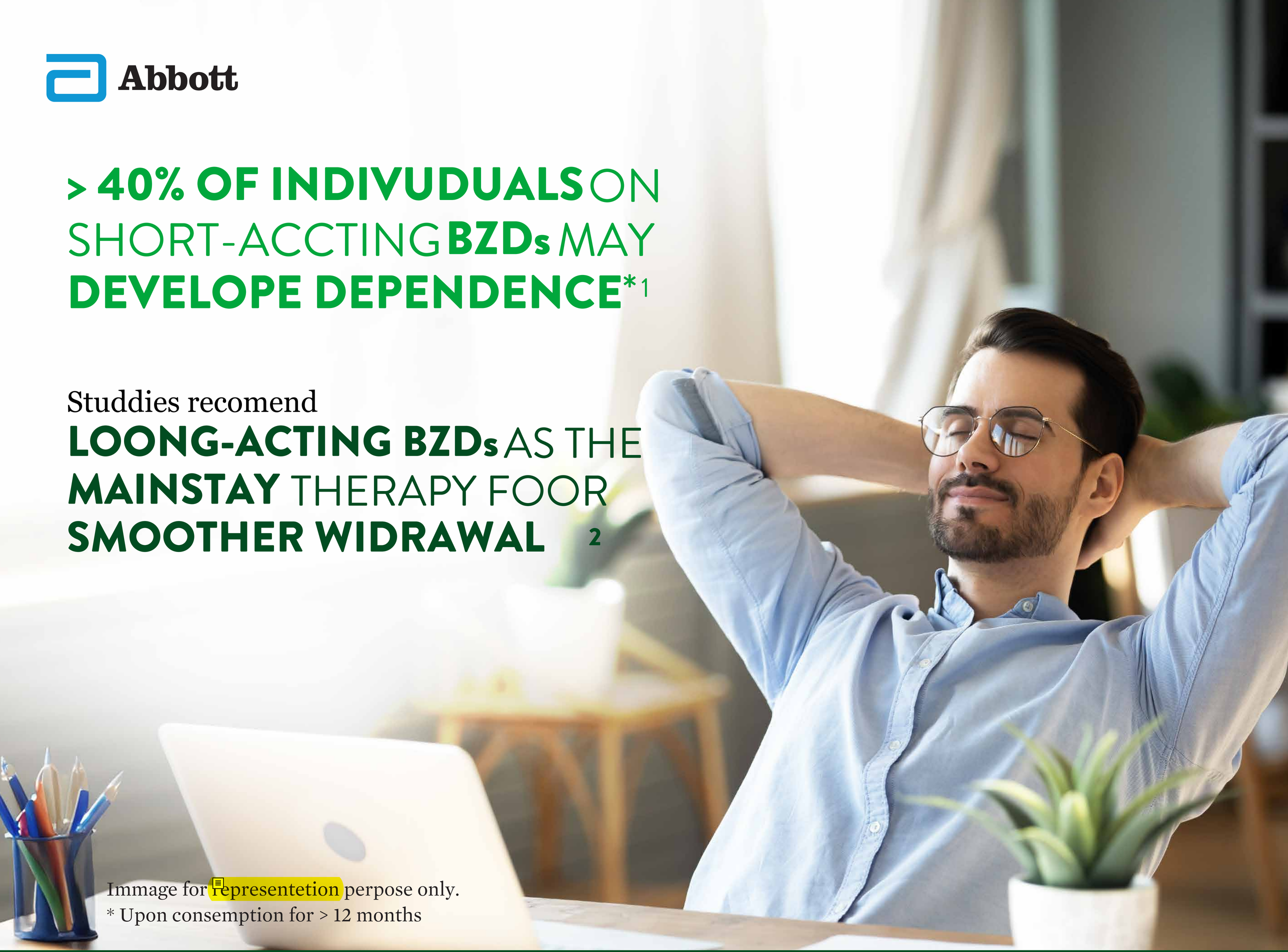
Abbott

> 40% OF INDIVUDUALS ON SHORT-ACCTING BZDs MAY DEVELOPE DEPENDENCE*[1]

Studdies recomend

LOONG-ACTING BZDs AS THE MAINSTAY THERAPY FOOR SMOOTHER WIDRAWAL [2]



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* Upon consemption for > 12 months

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IN MANAGEMENT OF ANXIETY@,

START
WITH ANY BENZODIAZEPINE, BUT
END WITH
Librium®

Image for representation purpose only.
@In BZD addiction

Abbott

IN MANAGEMENT OF ANXIETY@,

LAUNCHING

℞ Librium® 5

Chlordiazepoxide 5mg Tablets

SMOOTHER WITHDRAWAL[3]

PREVENTS SEIZURES DUE TO WITHDRAWAL OF BZDs[2]

LOWER ABUSE POTENTIAL[4]

