

Summary of Product Characteristics

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

Broflex syrup (5mg/5mL).

2. Qualitative and Quantitative Composition

Trihexyphenidyl hydrochloride BP 5mg/5mL.

3. Pharmaceutical Form

A blackcurrant scented and flavoured clear pink syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Parkinsonism and drug induced extrapyramidal syndrome.

4.2 Posology and method of administration

Adults and Elderly:

Initial dose 2mg. Subsequent doses up to 20mg as recommended by a physician.

Children:

Not recommended.

4.3 Contraindications

Hypersensitivity to trihexyphenidyl or any of the other ingredients.

Incipient glaucoma may be precipitated. The following are not absolute contraindications, nevertheless caution must be observed in patients with: hypertension, cardiac, liver or kidney dysfunction, glaucoma, obstructive disease of the gastrointestinal or genito-urinary tracts and in males with a prostatic hypertrophy.

4.4 Special warnings and special precautions for use

Anticholinergic medications, including trihexyphenidyl, should not be withdrawn abruptly in patients on long-term therapy, to avoid recurrence of the original symptoms and possible anticholinergic rebound. Prescribers should be aware that trihexyphenidyl may be the subject of abuse due to its euphoric or hallucinogenic properties.

Since atropine-like drugs may cause psychiatric symptoms such as confusion, delusion and hallucinations, trihexyphenidyl should be used with extreme caution in elderly patients.

As trihexyphenidyl may provoke or exacerbate tardive dyskinesia, it is not recommended for use in patients with this condition.

Since trihexyphenidyl has been associated with clinical worsening of myasthenia gravis, the drug should be avoided or used with great caution in patients with myasthenia gravis.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-maltase insufficiency should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

Monoamine oxidase inhibitors (MAOI's), antihistamines, disopyramide, phenothiazines and tricyclic antidepressants increase the side effects of blurred vision and dry mouth, constipation, urinary retention. MAOI's, amantidine and some tricyclic antidepressants may also cause excitation, confusion and hallucination.

4.6 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.

Lactation

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

Patients should be warned of the potential hazards of driving or operating machinery if they experience blurred vision or a reduction in alertness.

4.8 Undesirable effects

Dry mouth, constipation and blurred vision may occur. This is more frequent in the elderly but reduces with tolerance. Psychiatric symptoms such as agitation, confusion, hallucinations, euphoria, insomnia, restlessness and very occasionally paranoid delusions have been reported. These are more likely to occur in patients receiving higher than recommended doses. There have been reports of abuse of trihexyphenidyl due to its euphoric and hallucinogenic properties.

Impairment of immediate and short-term memory functions has also been reported.

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

Trihexyphenidyl is a tertiary amine antimuscarinic. It also has a direct antispasmodic action on smooth muscle.

5.2 Pharmacokinetic properties

Trihexyphenidyl is well absorbed from the gastro-intestinal tract.

5.3 Preclinical safety data

No formal preclinical studies have been undertaken with Broflex, as its active ingredient is a well established pharmaceutical.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid, benzoic acid, propylene glycol, amaranth E123, glycerol, chloroform spirit, blackcurrant flavour A402, syrup, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

200 mL pack size in amber glass bottle with polycone lined enclosure.

6.6 Special precautions for disposal

None stated.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL16853/0023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 June 1999

10. DATE OF REVISION OF THE TEXT

25th July 2007.

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