TRIHEXYPHENIDYL 2MG TABLETS
PL 08553/0068
TRIHEXYPHENIDYL 5MG TABLETS
PL 08553/0069

UKPAR

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LAY SUMMARY

The MHRA granted Dr Reddy's Laboratories (UK) Limited Marketing Authorisations (licences) for the medicinal products Trihexyphenidyl 2mg and 5mg Tablets (PL 08553/0068-9) on 15th November 2006. These prescription only medicines (POM) used in the management of Parkinson's Disease and also to control certain types of disorder, such as muscular rigidity, stiffness, tremor (fine shaking of the hand), and spasm that may be caused by certain drugs acting on the central nervous system (such as phenothiazine drugs and reserpine).

Trihexyphenidyl belongs to a group of medicines known as antispasmodics that act on the central nervous system to control certain involuntary muscular movements, such as spasm of muscles causing contractions, involuntary movements and troublesome restlessness. Trihexyphenidate also reduces muscular stiffness and saliva production. This medicine also reduces the rigidity (stiffness) of muscle spasm.

These applications are duplicates of the previously granted applications for Agitane/Benzehexol 2mg and 5 mg Tablets (PL 00225/5019R and 5020R) and as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Trihexyphenidyl 2mg and 5 mg Tablets (PL 08553/0068-9) outweigh the risks, hence Marketing Authorisations have been granted.

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PL 08553/0068
TRIHEXYPHENIDYL 5MG TABLETS
PL 08553/0069

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Trihexyphenidyl 2mg and 5mg Tablets (PL 08553/0068-9) to Dr Reddys Laboratories (UK) Ltd on 15th November 2006. The products are prescription-only medicines.

The applications were submitted as simple abridged applications according to Article 10c of Directive 2001/83/EC, cross-referring to Agitane/Benzehexol 2mg and 5 mg Tablets (PL 00225/5019R and 5020R), approved on 26th November 1987.

No new data were submitted nor were they necessary for these simple applications, as these data are identical to that of the previously granted cross-reference product. As the cross-reference products were granted prior to the introduction of current legislation, no PARs were generated for them.

The products contain the active ingredient trihexyphenidyl hydrochloride, which is an anticholinergic agents, tertiary amines indicated in the management of the symptoms of post-encephalitic arteriosclerotic and idiopathic Parkinsonism and also to control extrapyramidal disorders which may be caused by certain drugs acting on the central nervous system, such as phenothiazines and reserpine (these include tremor, rigidity and increased salivation which are commonly encountered in the disease; also dyskinesia manifested by spastic contractions and involuntary movements and akathisia characterised by troublesome restlessness, through decreasing sialorrhoea it is especially valuable as an adjunct in the treatment of arteriosclerotic Parkinsonism). Trihexyphenidyl reduces the rigidity of muscle spasm.

These applications for Trihexyphenidyl 2mg and 5 mg Tablets were submitted at the same time and were assessed concurrently. Consequently, all sections of this Scientific Discussion refer to both products.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 08553/0068-9
PROPRIETARY NAME:	Trihexyphenidyl 2mg and 5mg Tablets
ACTIVE(S):	Trihexyphenidyl Hydrochloride
COMPANY NAME:	Dr Reddys Laboratories (UK) Ltd
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC
LEGAL STATUS:	POM

1. INTRODUCTION

This is a simple, piggy back application for Trihexyphenidyl 2mg and 5mg Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is "Dr. Reddy's Laboratories (UK) Ltd, 6, Riverview Road, Beverley, East Yorks, HU17 0LD."

These applications cross refers to Agitane/Benzehexol 2mg and 5mg Tablets (PL 00225/5019R and 5020R), approved on 26th November 1987, which are currently registered in the UK. These applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the products are Trihexyphenidyl 2mg and 5mg Tablets. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The products contain trihexyphenidyl hydrochloride equivalent to 2mg and 5mg of trihexyphenidyl, respectively. It is to be stored in polypropylene containers and a lid with polyurethane/polythene inserts in pack sizes of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000. Not all proposed pack sizes are to be marketed and the applicant has confirmed that all packaging will be submitted for approval before marketing any pack size.

