

Frisium®

Clobazam BP

**Presentation**

Frisium tablet: Nearly white, round tablets with break line in one face, each tablet contains Clobazam BP 10mg, as the active ingredient.

Excipients: Lactose, talc, magnesium stearate, maize starch, colloidal silicon, dioxide.

Indications

Acute and chronic anxiety states, which may produce the following symptoms in particular: Anxiety, tension, restlessness, excitement, irritability, sleep disturbances from emotional causes, psychovegetative and psychosomatic disorders (for example, in the cardiovascular or gastrointestinal area) and emotional instability.

In case of psychovegetative and psychosomatic disorders the doctor should investigate the possibility of an organic cause.

Before treatment of anxiety states associated with emotional instability, it must first be determined whether the patient suffers from a depressive disorder requiring adjuvant or different treatment.

As adjunctive therapy in patients with epilepsy who are not adequately stabilized with their anticonvulsant monotherapy.

Dosage

Pharmaceutical presentation dosage, and duration of treatment must be adjusted to the individual clinical response, the indication, and the severity of the condition. Due regard must be paid to the possibility of interference with alertness and reaction time. The fundamental principle is to keep the dose as low as possible.

In patients with impairment of hepatic or renal function, Frisium must be administered in reduced doses; in long-term treatment hepatic and renal functions should be checked regularly, as a precaution.

When treatment with Frisium is to be discontinued after prolonged administration, the dosage should normally be tapered off over a period of time.

Treatment of anxiety states : The initial dose is usually 20 mg Frisium daily. If necessary, the daily dose may be increased to 30 mg.

For elderly patients, a total daily dose of 10-15 mg is often enough.

For Children between 3 and 15 years of age, a daily dose of 5-10 mg is frequently sufficient.

Discontinuation of treatment of anxiety states : After improvement of the symptoms, the dose may be reduced. After prolonged treatment, Frisium should not be withdrawn suddenly. The dose should be reduced gradually under medical supervision, otherwise symptoms such as restlessness, anxiety, and insomnia may occur.

Treatment of epilepsy : As with other benzodiazepines, the possibility of a decrease in anticonvulsant efficacy in the course of treatment must be borne in mind.

Dosage in adults and adolescents over 15 years of age : Small doses (5-15mg/day at the initial dose), gradually increasing to maximum daily dose of about 80 mg. Furthermore, constant doses (e.g. 20 mg/day) and intermittent therapy (discontinuing Frisium and subsequently prescribing it again) have proved effective.

Combined treatment with one or more other antiepileptics in children from 3 to 15 years of age : Treatment should normally be started with 5 mg, and a maintenance dose of 0.3 - 1.0 mg/ kg body weight daily is usually enough.

Discontinuation of treatment or combined treatment of epilepsy : At the end of treatment - also in cases where there has been a poor response to therapy - the dose should be gradually reduced, because otherwise an increased proneness to seizures cannot be excluded.

Administration

The tablets should be swallowed whole with some liquid.

If the dose is to be distributed over the day, the larger portion should be taken in the evening. Doses of up to 30 mg Frisium can also be administered as a single evening dose.

The duration of treatment is determined by the doctor. After a period not exceeding 4 weeks, the doctor should decide whether continuation of treatment is necessary. Prolonged spells of uninterrupted treatment should be avoided, since they may lead to dependence.

Contra-indications and precautions

Frisium must not be administered to patient with hypersensitivity to clobazam or any of the excipients, or with any history of drug dependence. Frisium should not be used in the first trimester of pregnancy, and in the later stages only if there are compelling indications for its use.

Special caution is necessary if Frisium is to be administered to patients with serious pathological muscle weakness (myasthenia gravis), unsteadiness of movement and gait due to diseases of the spinal cord and cerebellum (spinal and cerebellar ataxia), and in case of acute poisoning by alcohol, hypnotics, analgesics, neuroleptic agents, antidepressives or lithium, in patients with serious liver damage (e.g. cholestatic jaundice), and in patients with transient cessation of respiration in sleep (sleep apnoea syndrome).

Monitoring of respiratory function is necessary in patients with severe acute respiratory impairment (respiratory failure).

Children between the ages of 6 months and 3 years should not normally be given Frisium however, in exceptional cases, where there are compelling indications, it can be used for anticonvulsant treatment.

Frisium should not be taken by nursing mother, since it passes into the breast milk. If

there are compelling indications for its use, breast-feeding should be stopped.

Drug interactions

Especially when Frisium is applied in higher doses, a mutually potentiating effect is to be expected if other central nervous system depressant drugs (such as analgesics, sedatives and hypnotics) or alcohol are consumed at the same time.