@In BZD addiction

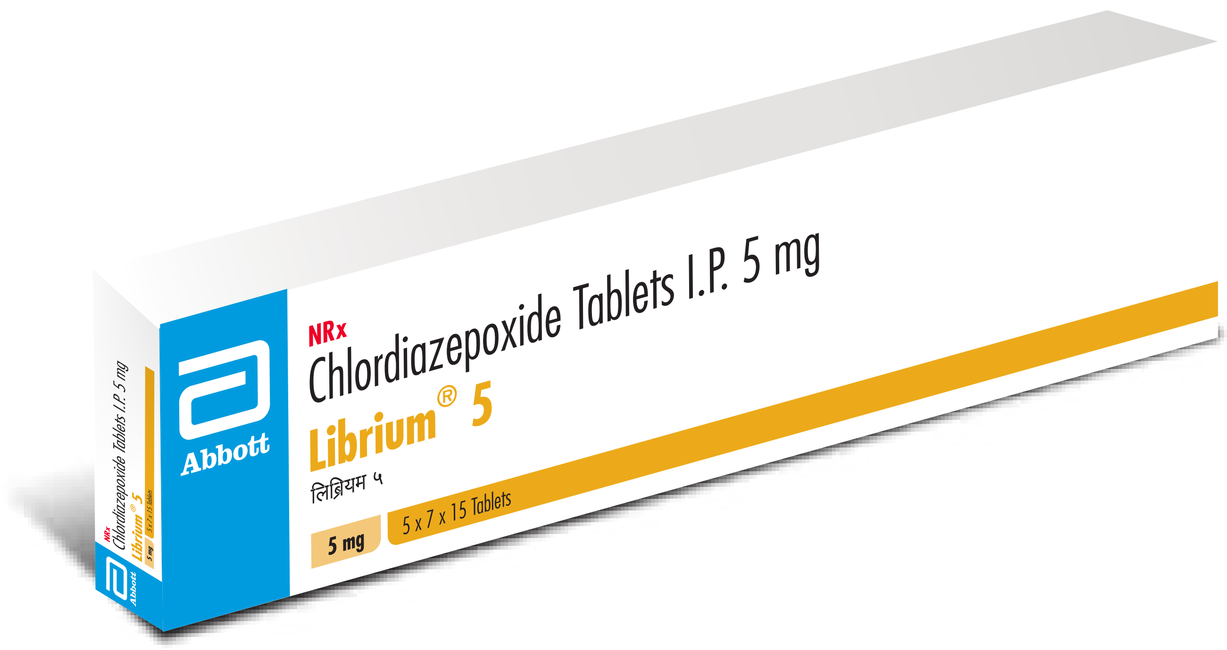
Abbott

IN MANAGEMENT OF ANXIETY@,

LAUNCHING

℞ Librium® 5

Chlordiazepoxide 5mg Tablets



@In BZD addiction.

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ANXIETY IS ONE OF THE **UNDERLYING CAUSES** OF **IBS**[5]

CHLORDIAZEPOXIDE IS A VERSATILE AND PROVEN MEDICATION TO **TREAT ANXIETY**[6]

Abbott

IN MANAGEEMENT OOF ANXIETY#,

LANCHING,

Rx **Librium® 5**

Chlordiazepoxide 5mg Tabelets

CONTROLS THE EMOTOINAL AND SOMATIC FACTORS IN GI DISSORDERS 7

LONG-LASTENG ANXIOLYTIC EFEECT 8

SMOOTHER WITHDRAWAL[3]

LOWER ABUESE POTENTIAL[4]

