Promivol®

دار الدواء
Dar Al Dawa

Bisoprolol Fumarate

DESCRIPTION:
Promivol® contains bisoprolol fumarate (2:1), a synthetic β1-selective (cardioselective) adrenoceptor blocking agent.
Inactive ingredients: Cellulose microcrystalline, silica colloidal anhydrous, croscarmellose sodium, sodium starch glycolate, magnesium stearate.

INDICATIONS:
- High blood pressure (hypertension).
- Coronary heart disease (angina pectoris).

CONTRAINDICATIONS:
Promivol® must not be used in cases of untreated myocardial insufficiency (decompensated heart failure), recent myocardial infarction, shock, disturbances of atrioventricular conduction (AV block grades II and III), sick sinus syndrome, disturbed stimulus conduction between the sinoatrial node and atrium (sinoatrial block), extremely slow pulse (bradycardia with less than 50 beats/min) prior to the start of treatment, extremely low blood pressure (hypotension), bronchial asthma and advanced stages of peripheral circulatory disturbances. In the case of adrenal tumor (phaeochromocytoma) **Promivol®** may only be administered after α-blockade.
Promivol® should not be used during pregnancy or lactation or by children, as here no experience has been made so far in man. Animal experiments have shown no damage to fertility or offspring.
Note: Precaution is warranted in diabetic patients with greatly fluctuating blood-glucose values, during prolonged periods of fasting and in patients with acidosis.

SIDE EFFECTS:
Particularly at the start of treatment tiredness, dizziness, mild headaches, perspiration, sleep disturbances, vivid dreams and depressive moods may occur. These symptoms are usually of a less severe nature and generally recede within 1-2 weeks after the start of treatment. In rare cases, gastrointestinal disturbances (diarrhea, constipation, nausea, abdominal pain) and skin reactions (e.g. erythema, pruritus) may occur.
Occasionally a marked decrease in blood pressure, slow pulse rate or a disturbance of AV conduction are observed. Treatment can occasionally lead to tingling and a sensation of coldness in the limbs and in rare cases to muscle weakness, muscle cramp and reduced lacrimation (to be taken into account if contact lenses are worn). In patients suffering from intermittent claudication and Raynaud's phenomenon at the start of therapy complaints might become aggravated, and myocardial insufficiency might intensify. An increase in airway resistance (difficulties in breathing in patients tending towards bronchospastic reactions, e.g. with asthmoid bronchitis) may occur in rare cases.
In elderly patients concurrently suffering from diabetes, glucose tolerance might be impaired. Signs of low blood-glucose levels (e.g. rapid heart rate) may be masked.

WARNINGS AND PRECAUTIONS:
Due to the antihypertensive effect of **Promivol®**, the ability to drive or to operate machinery may be impaired as a result of reactions to the drug varying from individual to individual. This is particularly the case at the start of treatment and with a change of medication as well as upon interaction with alcohol. Specific investigations have shown, however, that there is no fear of reactivity being directly impaired by **Promivol®**. If by way of exception **Promivol®** has been used during pregnancy, therapy should be terminated 72 hours prior to the expected date of birth due to the possibility of bradycardia, hypotension and hypoglycaemia occurring in the neonate. If this is not possible the neonate should be carefully monitored for 48-72 hours after delivery.

DRUG INTERACTIONS:
- **Promivol®** may potentiate the effect of other antihypertensive drugs concurrently administered.
- Concomitant therapy of **Promivol®** and reserpine, a-methyldopa, clonidine or guanfacine may cause a considerable decrease in heart rate.
- In concomitant treatment with clonidine, clonidine should not be discontinued unless administration of **Promivol®** has been terminated for a few days.
- The concurrent use of nifedipine may potentiate the antihypertensive effect of **Promivol®**.
- In concurrent use of **Promivol®** and calcium antagonists of the verapamil or diltiazem type or other antiarrhythmic agents, careful monitoring of the patient is indicated as this can cause hypotension, bradycardia and other arrhythmias. This intravenous administration of calcium antagonists and antiarrhythmic agents is therefore not recommended during treatment with **Promivol®**.
- The concurrent use of **Promivol®** and rifampicin can slightly reduce the half-life of **Promivol®**. An increase in dose is generally not necessary.
- The concurrent use of **Promivol®** and insulin or oral anti-hyperglycaemic agents may potentiate the effect of the latter. The symptoms of hypoglycaemia (in particular tachycardia) are masked or mitigated. Blood-glucose levels should be monitored regularly.
- As cardiac output may be impaired under anaesthesia, prior to an operation the anaesthetist should be informed if the patient is being treated with **Promivol®**.

DOSAGE AND ADMINISTRATION:
- According to the doctor's prescription, one tablet of **Promivol®** 5 mg or one tablet of **Promivol®** 10 mg once daily.
- In milder forms of the disease as well as at the start of treatment, 1 tablet of **Promivol®** 5 mg once daily is sufficient in most cases. If necessary, this dosage may be increased to 2 tablets of **Promivol®** 5 mg or 1 tablet of **Promivol®** 10 mg once daily. A dosage increase to 20 mg (2 tablets of **Promivol®** 10 mg once daily) may be necessary only in isolated cases.
- The tablets should be swallowed whole with some liquid. It is recommended to take **Promivol®** in the morning on an empty stomach or with breakfast.
- Dose adjustment is generally not required in patients with hepatic or renal insufficiency of mild or moderate severity. A daily dose of 10 mg **Promivol®** should not be exceeded in patients with terminal renal insufficiency (creatinine clearance <20 ml/min) and in patients with severe hepatic insufficiency. The dose should always be determined for each individual case, primarily in accordance with pulse rate and success of treatment.

DURATION OF TREATMENT:
Generally, treatment with **Promivol®** is a long-term therapy. The dosage of **Promivol®** must not be altered without the doctor's directions. Nor should therapy be discontinued without the doctor's directions. Therapy with **Promivol®** must not be discontinued abruptly but must fundamentally be discontinued on a gradual basis. Particular attention must be paid to this in patients suffering from coronary artery disease.

OVERDOSAGE:
In the case of overdosage or precarious drop in pulse rate and/or blood pressure, treatment with **Promivol®** must be discontinued. If necessary, the following antidotes should be administered alone or consecutively: Atropine intravenous 0.5–2.0 mg, orciprenaline slowly i.v. until it takes effect; also glucagons may be given at a dose of 1–5 (-10) mg.

PRESENTATIONS:
Promivol® 5 Tablets: Packs of 30 tablets. Each tablet contains 5 mg Bisoprolol Fumarate (2:1).
Promivol® 10 Tablets: Packs of 30 tablets. Each tablet contains 10 mg Bisoprolol Fumarate (2:1).

STORAGE CONDITIONS:
Store below 25°C.

This is a medicament.
- *Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.*
- *Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medicament.*
- *The doctor and the pharmacist are experts in medicine, its benefits and its risks.*
- *Do not, by yourself, interrupt the period of treatment prescribed.*
- *Do not repeat the same prescription without consulting your doctor.*

Keep medicament out of reach of children

Manufactured by Dar Al Dawa, Na'ur - Jordan

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