The proposed shelf-life (3 years) and storage conditions ('Do not store above 25ºC' and 'Store in original container') are consistent with the details registered for the cross-reference products.

2.3 Legal status

On approval, the products will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Dr. Reddy's Laboratories (UK) Ltd, 6, Riverview Road, Beverley, East Yorks, HU17 0LD

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification for each product is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
No materials of animal or human origin are included in the product. This is consistent with the cross reference products for which magnesium stearate was confirmed as being of vegetable origin.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed SPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference products. The marketing authorisation holder has provided a commitment to update the marketing authorisation no later than 1st July 2008 with a package leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups.

Blister

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for an application of this type.

CLINICAL ASSESSMENT

As these are duplicate applications for PL 00225/5019R and 5020R, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with that previously assessed for the cross-reference products and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Trihexyphenidyl is a well-known drug and has been used as an anticholinergic agent for many years. These applications are identical to previously granted applications for Agitane/Benzehexol 2mg and 5mg Tablets (PL 00225/5019R and 5020R).

No new or unexpected safety concerns arise from these applications.

The SPCs, PIL and labelling are satisfactory and consistent with those for the cross-reference products.

RISK BENEFIT ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products which, in turn, have been shown to be interchangeable with the innovator products. Extensive clinical experience with trihexyphenidyl is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

TRIHEXYPHENIDYL 2MG TABLETS
PL 08553/0068
TRIHEXYPHENIDYL 5MG TABLETS
PL 08553/0069

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 20/06/2003.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 21/07/2003.
3	Following assessment of the application the MHRA requested further information on 27/10/2003, 06/07/2004, 18/08/2004, 20/01/2006.
4	The applicant responded to the MHRA's requests, providing further information on 28/01/2004, 15/07/2004, 13/02/2006,
7	The application was determined on 15/11/2006

TRIHEXYPHENIDYL 2MG TABLETS
PL 08553/0068
TRIHEXYPHENIDYL 5MG TABLETS
PL 08553/0069

STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

TRIHEXYPHENIDYL 2MG TABLETS
PL 08553/0068
TRIHEXYPHENIDYL 5MG TABLETS
PL 08553/0069

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Trihexyphenidyl 2mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Trihexyphenidyl Hydrochloride 2mg

See 6.1 for excipients

3 PHARMACEUTICAL FORM
Tablets

The tablets are round, white and flat with a bevelled-edge. The 2mg tablets are unscored.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Trihexyphenidyl is indicated in the management of the symptoms of post-encephalitic arteriosclerotic and idiopathic Parkinsonism and also to control extrapyramidal disorders which may be caused by certain drugs acting on the central nervous system, such as phenothiazines and reserpine (these include tremor, rigidity and increased salivation which are commonly encountered in the disease; also dyskinesia manifested by spastic contractions and involuntary movements and akathisia characterised by troublesome restlessness. Through decreasing sialorrhoea it is especially valuable as an adjunct in the treatment of arteriosclerotic Parkinsonism).

Trihexyphenidyl reduces the rigidity of muscle spasm.

4.2 Posology and method of administration
Adults:
In all patients alterations in dosage either upward or downwards should only be by small increments over a period of days. At the commencement of therapy the dose should be 1 mg on the first day 2 mg on the second day and thereafter by increments of 2 mg per day at 3-5 day intervals, continued until the optimum dose is reached.

The maximum daily dose is 20mg.

The relationship of Trihexyphenidyl therapy with meals will vary according to the reaction of the patient. If when taken after meals thirst is induced this can be allayed by chewing gum, peppermints or drinking water. Should Trihexyphenidyl tend to dry the mouth excessively, it is wiser taken before meals unless nausea is troublesome.

The usual dosage for Parkinsonism is 6-10 mg per day, however patients, particularly those in the post-encephalitic group may require on average a daily dose of 12-15 mg. This should be given at mealtimes either three or four times a day.

On drug-induced Parkinsonism the normal dose usually lies between 5 mg and 15 mg per day. Some patients have been controlled by as little as 1 mg daily.

Children:
Trihexyphenidyl is not recommended for children.

The Elderly:
Patients over 60 years of age will be more sensitive and therefore require smaller amounts of

Trihexyphenidyl.

Trihexyphenidyl tablets are to be taken by mouth.