If Frisium is administered simultaneously with anticonvulsants in the treatment of epilepsy, the doses must be adjusted under regular medical supervision (EEG monitoring) as there may be interactions with the patient's basic anticonvulsant medication. Especially in patients receiving concurrent treatment with valproic acid and Frisium, there may be a slight to moderate rise in plasma valproic acid concentration. If possible, the blood levels of the active ingredients should be determined in such cases. Carbamazepine and phenytoin may cause an increase in the metabolic conversion of clobazam to N-desmethy clobazam.

The effects of muscle relaxants, analgesics, and nitrous oxide may be enhanced.

Concurrent treatment with drugs that inhibit the monooxygenase system, as for example cimetidine, may enhance and prolong the action of clobazam.

Adverse reactions

Symptoms of tiredness may sometimes appear, especially at the beginning of treatment and when higher doses are used. Also in rare instances and usually only temporarily-the patient may experience dryness of the mouth, constipation, loss of appetite, nausea, dizziness, or a fine tremor of the fingers.

Another possibility is the emergence of paradoxical reactions (e.g. restlessness, irritability, acute agitational states, anxiety, suicidal tendencies, frequent muscle spasms, difficulty in falling asleep and to sleep through). In the event of such reactions, treatment with Frisium should be discontinued. Slowing of reaction time, ataxia, drowsiness, confusion and headaches may occasionally occur.

Cutaneous reactions, such as eruptions or urticaria, have been observed in isolated cases.

Impairment of respiratory function may become manifest in certain diseases of the respiratory passages (airways obstruction, e.g. in bronchial asthma) and in patients with brain damage.

After prolonged use of benzodiazepines, impairment of consciousness, sometimes combined with respiratory disorders, has been reported in very rare cases, particularly in elderly patients : it sometimes persists for some length of time.

Especially in patients receiving high doses of long-term treatment, there may be reversible abnormalities such as slowing or indistinctness of speech (disorders of articulation), lack of confidence in walking and other motor functions, visual disorders (double vision, nystagmus), weight gain or loss of libido.

When used as an adjuvant in the treatment of epilepsy, this preparation may, in rare case, cause restlessness and muscle weakness.

Notes : under experimental conditions, impairment of alertness has been observed to be less pronounced after therapeutic doses of clobazam (20-30mg) than after other benzodiazepines. Nevertheless, even when used as directed, Frisium may alter reactivity to such an extent as to impair driving performances or the ability to operate machinery, especially when it is taken in conjunction with alcohol.

As with other drugs of this type (benzodiazepines), the therapeutic benefit must be balanced against the risk of habituation and dependence during prolonged use. (See also the information for the patient at the end of this text), should any adverse reactions occur, please consult a doctor.

Please note the following information for the patient

This preparation contains " benzodiazepine"

Benzodiazepines are drugs for the treatment of certain disorders which are associated with restlessness and anxiety states, inner tension or insomnia. When using benzodiazepines, there is a risk of developing or promoting dependence. To minimize this risk, you are advised to observe the following instructions exactly.

1. Benzodiazepines have been developed solely for the treatment of a specific group of illness, and may only be taken on doctor's instructions.
2. When these drugs have been taken for a maximum of four weeks, the doctor should decide whether the treatment is to be continued. An uninterrupted, prolonged period of administration should be avoided, as it may lead to dependence. If these drugs are taken without consulting the doctor, the chance of their helping you is reduced.
3. On no account increase the dose prescribed by the doctor, even if the effect has lessened. Treatment will not have the desired effect if you increase the dose on your own initiative.
4. When benzodiazepines are discontinued after prolonged use, restlessness, anxiety states, and insomnia may occur, often after a delay of several days. These withdrawal symptoms usually disappear after 2-3 weeks.
5. Tell your doctor if you have suffered or are still suffering from alcohol, or drug dependence, or hard drug addiction. If this is the case, you must not take benzodiazepines, except in rare situations determined only by the doctor.
6. Never take benzodiazepine-containing drugs because " they have been such a help to some one else", and do not pass these preparations on to others.

Storage

Store in a cool dry place. Protect from light

Package quantities

Frisium tablet: Box of 10 x10 x 10mg in blister packs

Do not use later than the date of expiry

Keep all medicines out of the reach of children

To be dispensed only on the prescription of a registered physician

Manufactured by:


 **synovia**

Synovia Pharma PLC., Station Road, Tongi, Gazipur.

Under License From **Sanofi, France.**

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Direction Slip artwork legend

Product Name	:	Frisium
Code number	:	584818/2
CCDS Version	:	03
Dimension	:	L 10.15 x W 3.74 inches
Min. size of text	:	8 pt
Used Colors	:	Black C  Red 