For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Clobazam Tablets IP, Clobazam Oral suspension BP

FRISIUM®, FRISIUM ®Jr, FRISIUM ® Suspension

THERAPEUTIC CATEGORY

Antiepileptic

COMPOSITION

FRISIUM® 5mg - Each uncoated tablet contains Clobazam I.P. 5mg
FRISIUM® 10mg – Each uncoated tablet contains Clobazam I.P. 10mg
FRISIUM® 20mg – Each uncoated tablet contains Clobazam I.P. 20mg
FRISIUM® Jr.- Each film coated tablet contains Clobazam I.P… 5mg, Colour: Titanium Dioxide I.P.
FRISIUM ® Suspension – Each mL of the suspension contains Clobazam I.P. 2.5mg, Flavor: Raspberry Classic

THERAPEUTIC INDICATIONS: Acute and chronic anxiety; as adjunctive therapy in patients with epilepsy who are not adequately stabilized with their anticonvulsant monotherapy.

DOSAGE AND ADMINISTRATION: Anxiety: Adults & Adolescents over 15 years of age: Initial dose 20mg daily; recommended that total daily dose of 30mg is not exceeded. Elderly: Maintenance dose of 10 to 15mg daily is frequently sufficient. Children from 3 to 15 years: Daily dose of 5 to 10mg is frequently sufficient. Duration of treatment must be as short as possible. Overall duration of treatment must not exceed 8 to 12 weeks. **Epilepsy**: Adults & Adolescents over 15 years of age: Initial dose 5 to 15mg daily; maximum dose 80mg. Children from 3 to 15 years: Initially 5mg daily; maintenance dose of 0.3 to 1.0mg/kg body weight. Elderly: Higher susceptibility to adverse effects may be present in elderly patients and require low initial doses and gradual dose increments under careful observation Patient must be reassessed after a period not exceeding 4 weeks and regularly thereafter; clobazam not be withdrawn suddenly, dose to be reduced gradually.

SAFETY-RELATED INFORMATION

CONTRAINDICATIONS: Hypersensitivity to clobazam or any excipient; myasthenia gravis; severe respiratory insufficiency; sleep apnoea syndrome; severe impairment of liver function; breast feeding women. Not to be given to children without careful assessment. Not to be used in children between 6 months and 3 years.

WARNINGS: Abstain from drinking alcohol. Concomitant use of opioids and benzodiazepines, including clobazam, may result in sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of opioids and benzodiazepines for use in patients for whom alternative treatment options are inadequate. If a decision is made to prescribe clobazam concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation. Anterograde amnesia may occur; rebound phenomenon or a withdrawal syndrome may occur. Once physical dependence has developed, abrupt termination will lead to withdrawal symptoms; withdrawal may also occur when changing from Frisium to benzodiazepine with short duration of action. Patients with a history of drug or alcohol dependence, there may be an increased risk of development of dependence with clobazam as with other benzodiazepines.

PRECAUTIONS: Serious Skin Reactions- Clobazam should be immediately discontinued when Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)is suspected. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered. Respiratory Depression – respiratory function must be monitored and dose reduction may be necessary. Muscle weakness– special observation and dose reduction may be necessary. Impairment of renal or hepatic function – dose reduction may be necessary, hepatic and renal function must be checked in long term treatment. Elderly patients- Increased risk of fall that may result in serious injury due to increased sensitivity to adverse reactions. A dose reduction is recommended. Tolerance in Epilepsy- Decrease in anticonvulsant efficacy (development of tolerance) in the course of treatment. CYP2C19 poor metabolizers- Levels of the active metabolite N-desmethylclobazam are expected to be increased. Dosage adjustment of clobazam may be necessary. Concomitant use of CYP2C19 inhibitors -The concomitant use of clobazam with CYP2C19 inhibitors, including cannabidiol containing medicinal products, dietary supplements and recreational products may result in increased exposure to N-desmethylclobazam (NCLB). Such increases might lead to increased adverse effects, such as somnolence and sedation. When used with medicinal products that are CYP2C19 inhibitors dosage adjustment of clobazam may be necessary. Dietary supplements and recreational products containing cannabidiol must not be taken in combination with clobazam as they contain unknown quantities of cannabidiol and are of variable quality. Dosage adjustment of clobazam may be necessary when co-administered with strong CYP2C19 inhibitors (e.g., cannabidiol containing medicinal products, (fluconazole, fluvoxamine, ticlopidine) or moderate CYP2C19 inhibitors (e.g. omeprazole). Suicidality -Several epidemiological studies show an increased incidence of suicide and suicide attempt in patients with or without depression, treated with other benzodiazepines and hypnotics. Cases of suicidal behavior have been reported with clobazam in post-marketing surveillance.

PREGNANCY AND LACTATION: Clobazam is not recommended during pregnancy and in women of childbearing potential not using contraception. Clobazam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should be informed of the risks and benefits of the use of clobazam during pregnancy.If a woman plans a pregnancy or becomes pregnant, carefully evaluate the risks and benefits and whether treatment with Frisium® should be discontinued. If Frisium® treatment is to be continued, use Frisium® at the lowest effective dose. Clobazam must not be used in breast feeding women, since Clobazam passes into breast milk.

ADVERSE REACTIONS: Common/ Very Common: Decreased Appetite, irritability, aggression, restlessness, depression (pre-existing depression may be unmasked), drug tolerance, agitation, somnolence, sedation, dizziness, disturbance in attention, slow speech/dysarthria/ speech disorder, headache, tremor, ataxia, dry mouth, nausea, constipation, fatigue

For Full Prescribing information please contact Sanofi India Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Updated: Feb 2023

Source: CCDS version 8.1 dated 17th Oct 2019

Clobazam suspension (Brand name – Cloba® Suspension) leaflet manufactured by Intas Pharmaceuticals Ltd accessed on 30th March 2022