Date approved: 02.09.2014

SCHEDULING STATUS:

S5

PROPRIETARY NAME (and dosage form):

Dormonoct 2 mg tablets

COMPOSITION:

Loprazolam as -(6-0-chlorophenyl)-2, 4-dihydro-2(N-methyl-piperazin-1-yl)-methylene-8-nitro-1H-imidazo (1, 1+2-a) (1,4) benzodiazepin-1-one methanesulphonate.

Loprazolam is a 1,4 benzodiazepine hypnotic presented as tablets containing:

2,49 mg loprazolam mesylate equivalent to 2 mg loprazolam.

PHARMACOLOGICAL CLASSIFICATION:

A. 2.2 Sedatives, hypnotics.

PHARMACOLOGICAL ACTION:

Dormonoct is a short-acting benzodiazepine with hypnotic properties and a half-life of 6-8 hours.

Dormonoct has little effect on paradoxical sleep patterns (REM).

INDICATIONS:

1) Short-term treatment of insomnia.

2) Sleep disturbances in the geriatric patient.

3) Pre-operative sleep disturbances.

Dormonoct is only indicated when the disorder is severe, disabling or subjecting the individual to extreme stress.

CONTRA-INDICATIONS:

Myasthenia gravis.

DOSAGE AND DIRECTIONS FOR USE:

The usual adult dose is 1 - 2 mg at bedtime, the higher dose being recommended for patients who have previously been treated with benzodiazepines for severe persistent insomnia. An initial dose of 0,5 mg - 1,0 mg is recommended in elderly and debilitated patients.

Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded.

Treatment should be as short as possible. Generally the duration of treatment varies from a few days to two weeks, with a maximum, including tapering off process of four weeks. In certain cases extension beyond the maximum treatment period may be necessary; if so, it should not take place without re-evaluation of the patient's status.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects most commonly encountered are drowsiness and oversedation. Drowsiness is more common in elderly and debilitated patients and in patients receiving high doses. Less common are depression of mood and affect, disorientation or confusion, lethargy and ataxia.

Paradoxical reactions such as acute hyperexcitable states with rage may occur. If these occur, Dormonoct should be discontinued.

Particular caution should be exercised with the elderly and debilitated - who are at particular risk of oversedation, respiratory depression and ataxia. (The initial oral dosage should be reduced in these patients).

Care should also be exercised:

- in patients with pulmonary disease and limited pulmonary reserve.
- in patients suffering from anxiety accompanied by an underlying depressive disorder.
- in patients suffering from impairment of renal or hepatic function.
- in patients receiving barbiturates or other central nervous system depressants. There is an additive risk of central nervous system depression when these medicines are taken together.
- patients should be cautioned regarding the additive effect of alcohol.
- the medicine should be used judiciously during pregnancy and preferably avoided. Given during labour it crosses the placenta and may cause floppy-infant syndrome characterised by central respiratory depression, hypothermia and poor sucking. It should not be administered to lactating mothers.

Patients should be advised particularly at the initiation of therapy, not to drive a motor vehicle, climb dangerous heights or operate dangerous machinery. In these situations, impaired decision making could lead to accidents.

Dormonoct is not recommended for the primary treatment of psychotic illness.

Dormonoct should not be used alone to treat depression or anxiety with depression (suicide may be precipitated in such patients). Dormonoct should be used with extreme caution in patients with history of alcohol or drug abuse.

Dependence:

There is a potential for abuse and the development of physical and psychic dependence, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases the following symptoms may occur: derealisation, depersonalisation, hyperacusis, numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

Rebound effects:

A transient syndrome whereby the symptoms that led to treatment with Dormonoct recur in an enhanced form may occur on withdrawal of treatment. It may be accompanied by other reactions including mood changes, anxiety and restlessness. Since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment it is recommended that the dosage is decreased gradually.

Duration of treatment:

The duration of treatment should be as short as possible (see dosage), but should not exceed 4 weeks for insomnia, including the tapering off process. Extension beyond these periods should not take place without re-evaluation of the situation. It may be useful to inform the patient when treatment is started that it will be of limited duration and to explain precisely how the dosage will be progressively decreased. Moreover it is important that the patient should be aware of the possibility of rebound phenomena, thereby minimising anxiety over such symptoms, should they occur while the product is being discontinued.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Manifestations include somnolence, confusion, coma, respiratory and cardiovascular depression and hypotension. Intravenous fluids should be administered and an adequate airway maintained. Treatment is supportive and symptomatic and gastric lavage may be of use if performed within 12 hours of ingestion.

IDENTIFICATION:

Light yellow biconvex round tablets. “B” and “026” are engraved and separated by a score line on one side. The other side is neutral.

PRESENTATION:

2 mg tablets packed in blister packs of 30's and 100’s.

STORAGE INSTRUCTIONS:

Store below 25 °C.

Protect from light, heat and humidity.

Keep out of reach of children.

REGISTRATION NUMBER:

Q/2.2/355

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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