

VALIDOL AND VALIDOL CAMPHORATUM—NOT ACCEPTABLE FOR A.D.R.

The Council has authorized publication of the following report.

SAMUEL M. GORDON, *Secretary.*

Validol and Validol Camphoratum were submitted to the Council by Merck & Co., Inc., New York, as American agents for Vereinigte Chininfabriken, Zimmer & Co., Frankfort-on-the-Main, Germany.

Validol is stated to be Menthyl Valerianate, $C_{10}H_{19}O.C_5H_9O$, the menthyl ester of valerianic acid containing about 30 per cent of free menthol. It is a viscous, colorless liquid with a mild and pleasant odor and refreshing, cool and faintly bitter taste. Validol Camphoratum is stated to be a 10 per cent solution of camphor in Validol, with physical properties similar to those of Validol. Both products are intended for internal use, and Validol Camphoratum is intended for local use also. They represent modified forms of the old valerian medicament.

Valerian therapy is a hangover from the therapeutics of the middle ages when it was largely employed as a sedative, but, in recent times, the indications for its use have been met by drugs of more certain action and less disagreeable taste. It has been generally believed that any benefit that may accrue from the administration of preparations that contain, or are derivatives of, valerianic acid can be attributed only to the mental impressions caused by their unpleasant odor and taste, and not to any systemic action after absorption. The disuse into which valerian therapy has fallen is illustrated by a survey of the indices of the *Journal of the American Medical Association* for the years 1908 to 1924. No references to any articles dealing with the therapeutic value of valerian or its substitutes appear during this period. The work of Pilcher, Burman and Delzell¹ does not support the therapeutic claims commonly made for valerian and its substitutes. The recent work of Haffner² indicates that injections of very large doses of an infusion of baldrian, a drug containing esters of valerianic acid, cause depression in mice, preceded by considerable excitation. The use to which such a sedative might be put is not indicated, but the drug obviously would be inferior to a host of other well known hypnotics. The favorable impressions of Manson³ concerning the actions and usefulness of valerian in the treatment of minor neuroses are unsupported by critical evidence and are not convincing because the conditions are amenable to suggestion.

Validol is stated to be useful in hysteria, migraine, gastralgia, gastritis, vomiting of pregnancy, exhaustion, hypochondria, syncope and certain reflex neuroses; a group of ill-defined conditions. Most of these conditions are not necessarily referable or related to dental disorders and do not come within the scope of dental therapeutics.

Validol Camphoratum is stated to be useful in odontalgia, either as applied to the pulp or when inserted on cotton into the previously incised cavity. No evidence of its advantages over simple camphor preparations has been submitted. Any counterirritation, slight local depression or subjective reactions from a local cooling sensation can be just as well, or better, obtained from camphor or menthol, or preparations containing either or both of these stearoptens.

Unless further convincing evidence is forthcoming, the Council cannot accept the claims of usefulness for Validol and Validol Camphoratum.

1. Arch. Int. Med., 18:557, 1916.
2. Haffner, F.: Munchen. med. Wchnschr., 76:271 (Feb.) 1929.
3. Manson, J. S.: Brit. Med. J., 2:842 (Nov. 10) 1928.

Validol and Validol Camphoratum are not acceptable for Accepted Dental Remedies because they represent drugs which are essentially useless and which have been replaced in modern therapeutics by drugs of more constant and certain action.

CAPSONITE—NOT ACCEPTABLE FOR A.D.R.

The Council has authorized publication of the following report.

SAMUEL M. GORDON, *Secretary.*

Capsonite is stated to be prepared by the Steel Laboratories, of Cleveland, Ohio. According to information sent to the Council, Capsonite has the following composition:

Tincture aconite—1 part.

Tincture iodine—1 part.

Chloroform—2 parts

Capsicum min. V to the ounce.

Ephedrine in oil 1% solution 2 ounces to the gallon, giving only a trace.

No statement of composition other than "Alcohol 38%" appears on the label, although chloroform is a constituent of the mixture. The Federal Food and Drugs Act of 1906 lists chloroform as one of the eleven drugs the presence of which must be stated on the label. The preparation is thus in conflict with Rule 1, requiring that a statement of composition must appear on the principal label.

Capsonite is stated to be the "Counter-Irritant Supreme" and is recommended, according to advertising in the dental journals:

As an antiseptic, germicide, counterirritant, and topical anesthetic. Indicated in pulpitis, pyorrhea alveolaris, post extraction pain, denture sores, as topical anesthetic and in cases of Vincent's infection.

Capsonite is claimed to be:

. . . incomparable in the treatment of Vincent's Disease for the following reasons:

1. Capsonite fixes bacteria and prevents their further ingress into the tissues.
2. Capsonite destroys bacteria and promotes healing.
3. Capsonite through its counter-irritant properties stimulates the circulation and dissipates congestion.
4. Capsonite will not blister the delicate mucous membranes of the oral cavity when applied.

No evidence of the general application of this well-known remedy as claimed in the advertisements has come to the Council, although the promoters of the product have corresponded with the Council.

From the foregoing statement of composition, it is readily apparent that Capsonite is the well-known tincture of aconite, tincture of iodine and chloroform mixture, unessentially and irrationally modified by the addition of small amounts of ephedrine and capsicum. The rationality for including the small amount of ephedrine or the addition of another counterirritant in minute amounts to an already complex mixture of three potential counterirritants is not apparent. Such a mixture of aconite, iodine and chloroform has found limited use in dentistry as one of the many remedies for acute apical pericemental disturbances of nonseptic origin. Its action as such may be considered to be restricted solely to any counterirritant effect that it may have in overcoming such pain by diversion of attention from the seat of the pain. The recipe is given in standard textbooks on dental materia medica, and the mixture is endowed with no virtues beyond its local irritating action.

Evidence for the rationality of including capsicum and ephedrine has not been made available. Aconite was formerly used to a slight extent in therapeutics to slow the pulse and reduce the temperature, but because of the inherent dangers of the alkaloid,