1. Name of the medicinal product

RODENAL 2 mg and 5 mg tablets

2. Qualitative and quantitative composition

RODENAL 2mg tablets contains
RODENAL 5mg tablets contains

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablets

Route of administration:
Rodenal Tablets are for oral administration.

4. Clinical particulars

4.1 Therapeutic indications

Rodenal tablet is an adjunct medicine in the therapy of all forms of Parkinsonism (postencephalitic, arteriosclerotic and idiopathic),It is also indicated to control extrapyramidal disorders due to central nervous system drugs such as phenothiazines

4.2 Posology and method of administration

Adults only: Optimal dosage should always be determined empirically, usually by initiating therapy at a relatively low level and by subsequent graduated increments.

The usual dosage for Parkinsonism is **6-10mg per day** although some patients chiefly in the post-encephalitic group may require an average total dose of 12-15mg daily. It should be given orally either three or four times a day at mealtimes.

In all cases, Rodenal tablets dosage should be increased or decreased only by small increments over a period of several days. In initial therapy the dose should be 1mg the first day, 2mg the second day with further increases of 2mg per day at three to five-day intervals until the optimum dose is reached.

If patients are already being treated with other parasympathetic inhibitors, Rodenal tablet should be substituted as part of the therapy. Careful adjustment is necessary, depending on side effects and the degree of symptom control. Rodenal tablets dosage of 3-6mg daily in divided doses is usually adequate.

Rodenal tablet may be taken before or after meals according to the way the patient reacts. If Rodenal tablet tends to dry the mouth excessively, it may be better to take it before meals,

unless it causes nausea. If taken after meals, induced thirst can be allayed by peppermint, chewing gum or water.

Treatment of drug-induced extrapyramidal disorder: The size and frequency of dose of Rodenal tablet needed to control extrapyramidal reactions to commonly employed tranquillisers, notably the phenothiazines, thioxanthenes, and butyrophenones must be determined empirically. The total daily dosage usually ranges between 5 and 15mg, although in some cases, these reactions have been controlled by as little as 1mg daily.
Satisfactory control may sometimes be more rapidly achieved by temporarily reducing the dosage of both drugs until the desired ataractic effect is retained without concomitant extrapyramidal reactions.
It is sometimes possible to maintain the patient on reduced Rodenal tablet dosage after the reactions have remained under control for several days. Since these reactions may remain in remission for long periods after discontinuation of Rodenal tablet therapy, such therapy should be of minimal duration and discontinued after symptoms have subsided for a reasonable period of time.

Elderly: Patients over 65 years of age tend to be relatively more sensitive and require smaller amounts of the drug.

Children: Not recommended.

4.3 Contraindications

Hypersensitivity to Benzhexol or any of the other ingredients.

4.4 Special warnings and precautions for use

Precautions: Since the use of Rodenal tablet may, in some cases, continue indefinitely, the patient should be under careful observation over the long term. It should be administered with care to avoid allergic or other untoward reactions.
Except in the case of vital complications, abrupt discontinuation of the drug should be avoided.
Incipient glaucoma may be precipitated by para-sympatholytic drugs such as benzhexol.
Hypertension, cardiac, liver or kidney disorders are not contra-indicated, but such patients should be followed closely. As Rodenal tablet may provoke or exacerbate tardive dyskinesia, it is not recommended for use in patients with this condition.
Rodenal tablet should be used with caution in patients with glaucoma, obstructive disease of the gastro-intestinal or genito-urinary tracts, and in elderly males with possible prostatic hypertrophy.
Since Rodenal tablet has been associated with the clinical worsening of myasthenia gravis, the drug should be avoided or used with great caution in patients with this condition.
Since certain psychiatric manifestations such as confusion, delusions and hallucinations, all of which may occur with any of the atropine-like drugs, have been reported rarely with Rodenal tablet, it should be used with extreme caution in elderly patients (see Dosage and Administration).

Warnings: Rodenal tablet may be the subject of abuse (on the basis of hallucinogenic or euphoriant properties, common to all anti-cholinergic drugs) if given in sufficient amounts.

Each tablet from Rodenal 2 mg contains 135.5 mg of lactose and each tablet from Rodenal 5 mg contains 134.4 mg of lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction

Extra care should be taken when Rodenal tablet is given concomitantly with phenothiazines, clozapine, antihistamines, disopyramide, nefopam and amantadine because of the possibility of increased antimuscarinic side-effects.
Synergy has been reported between Rodenal tablet and tricyclic antidepressants, probably because of an additive effect at the receptor site. This can cause dry mouth, constipation and blurred vision. In the elderly, there is a danger of precipitating urinary retention, acute glaucoma or paralytic ileus.
Monoamine oxidase inhibitors can interact with concurrently administered anticholinergic agents including Rodenal tablet. This can cause dry mouth, blurred vision, urinary hesitancy, urinary retention and constipation.
In general, anticholinergic agents should be used with caution in patients who are receiving tricyclic antidepressants or monoamine oxidase inhibitors. In patients who are already on antidepressant therapy the dose of Rodenal tablet should be initially reduced and the patient reviewed regularly.
Rodenal tablet may be antagonistic with the actions of metoclopramide and domperidone on gastro-intestinal function.
The absorption of levodopa may possibly be reduced when used in conjunction with Rodenal tablet.
Rodenal tablet may be antagonistic with the actions of parasympathomimetics.