4.3 Contraindications

Sensitivity to Trihexyphenidyl or to any of the excipients in Trihexyphenidyl. Trihexyphenidyl is contra-indicated for patients with glaucoma and is also contra-indicated for patients with obstructive disease of the genitourinary and gastro-intestinal tracts, particularly in patients with a history of prostatic hypertrophy and prostatism.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use

The Patient should be under careful observation over the long term. It should be administered with care to avoid allergic or other untoward reactions.

Abrupt discontinuation of treatment should be avoided.

Incipient glaucoma may be precipitated by parasympatholytic drugs such as Trihexyphenidyl. Hypertension, cardiac, liver or kidney disorders are not contra-indications, but such patients should be followed closely.

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. Trihexyphenidyl may be the subject of abuse due to its euphoric effect.

4.5 Interaction with other medicinal products and other forms of interaction

Increased antimuscarinic side-effects such as dry mouth, urine retention and constipation may occur with concomitant use of other anti-muscarinics, nefopam, disopuridamide, amantidine, antihistamines, phenothiazines, tricyclic antidepressants and MAOI's. Concomitant use with other antimuscarinics may also lead to confusion in the elderly. Antagonism of effect with parasympathomimetics. Antimuscarinics antagonise the gastro-intestinal effects of metoclopramide and Domperidone. Reduced absorption of ketoconazole. The effect of sublingual nitrates may be reduced if dry mouth prevents dissolution under the tongue.

4.6 Pregnancy and lactation

Problems in humans have not been documented and it is not known whether the drug is excreted in breast milk. However, lactation may be inhibited.

4.7 Effects on ability to drive and use machines

May affect performance at skilled tasks (e.g. driving)

4.8 Undesirable effects

Dryness of mouth, gastro-intestinal disturbances, blurring of vision, dizziness and mild nausea or nervousness will be experienced by 30-50% of all patients. These reactions tend to become less pronounced as treatment continues.

Patients with a history of drug idiosyncrasies may exhibit reactions of mental confusion, agitation, or nausea and vomiting. Such patients should be allowed to develop a tolerance using the smaller initial dose, with gradual increases until the effective level is reached.

Less common side effects include: urinary retention, tachycardia, hypersensitivity and with high doses in susceptible patients, confusion, excitement, agitation, hallucinations, insomnia and psychiatric disturbances which may necessitate discontinuation of treatment; impaired memory also reported.

4.9 Overdose

No specific antidote. Gastric lavage, emetic, high enema. Usual general treatment plus cold compress and forcing of fluid are mandatory. Atropine antagonists may be useful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

It is believed that Trihexyphenidyl acts through partially blocking central (striatal) cholinergic receptors. Trihexyphenidyl has a direct anti-spasmodic effect on smooth muscles and in small doses depresses the Central Nervous System but larger doses may cause cerebral excitation.
ATC Code: N04A A01. Classification: Anticholinergic agents, Tertiary amines.

5.2 Pharmacokinetic properties

Trihexyphenidyl is absorbed in the gastro-intestinal tract with an onset of action of 1 hour and duration of action of 6 to 12 hours.

5.3 Pre clinical safety data

No additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Pregelatinised maize starch
Sodium starch glycollate
Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years (36 months).

6.4 Special precautions for storage

Do not store above 25° C in a dry place.

Protect from light.

6.5 Nature and contents of container

Polypropylene container and lid with polyurethane/polythene inserts. Pack sizes: 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Dr. Reddy's Laboratories (UK) Limited
6 Riverview Road, Beverley,
HU17 0LD
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

08553/0068

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/11/2006

10 DATE OF REVISION OF THE TEXT

15/11/2006

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Trihexyphenidyl 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Trihexyphenidyl Hydrochloride 5mg

See 6.1 for excipients

3 PHARMACEUTICAL FORM

Tablets

The tablets are round, white and flat with a bevelled-edge. The 5mg tablets are scored.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Trihexyphenidyl is indicated in the management of the symptoms of post-encephalitic arteriosclerotic and idiopathic Parkinsonism and also to control extrapyramidal disorders which may be caused by certain drugs acting on the central nervous system, such as phenothiazines and reserpine (these include tremor, rigidity and increased salivation which are commonly encountered in the disease; also dyskinesia manifested by spastic contractions and involuntary movements and akathisia characterised by troublesome restlessness. Through decreasing sialorrhoea it is especially valuable as an adjunct in the treatment of arteriosclerotic Parkinsonism).

