SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Trihexyphenidyl 2mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2mg of trihexyphenidyl hydrochloride

Excipient(s) with known effect
Lactose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White, flat bevel edged tablets with a breakline.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Treatment of parkinsonism
2. Prevention and control of drug-induced extrapyramidal symptoms (excluding tardive dyskinesia)

4.2 Posology and method of administration

Posology

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

Normal dosage for drug-induced Parkinsonism is usually between 5 mg and 15 mg per day, although some cases have been controlled by 1 mg daily.

In all cases, trihexyphenidyl 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, trihexyphenidyl should be substituted as part of the therapy. When trihexyphenidyl is used concomitantly with levodopa the usual dose of each may need to be reduced. Careful adjustment is necessary, depending on side effects and the degree of symptom control. Trihexyphenidyl dosage of 3-6mg daily in divided doses, is usually adequate.

Trihexyphenidyl may be taken before or after meals according to the way the patient reacts. If trihexyphenidyl 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 trihexyphenidyl 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 trihexyphenidyl dosage after the reactions have remained under control for several days. Since these reactions may remain in remission for long periods after discontinuation of trihexyphenidyl 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.

Paediatric population: Not recommended.

Method of administration

For oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Precautions: Since the use of trihexyphenidyl 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 trihexyphenidyl.

Hypertension, cardiac, liver or kidney disorders are not contra-indicated, but such patients should be followed closely. As trihexyphenidyl may provoke or exacerbate tardive dyskinesia, it is not recommended for use in patients with this condition.

Trihexyphenidyl 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 trihexyphenidyl has been associated with 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 trihexyphenidyl, it should be used with extreme caution in elderly patients (see section 4.2).

Warnings: Trihexyphenidyl 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.

Patients with rare hereditary problems of galactose intolerance, total 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 trihexyphenidyl 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 trihexyphenidyl 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 trihexyphenidyl. 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 trihexyphenidyl should be initially reduced and the patient reviewed regularly.

Trihexyphenidyl 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 trihexyphenidyl.

Trihexyphenidyl may be antagonistic with the actions of parasympathomimetics.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There is inadequate information regarding the use of trihexyphenidyl 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. Trihexyphenidyl should not be used during pregnancy unless clearly necessary.

Breast-feeding

It is unknown whether trihexyphenidyl is excreted in human breast milk. The excretion of trihexyphenidyl in milk has not been studied in animals. Infants may be very sensitive to the effects of antimuscarinic medications. Trihexyphenidyl should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Trihexyphenidyl hydrochloride may affect the performance of skilled tasks such as driving and operating machinery as it 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 trihexyphenidyl. 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 trihexyphenidyl 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Pharmacotherapeutic group: anti-cholinergic agents, ATC code: NO4AA01.

Trihexyphenidyl 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 heart rate, dilates pupils and reduces spasm of smooth muscle.

5.2 Pharmacokinetic properties

Trihexyphenidyl 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

There are no preclinical data of relevance to the presciber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Maize starch
Pregelatinised maize starch
Lactose

6.2 Incompatibilities

None.

6.3 Shelf life

5 years for opaque plastic containers.
2 years for aluminium/opaque PVC blister packs.

6.4 Special precautions for storage

Plastic Containers: Keep the container tightly closed
Blister Packs: Store in the original package

6.5 Nature and contents of container

Trihexyphenidyl tablets BP 2 mg are packed in the following containers and closures.

Opaque plastic containers (securitainers) with plastic caps for all pack sizes.

Opaque plastic container composed of either high density polypropylene or high density polyethylene with a tamper-evident or child resistant tamper evident closure composed of high density polyethylene for all pack sizes (28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000) and packaging inclusion of standard polyether foam or polyethylene or polypropylene made filler.

Blister packs of aluminium/opaque PVC. It is subsequently packed in printed boxboard cartons in pack sizes of 28, 30, 42, 56, 60, 84, 90 and 112.

6.6 Special precautions for disposal

No special instructions for use/handling.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 55612/0143

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

24/07/2026