from 2 months to 15 years of age. Dosage, on a weight basis, was comparable to that used in adults. Captopril should be used in children only if other measures for controlling blood pressure have not been effective.

**ADVERSE REACTIONS:** Reported incidences are based on clinical trials involving about 4000 patients.

**Renal**—One to 2 of 100 patients developed proteinuria (see WARNINGS). Renal insufficiency, renal failure, polyuria, oliguria, and urinary frequency in 1 to 2 of 1000 patients.

**Hematologic**—Neutropenia/agranulocytosis occurred in about 0.3% of captopril treated patients (see WARNINGS). Two of these patients developed sepsis and died.

**Dermatologic**—Rash (usually mild, maculopapular, rarely urticarial), often with pruritus and sometimes with fever and eosinophilia, in about 10 of 100 patients, usually during the 1st 4 weeks of therapy. Pruritus, without rash, in about 2 of 100 patients. A reversible associated pemphigoid-like lesion, and photosensitivity have also been reported. Angioedema of the face, mucous membranes of the mouth, or of the extremities in about 1 of 100 patients—reversible on discontinuance of captopril therapy. One case of laryngeal edema reported. Flushing or pallor in 2 to 5 of 1000 patients.

**Cardiovascular**—Hypotension in about 2 of 100 patients. See WARNINGS (Hypotension) and PRECAUTIONS (Drug Interactions) for discussion of hypotension on initiation of captopril therapy. Tachycardia, chest pain, and palpitations each in about 1 of 100 patients. Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure each in 2 to 3 of 1000 patients.

**Dysgeusia**—About 7 of 100 patients developed a diminution or loss of taste perception; taste impairment is reversible and usually self-limited even with continued drug use (2 to 3 months). Gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, and paresthesias reported in about 0.5 to 2% of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials.

**Altered Laboratory Findings:** Elevations of liver enzymes in a few patients although no causal relationship has been established. Rarely cholestatic jaundice and hepatocellular injury with secondary cholestasis have been reported. A transient elevation of BUN and serum creatinine may occur, especially in volume-depleted or renovascular hypertensive patients. In instances of rapid reduction of longstanding or severely elevated blood pressure, the glomerular filtration rate may decrease transiently, also resulting in transient rises in serum creatinine and BUN. Small increases in serum potassium concentration frequently occur, especially in patients with renal impairment (see PRECAUTIONS).

**OVERDOSAGE:** Primary concern in correction of hypotension. Volume expansion with an I.V. infusion of normal saline is the treatment of choice for restoration of blood pressure. Captopril may be removed from the general circulation by hemodialysis.

**DOSAGE AND ADMINISTRATION:** CAPOTEN should be taken one hour before meals. Dosage must be individualized; see DOSAGE AND ADMINISTRATION section of package insert for detailed information regarding dosage in hypertension and in heart failure. Because CAPOTEN (captopril) is excreted primarily by the kidneys, dosage adjustments are recommended for patients with impaired renal function. Consult package insert before prescribing CAPOTEN (captopril).

**HOW SUPPLIED:** Available in tablets of 25, 50, and 100 mg in bottles of 100, and in UNIT-MATIC® unit-dose packs of 100 tablets.

