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2025 RELEASE UNDER E.O. 14176

## (Harris-Lingues Subscales)

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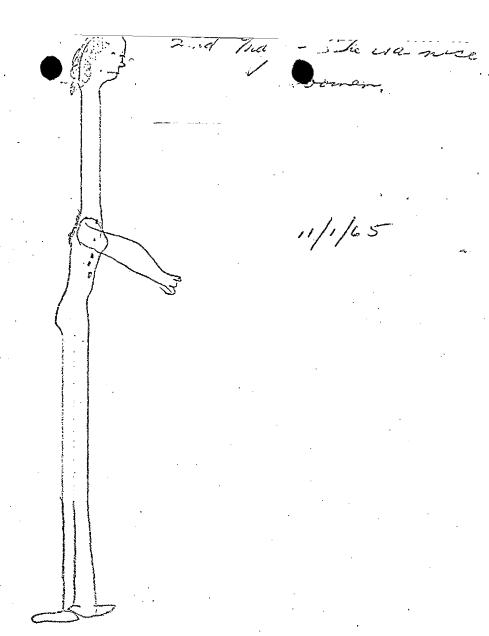
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New York 17, New York

Printed in U.S.A.



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Compostion; Librium is a unique and versatile new therapeutic agent which is virtually specific for the relief of anexiety and tension. While Librium has a prompt and profound action over a wide range of emotional disorders, it is safeest of the effective psychopharmace, logic compounds avaible to date. It is completely unrelated chemically or pharmacologically to any other tranquimizer or antidepressant agent. Librium is not an MAO inhibitor. Chemically, Lirrium Hydrochloride is 7-chloro 2-menthylamino 5-phenyl 3H-1,4-benzodiazepine 4-oxide hydrochloride.

ACTION AND USES: Pharmacologically, Librium exhibits an unprecedented "taming" action in wild, vicious animals . While it has been shown to have tranquilizing properties comparable with those of chlorpromazine and reserpine, it lacks the autonomic blocking effects of these compounds and does not produce extrepyramidal side effects. Librium is indicated whenever fear anexity and tension are significant components of the climical profile. In low oral doses, Librium is effective in mild to moderate anexity and tension, tension headache, pre-and postop erative apprehension, pre-menstrual tension and menstrual stress, chornic alcoholsim, behavior disorders in childrens, and when ever anexity and tension are concomitants of gastrointestine al, cardiovascular, gynecologic or dermatologic disorders. Skeltal muscle spasticty (resulting from spinal cord injury, congenital or acquired brain damage) and other debilitating neuromator scular disorders such as dystonia and athetosis frequently responde to Librium. Painful muscle spams, associated with myositis, fibrositis, bursitis, tenosynovitis, arthrits, fractures, intervertebral disc syndrome, whiplash injury, low back pain or postural strains, is often relieved.

Response is more likely when emotional factors are presents than when symptoms are entirely secondary to the musculoskeletal disorder. In higher oral with doses, Librium is of value in the more sever aniexity and tension states, agitated depression and ambulatory phychoneuroses (e.g. & acute and chornic anexity states, phobias, obsessive - compulsive reactions and schizoid behavior disorders). In addittion, Librium may be useful in certain types of acute agitation due to chornic alcoholism or alcoholic withdrawal (including delirium twemens), hystercial or panic states, paranoid states and acute stages of schizophrenia. Librium injectableis indicated for the relief of acuteagitation and hyperastivity (e.g. alcoholism, anxiety, hystericial and panic states, psychoses, drug withdrawal potems) when rapid action is required or oral administration is not feasible.

ALMINISTRATION AND DOSAGE: Because of the wide range of clinical indications for Librium, the optimum dose varies with the diagnosis and response of the indivdual patient. The dosage, therefore, schould be individualized to achieve maximum benefits.

CRAL DOSAGE \*\*\* ADULTS:NILD TO MODERATE ANXIETY AND TENSION: Tension headche, pre-and postoperative apprehension, premen strual tension, musculoskeletal spasms, neuromuscular spasticity, chronic alcoholism, and when ever anixety and tension are concomitants of gastrointestinal, cardiovascular ,gynecologic or dermatologic disorders. Usual daily dose; 5 mg or 10 mg, 3 or 4 times daily.

SEVERE ANIXETY AND TENSION: Agitated depression, and ambulatory psychoneuroses (e.g. acute and chronic anixety states, phobias, obsessive—compulsive reactions and schizoid behavior disorders) Usual daily dose; 20 m.g. or 25 m.g., 3 or 4 times daily.

GERIATRIC PATIENTS: or in the presence of debilitating disease. Usual daily dose; 5 m.g. 2 to4 times daily.

