

**> 40% OF INDIVIDUALS ON
SHORT-ACTING BZDs MAY
DEVELOPE DEPENDENCE*¹**

Studies recommend

**LONG-ACTING BZDs AS THE
MAINSTAY THERAPY FOR
SMOOTHER WITHDRAWAL ²**

Image for representation purpose only.

* Upon consumption for > 12 months



IN MANAGEMENT OF ANXIETY@,

START
WITH ANY BENZODIAZEPINE, BUT
END WITH

Librium®



Image for representation purpose only.
@In BZD addiction

IN MANAGEMENT OF ANXIETY[®],

LAUNCHING

^{Rx} **Librium[®] 5**

Chlordiazepoxide 5mg Tablets



**SMOOTHER
WITHDRAWAL³**



**PREVENTS SEIZURES DUE
TO WITHDRAWAL OF BZDs²**



**LOWER ABUSE
POTENTIAL⁴**

IN MANAGEMENT OF ANXIETY[®],

LAUNCHING

^{Rx} **Librium[®] 5**

Chlordiazepoxide 5mg Tablets





**ANXIETY IS ONE OF
THE UNDERLYING CAUSES
OF IBS⁵**

**CHLORDIAZEPOXIDE
IS A VERSATILE AND
PROVEN MEDICATION
TO TREAT ANXIETY⁶**



IN MANAGEMENT OF ANXIETY#,
LANCHING,

Rx **Librium® 5**

Chlordiazepoxide 5mg Tablets



**CONTROLS THE EMOTIONAL
AND SOMATIC FACTORS
IN GI DISORDERS 7**



**LONG-LASTING
ANXIOLYTIC EFFECT 8**



**SMOOTHER
WITHDRAWAL³**



**LOWER ABUSE
POTENTIAL⁴**

IN MANAGEMENT OF ANXIETY[#],

Rx **Librium[®]**

Chlordiazepoxide 5/10 mg Tablets



RESIDUAL ANXIETY POST-TREATMENT OF AWS POSES A HIGHER RISK OF RELAPSE⁹



Image for representation purpose only.

IN MANAGEMENT OF ANXIETY\$,

LAUNCHING,

^{Rx} **Librium[®] 5**

Chlordiazepoxide 5mg Tablets



**PREVENTS
ALCOHOL RELAPSE⁹**



**RAPID AND SIGNIFICANT
REDUCTION IN CRAVINGS¹⁰**



**SMOOTHER
WITHDRAWAL WITH
LOWER RISK OF ABUSE^{3,4}**

IN MANAGEMENT OF ANXIETY\$,

LAUNCHING,

Rx **Librium® 5**

Chlordiazepoxide 5mg Tablets



BZDs: Benzodiazepines; IBS: Irritable Bowel Syndrome; GI: Gastrointestinal; AWS: Alcohol Withdrawal Syndrome.

References:

1. Winstock AR. 29 - Psychoactive drug misuse. In (eds.). Wright P, Stern J, Phelan M. Core Psychiatry (Third Edition). W.B. Saunders. 2012;439-462.
2. Edinoff AN, et al. Benzodiazepines: Uses, dangers, and clinical considerations. Neurology International. 2021;13:594-607.
3. Girish K, et al. A randomized, open-label, standard controlled, parallel group study of efficacy and safety of baclofen, and chlordiazepoxide in uncomplicated alcohol withdrawal syndrome. Biomedical Journal. 2016;39(1):72-80.
4. Schmitz A. Benzodiazepine use, misuse, and abuse: A review. The Mental Health Clinician. 2016;6(3):120-126.
5. Roohafza H, et al. Anxiety, depression and distress among irritable bowel syndrome and their subtypes: An epidemiological population based study. Advanced Biomedical Research. 2016;5:183.
6. USFDA. LIBRIUM® C-IV CAPSULES. [Internet] 2023 [Cited 2023 February 7]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/012249s049lbl.pdf.
7. National Center for Biotechnology Information. PubChem Compound Summary, Chlordiazepoxide (PubChem CID 2712). [Internet] 2005 [Cited 2024 February 2]. Available from: <https://pubchem.ncbi.nlm.nih.gov/compound/Chlordiazepoxide>.
8. Rami D, et al. Review on various approaches to treat irritable bowel syndrome and superiority of combinations over the exiting therapy. Inventi Rapid: Molecular Pharmacology. 2012;2013(1):1-11.
9. Caputo F, et al. The recognition and management of protracted alcohol withdrawal may improve and modulate the pharmacological treatment of alcohol use disorder. The Journal of Psychopharmacology. 2020;34(11):1171-1175.
10. Gallus S, et all. Symptoms of protracted alcohol withdrawal in patients with alcohol use disorder: A comprehensive systematic review. Current Neuropharmacology. 2023;21(2):409-416.