4.6 Pregnancy and lactation

Pregnancy: There is inadequate information regarding the use of Rodenal tablet in pregnancy. Animal studies are insufficient with regard to effects on pregnancy, embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown. Rodenal tablet should not be used during pregnancy unless clearly necessary.

Lactation*:* It is unknown whether Rodenal tablet is excreted in human breast milk. The excretion of Rodenal tablet in milk has not been studies in animals. Infants may be very sensitive to the effects of antimuscarinic medications. Rodenal tablet should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Rodenal tablets can cause blurring of vision, dizziness and mild nausea. Also mental confusion in some cases.

4.8 Undesirable effects

Modern clinical data required to determine the frequency of undesirable effects are lacking for Rodenal tablet. Minor side effects such as dryness of mouth, constipation, blurring of vision, dizziness, mild nausea or nervousness will be experienced by 30-50% of all patients. These reactions tend to become less pronounced as treatment continues. Patients should be allowed to develop a tolerance using the smaller initial dose until an effective level is reached.

Immune system disorders: Hypersensitivity.
Psychiatric disorders*:* Nervousness, restlessness, confusional states, agitation, delusions, hallucinations, insomnia, especially in the elderly and patients with arteriosclerosis. The development of psychiatric disturbances may necessitate discontinuation of treatment.
Euphoria may occur. There have been reports of abuse of Rodenal tablet due to its euphoric and hallucinogenic properties.
Nervous *system disorders:* Dizziness.
Impairment of immediate and short-term memory function has been reported.
Worsening of myasthenia gravis may occur (see section 4.4).
Eye disorders*:* Dilatation of the pupils with loss of accommodation and photophobia, raised intraocular pressure (see section 4.4).
Cardiac disorders*:* Tachycardia.
Respiratory, thoracic and mediastinal disorders**:** Decreased bronchial secretions.

***Gastrointestinal disorders**:* Dry mouth with difficulty swallowing, constipation, nausea, vomiting.
***Skin and subcutaneous tissue disorders**:* Flushing and dryness of skin, skin rashes.
***Renal and urinary disorders**:* Urinary retention, difficulty in micturition.
***General disorders**:* Thirst, pyrexia.

4.9 Overdose

Symptoms: Symptoms of overdose with antimuscarinic agents include flushing and dryness of the skin, dilated pupils, dry mouth and tongue, tachycardia, rapid respiration, hyperpyrexia, hypertension, nausea, vomiting. A rash may appear on the face or upper trunk. Symptoms of CNS stimulation include restlessness, confusion, hallucinations, paranoid and psychotic reactions, incoordination, delirium and occasionally convulsions. In severe overdose, CNS depression may occur with coma, circulatory and respiratory failure and death.
Treatment: Treatment should always be supportive. An adequate airway should be maintained. Diazepam may be administered to control excitement and convulsions but the risk of central nervous system depression should be considered. Hypoxia and acidosis should be corrected. Antiarrhythmic drugs are not recommended if dysrhythmias occur.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Benzhexol hydrochloride is an anticholinergic agent. It is an antispasmodic drug which exerts a direct inhibitory effect on the parasympathetic nervous system. It diminishes salivation, increases the heart rate, dilates the pupils and reduces spasm of smooth muscle.

5.2 Pharmacokinetic properties
Benzhexol hydrochloride is well absorbed from the gastrointestinal tract. It disappears rapidly from the plasma and tissues and does not accumulate in the body during continued administration of conventional doses.

5.3 Preclinical safety data
None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Rodenal 2 mg tablets: Lactose, maize starch, microcrystalline cellulose, magnesium stearate, gelatin

Rodenal 5 mg tablets: Lactose, maize starch, microcrystalline cellulose, magnesium stearate, gelatin, edicol supra blue

6.2 Incompatibilities
None
6.3 Shelf life
36 months.

6.4 Special precautions for storage

The products should be stored below 25°C and in dark and dry place. The products should be stored in either the original pack or in containers which prevent access of moisture.

6.5 Nature and contents of container

Rodenal 2 mg tablets: A White flat bevelled edges tablet, scored in half REKAH engraved on one side, plain on the other. Blister packs: 30 tablets

Rodenal 5 mg tablets: A pale – blue flat bevelled edges tablet, scored in half REKAH engraved on one side, plain on the other. Blister packs: 30 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder and manufacture

Rekah pharmaceutical industry ldt
30 hamelacha street
58859 Holon Israel

8. Marketing authorization number(s)

Rodenal 2 mg tablets: **111-02-21626-01**

Rodenal 5 mg tablets: **111-01-21615-01**

10. Date of revision of the text

21.09.2014