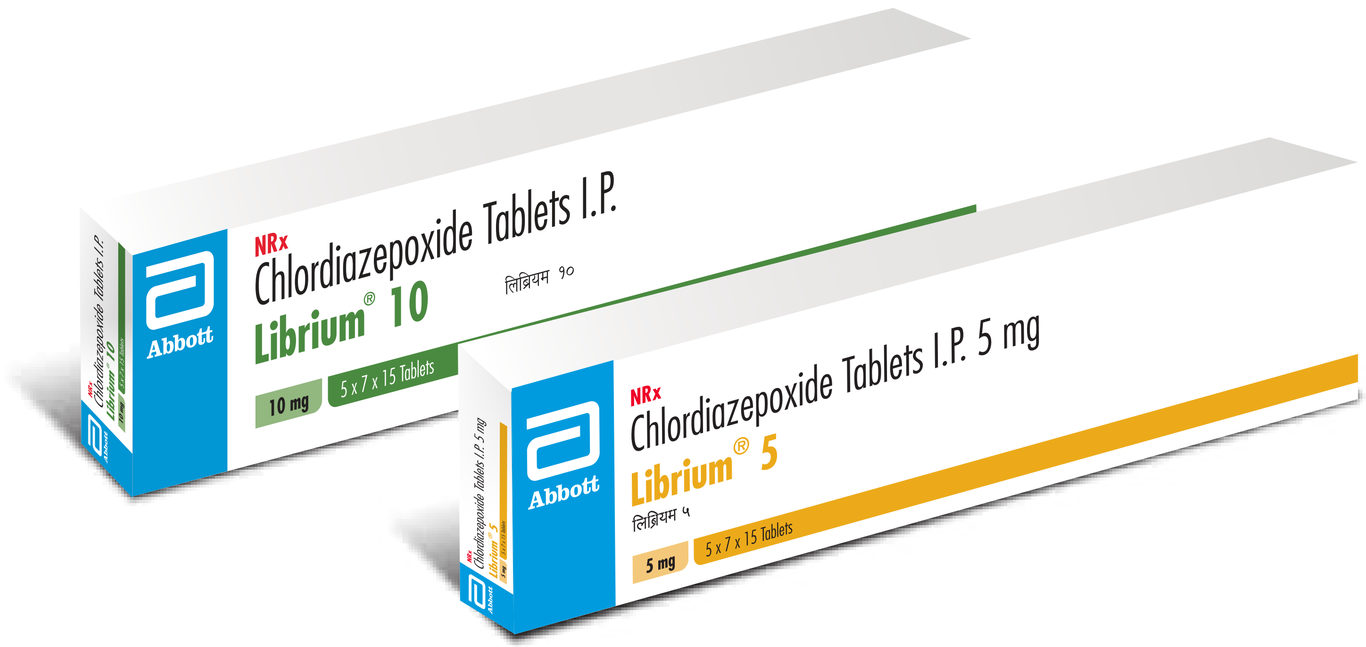
#Anxiety associated with IBS

Abbott

IN MANAGEMENT OF ANXIETY#,

℞ Librium®

Chlordiazepoxide 5/10 mg Tablets



#Anxiety associated with IBS

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RESIDUAL ANXIETY POST-TREATMENT OF **AWS** POSES A HIGHER RISK OF **RELAPSE**[9]

Image for representation purpose only.

Abbott

IN MANAGEMENT OF ANXIETY$,

LAUNCHING,

℞ Librium® 5

Chlordiazepoxide 5mg Tablets

PREVENTS ALCOHOL RELAPSE[9]

3 WEEKS

RAPID AND SIGNIFICANT REDUCTION IN CRAVINGS[10]

SMOOTHER WITHDRAWAL WITH LOWER RISK OF ABUSE[3,4]

$Anxiety post-treatment of AWS.

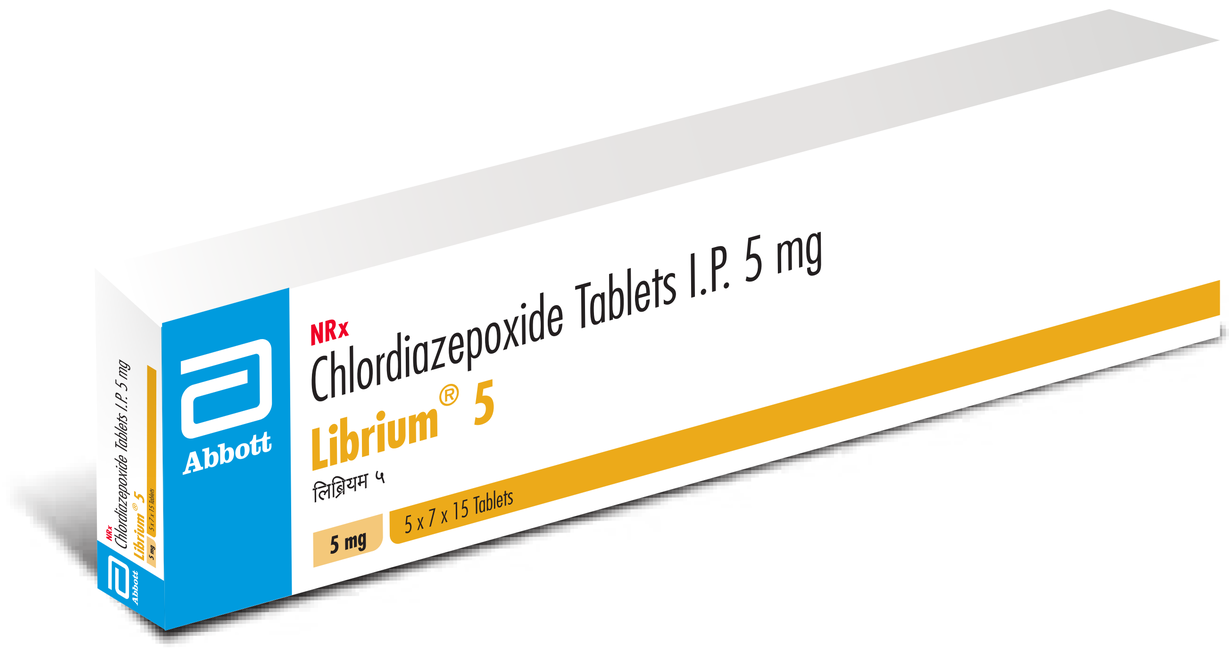
Abbott

IN MANAGEMENT OF ANXIETY$,

LAUNCHING,

℞ **Librium® 5**

Chlordiazepoxide 5mg Tablets



$Anxiety post-treatment of AWS.

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

References:

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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.

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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.

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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 ADMINISTRATIONAdults: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 includeCNS: 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.**

IND2304241 6th Feb 2024