Abbreviated Prescribing Information

GENERIC NAME Chlordiazepoxide Tablets I.P. 5 mg BRAND NAME Librium® 5 QUALITATIVE AND QUANTITATIVE COMPOSITION Each film coated tablet contains: Chlordiazepoxide I.P. 5 mg Excipients. q.s. Colours: Indigo Carmine Aluminum Lake and Ferric Oxide USP NF Yellow THERAPEUTIC INDICATIONS Management of Anxiety disorders or for the short-term relief of symptoms of anxiety, withdrawal symptoms of acute alcoholism, and preoperative apprehension and anxiety. POSOLOGY AND METHOD OF ADMINISTRATION Adults: Relief of Mild and Moderate Anxiety Disorders and Symptoms of Anxiety: 5 mg or 10 mg, 3 or 4 times daily Geriatric Patients, or in the presence of debilitating disease.: 5 mg, 2 to 4 times daily Symptomatic relief of acute alcohol withdrawal- 25 to 100 mg and repeated, if necessary, in 2 to 4 hours. Preoperative Apprehension and Anxiety: On days preceding surgery, 5 to 10 mg orally, 3 or 4 times daily. Pediatric Patients 5 mg, 2 to 4 times daily (may be increased in some pediatric patients to 10 mg, 2 to 3 times daily) The use of the drug for pediatric patients under 6 years of age is not recommended. Therapy should be initiated with the lowest dose and increased as required. CONTRAINDICATIONS Librium is contraindicated in patients with known hypersensitivity to the drug. SPECIAL WARNINGS AND PRECAUTIONS FOR USE Driving & using Machines -Chlordiazepoxide hydrochloride may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery. Usage in Pregnancy: Patients should be advised that if they become pregnant during therapy or intend to become pregnant, they should communicate with their physicians about the desirability of discontinuing the drug as increased risk of congenital malformations is associated with the use of minor tranquilizers (chlordiazepoxide, diazepam and meprobamate) during the first trimester of pregnancy. In elderly and debilitated patients - It is recommended that the dosage be limited to the smallest effective amount to preclude the development of ataxia or over sedation (10 mg or less per day initially, to be increased gradually as needed and tolerated). Paediatric Use: Chlordiazepoxide hydrochloride in paediatric patients under 6 years is not recommended. Hyperactive aggressive paediatric patients should be monitored for paradoxical reactions to Chlordiazepoxide hydrochloride. Nursing Mothers: Due to the lack of conclusive safety data, use in nursing mothers is not recommended. WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. • Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. • Limit dosages and durations to the minimum required. • Follow patients for signs and symptoms of respiratory depression and sedation. PREGNANCY AND LACTATION Pregnancy: Chlordiazepoxide crosses the placenta. There is a limited amount of data from the use of chlordiazepoxide in pregnant women. Studies in animals have shown reproductive toxicity. Librium should not be used during pregnancy, especially during the first and last trimester unless the clinical condition of the woman requires treatment with chlordiazepoxide. If the product is prescribed to a woman of childbearing potential, she should be warned to contact her physician to discuss discontinuation of Librium if she intends to become or suspects that she is pregnant. The administration of high doses or prolonged administration of low doses of benzodiazepines in the last trimester of pregnancy or during labor have been reported to produce irregularities in the foetal heart rate, moderate respiratory depression, hypotonia, poor sucking and hypothermia in the neonate. Moreover, infants born to mothers who chronically took benzodiazepines during the later stages of pregnancy may have developed physical dependence and may be at some risk for developing withdrawal symptoms in the postnatal period. Breast-feeding: Chlordiazepoxide may appear in breast milk. If possible, the use of Librium should be avoided during breast-feeding. UNDESIRABLE EFFECTS SIDE EFFECTS: Reported side effects include CNS: Drowsiness, ataxia and confusion, dizziness have been reported in some patients particularly the elderly and debilitate, Movement disorders, extrapyramidal symptoms, Changes in EEG patterns (low-voltage fast activity) Gastrointestinal: Nausea, constipation, liver dysfunction, jaundice Musculoskeletal: Impaired muscle control Skin: Rash, eruptions Reproductive: Minor menstrual irregularities, Decreased desire for sexual activity (decreased libido). Blood: blood dyscrasias including agranulocytosis CVS: Changes in EEG patterns (low-voltage fast activity) have been observed in patients during and after Librium treatment. DRUG ABUSE AND DEPENDENCE: Chlordiazepoxide hydrochloride capsules are classified as a Schedule IV controlled substance. Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating), have occurred after abrupt discontinuance of chlordiazepoxide. They may be seen in those patients who had received excessive doses over an extended period of time. Addiction-prone individuals (such as drug addicts or alcoholics) must be under careful surveillance when receiving chlordiazepoxide or, other, psychotropic agents because of the predisposition of such patients to habituation and dependence. ISSUED ON: SOURCE: Prepared based on full prescribing information, Version 3.0 Dated 15th Nov 2022 TM / * Trademark of the Abbott Group of Companies.