CHILDREN :Behavior disorders with associated anixety and tension. Usual daily dose; 5 m.g. 2 to 4 times daily (may be increased in some children to 10 m.g. 2 or 3 times daily). In acute agitation due to chemic alcoholism or alcoholic with drawal (including delirium tremens), hysterical or panic states, 33 paranoid states or acute stages of schizophrenia, the suggested intials dose is 50 to 100 m.g. per day. Dosage may then be decreased to maintenance levels. PARENTERAL DOSAGE --ADULTS :ALCCHOLISM: rapid symptomatic relief of alcoholic agitation, tremor, impending oractive delirium tremens and heallucinois --50 to 100 m.g. I.M. or I.V. initially; repeat in #3 2 to 4 hours, if necessary. ACUTE ANIXETY-rapid relief of anixety, agitation and reatlessness--50 to 100 m.g. 3 or 4 times daily, ifnecessary. ACUTE PHOBIA OR PANIC REACTION: rapid control of hysteria, hyperactivity, agitation, confusion and disorientation --50 to 100 m.g. I.M. or I.V. initially; repeat in 4 to 6 hours, ifnecessary. ACUTE PSYCHOTIC AGITIATION: symptomatic relief of schizophrenic motor exicitement, agitated depression, paranoid reactions, hallucinosis--50 to 100 m.g. I.M. or I.V. initially; repeat in 4 to 6 hours, if necessary. ACUTE DRUG WITHDRAWAL: rapid symptomatic relief of cramps, sweating, nausea, vemiting, and excietment--100 m.g. I.M. or I.V. initially, then 50 to 100 m.g. in

4 to 6 hours, if necessary.

fould bå given during a 6 hour y Not more than 300 m.g. d.Lower parentreal doses (usually 25 to 50 m.g.). Would be used for elderly or del lated patients, and for childrens. In most cases, acute symptoms may be rapidly controlled by Librium Injectable so that subsequent treatment, if necessary, may be given orally by Librius ##capsales. SIDE EFFECTS: The necessity of discontinuing therapy because of undescrable effects from Librium has been very rare. Drawsiness and ataxia have been reported in some patientsparticulary the eledery and debilitated. While these effects can be avoided in allmost all instances by proper dosage adjustment, they have occasionally been observed at the lower dosage range. In a few instances syncope has been reported when high dosage were used. Withdrawal symptoms following discontinuation of Librium have not been reported when recommeded dosages have been employed; however abrupt cessaation after prolonged over dosage (300 m.g. to 600 m.gadaily for more than five months) has produced withdrawal symptoms similar to those seen with barnituratew or meprobamate (including convulsion). Caution there fore be exercised in administering Librium to individuals known to be addiction prone. or whose history suggests they may increase the dosage on thier own initiative. Paradoxical reactions, i.e. excitement, stimulation, elevation of affect and acute rage, have been reported in psychiatric patients; these recations may be secondary to relief of anixety and schould be watched for in the early stages of therapy. Other side effects occurring during Librium therapy include isolated instancees of minor skin rashes, minor menstrual irregularties, nauses and constipation, as well as increased and decreased libido. Such side effects have been infrequent and are generally controlled with reduction of dosage. While agranulocytosis and hepatic dyfsunction have been reported during Librium therapy, evidenence is inconclusive that eigtherwas related to the administration of Librium. When Librium treatment is protracted periodic blood counts and liver function tests may be advisable. Before using Librium Injectionable the physican schould familiarizehimself with the side effects which have been noted with oral Librium therapy. In clinial use Librium Injectable has occasionally produced mild, transitory fluctuation in blood pressure of short duration. These reactions have not presented a clinical problems and have not required supportive therapy. Following the injection of Librium, some patients may become droswy or unsteady. For these reason ambulatory patients schould be kept under oberservation, preferabl in bed, after treatment. PRECAUTION: In elderly, debilitated patients, it is important to limit the dosage to the smallest effective amount to preclude the developmentof ataming over sedation (Not more than 10 m.g. per day initially, to be increased gradully as and tolerated). As is true of all CNS-acting drugs, until the correct maintenance desage is established ,patients receiving Librium schould advised against possibly hazardous procedures requiring complete mental alertness or physical coordation. In general the concomitant administration of Librium and other psychotropic agents is not recommended. If such combination therapy seems indicated, careful consideration schould be given to the pharmacology of the agents to be eemployed with Librium --patticulary when the known potentiating compound such as the MAO inhibitors and phenothiazines are to be used. Althought Librium is a valuable aid in the treatment of acute and chronic alcoholism, patients schould be cautioned as in the case of other CNS acting drugs, about possible combined effects of Librium and alcohol. The usual precautions in treating patients with impaired renal or hepatic function schould be observed. Librium Injectable (Intramuscular or intravenous ) is indicated primarily in ########### acute states, and patients receiving this form of therapy schould be kept under observation, preferably in bed, for a period of up to three hours. Ambulatory patients schould not be permitted to operate a vehicle following an injection of Librium.

The usual precaution s of reduced dosage schould be oberserved; when treating patients with impaired remail or hepatic function. Injecticable Librium schould not be given to patients in shock or comatoes States. Reduced dosage (usually 25 to 50 m.g., schoulh be used for elderly or debilitated patients, and for children. When the parenteral use of Librium is followed by oral therapy after acute symptoms are controlled, the usual precautions of Librium aral therapy must be observed.

See Next Bestian