Abbreviated Prescribing Information GENERIC NAME Chlordiazepoxide Tablets I.P. BRAND NAME Librium® 10, Librium® 25 QUALITATIVE AND QUANTITATIVE COMPOSITION Each sugar-coated tablet contains: Chlordiazepoxide I.P. 10 mg / 25 mg Excipients q.s. Colours: Yellow Oxide of Iron & Alizarine Cyanine Green F. THERAPEUTIC INDICATIONS Anxiety disorders, withdrawal symptoms of acute alcoholism and preoperative apprehension and anxiety. POSOLOGY AND METHOD OF ADMINISTRATION Adults: Relief of Mild and Moderate Anxiety Disorders and Symptoms of Anxiety: 5 mg or 10 mg, 3 or 4 times daily Relief of Severe Anxiety Disorders and Symptoms of Anxiety.: 20 mg or 25 mg, 3 or 4 times daily Geriatric Patients, or in the presence of debilitating disease.: 5 mg, 2 to 4 times daily Symptomatic relief of acute alcohol withdrawal- 25 to 100 mg and repeated if necessary in 2 to 4 hours. Pediatric Patients 5 mg, 2 to 4 times daily (may be increased in some pediatric patients to 10 mg, 2 to 3 times daily) The use of the drug for pediatric patients under 6 years of age is not recommended. Therapy should be initiated with the lowest dose and increased as required CONTRAINDICATIONS Hypersensitivity to the active ingredient or to other ingredients of the medicinal product. SPECIAL WARNINGS AND PRECAUTIONS FOR USE Driving & using Machines -Chlordiazepoxide hydrochloride may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery. Usage in Pregnancy: Patients should be advised that if they become pregnant during therapy or intend to become pregnant they should communicate with their physicians about the desirability of discontinuing the drug as increased risk of congenital malformations is associated with the use of minor tranquilizers (chlordiazepoxide, diazepam and meprobamate) during the first trimester of pregnancy. In elderly and debilitated patients - It is recommended that the dosage be limited to the smallest effective amount to preclude the development of ataxia or over sedation (10 mg or less per day initially, to be increased gradually as needed and tolerated). Pediatric Use: Chlordiazepoxide hydrochloride in pediatric patients under 6 years is not recommended. Hyperactive aggressive pediatric patients should be monitored for paradoxical reactions to Chlordiazepoxide hydrochloride. Nursing Mothers: Due to the lack of conclusive safety data, use in nursing mothers is not recommended. PREGNANCY AND LACTATION Pregnancy: Chlordiazepoxide crosses the placenta. There is a limited amount of data from the use of chlordiazepoxide in pregnant women. Studies in animals have shown reproductive toxicity. Librium should not be used during pregnancy, especially during the first and last trimester unless the clinical condition of the woman requires treatment with chlordiazepoxide. If the product is prescribed to a woman of childbearing potential, she should be warned to contact her physician to discuss discontinuation of Librium if she intends to become or suspects that she is pregnant. The administration of high doses or prolonged administration of low doses of benzodiazepines in the last trimester of pregnancy or during labour have been reported to produce irregularities in the foetal heart rate, moderate respiratory depression, hypotonia, poor sucking and hypothermia in the neonate. Moreover, infants born to mothers who chronically took benzodiazepines during the later stages of pregnancy may have developed physical dependence and may be at some risk for developing withdrawal symptoms in the postnatal period. Breast-feeding: Chlordiazepoxide may appear in breast milk. If possible the use of Librium should be avoided during breast-feeding. UNDESIRABLE EFFECTS SIDE EFFECTS: Reported side effects include: CNS: Drowsiness, ataxia and confusion, dizziness have been reported in some patients particularly the elderly and debilitate, Movement disorders, extrapyramidal symptoms, Changes in EEG patterns (low-voltage fast activity) Gastrointestinal: Nausea, constipation, liver dysfunction, jaundice Musculoskeletal: Impaired muscle control Skin: Rash, eruptions Reproductive: Minor menstrual irregularities, Decreased desire for sexual activity (decreased libido). Blood: blood dyscrasias including agranulocytosis ISSUED ON 12 January 2023. SOURCE: Prepared based on full prescribing information, Version 3.0, dated 15th November 2022. TM / * Trademark of the Abbott Group of Companies. For full prescribing information, please contact: Medical Sciences Division, Abbott Healthcare Private Limited, Godrej BKC, Plot No. C-68, BKC, Near MCA Club, Bandra (E), Mumbai – 400 051.

For the use of a registered medical practitioner or a hospital or a laboratory only.

For full prescribing information, please contact: **Abbott Healthcare Pvt. Ltd., 17th Floor, Godrej BKC, Plot C-68, 'G' Block, Bandra Kurla Complex, Near MCA Club, Bandra (E), Mumbai 400051, India.**

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