Trihexyphenidyl reduces the rigidity of muscle spasm**.**

4.2 Posology and method of administration

Adults:

In all patients alterations in dosage either upward or downwards should only be by small increments over a period of days. At the commencement of therapy the dose should be 1 mg on the first day 2 mg on the second day and thereafter by increments of 2 mg per day at 3-5 day intervals, continued until the optimum dose is reached.

The maximum daily dose is 20mg.

The relationship of Trihexyphenidyl therapy with meals will vary according to the reaction of the patient. If when taken after meals thirst is induced this can be allayed by chewing gum, peppermints or drinking water. Should Trihexyphenidyl tend to dry the mouth excessively, it is wiser taken before meals unless nausea is troublesome.

The usual dosage for Parkinsonism is 6-10 mg per day, however patients, particularly those in the post-encephalitic group may require on average a daily dose of 12-15 mg. This should be given at mealtimes either three or four times a day.

On drug-induced Parkinsonism the normal dose usually lies between 5 mg and 15 mg per day. Some patients have been controlled by as little as 1 mg daily.

Children:

Trihexyphenidyl is not recommended for children.

The Elderly:

Patients over 60 years of age will be more sensitive and therefore require smaller amounts of Trihexyphenidyl.

Trihexyphenidyl tablets are to be taken by mouth.

4.3 Contraindications

Sensitivity to Trihexyphenidyl or to any of the excipients in Trihexyphenidyl. Trihexyphenidyl is contra-indicated for patients with glaucoma and is also contra-indicated for patients with obstructive disease of the genitourinary and gastro-intestinal tracts, particularly in patients with a history of prostatic hypertrophy and prostatism.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use

The Patient should be under careful observation over the long term. It should be administered with care to avoid allergic or other untoward reactions.

Abrupt discontinuation of treatment should be avoided.

Incipient glaucoma may be precipitated by parasympatholytic drugs such as Trihexyphenidyl. Hypertension, cardiac, liver or kidney disorders are not contra-indications, but such patients should be followed closely.

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.

Trihexyphenidyl may be the subject of abuse due to its euphoric effect.

4.5 Interaction with other medicinal products and other forms of interaction

Increased antimuscarinic side-effects such as dry mouth, urine retention and constipation may occur with concomitant use of other anti-muscarinics, nefopam, disopuridamide, amantidine, antihistamines, phenothiazines, tricyclic antidepressants and MAOI's. Concomitant use with other antimuscarinics may also lead to confusion in the elderly. Antagonism of effect with parasympathomimetics. Antimuscarinics antagonise the gastro-intestinal effects of metoclopramide and Domperidone. Reduced absorption of ketoconazole. The effect of sublingual nitrates may be reduced if dry mouth prevents dissolution under the tongue.

4.6 Pregnancy and lactation

Problems in humans have not been documented and it is not known whether the drug is excreted in breast milk. However, lactation may be inhibited.

4.7 Effects on ability to drive and use machines

May affect performance at skilled tasks (e.g. driving).

4.8 Undesirable effects

Dryness of mouth, gastro-intestinal disturbances, blurring of vision, dizziness and mild nausea or nervousness will be experienced by 30-50% of all patients. These reactions tend to become less pronounced as treatment continues.

Patients with a history of drug idiosyncrasies may exhibit reactions of mental confusion, agitation, or nausea and vomiting. Such patients should be allowed to develop a tolerance using the smaller initial dose, with gradual increases until the effective level is reached.

Less common side effects include: urinary retention, tachycardia, hypersensitivity and with high doses in susceptible patients, confusion, excitement, agitation, hallucinations, insomnia and psychiatric disturbances which may necessitate discontinuation of treatment; impaired memory also reported.

4.9 Overdose

No specific antidote. Gastric lavage, emetic, high enema. Usual general treatment plus cold compress and forcing of fluid are mandatory. Atropine antagonists may be useful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

It is believed that Trihexyphenidyl acts through partially blocking central (striatal) cholinergic receptors. Trihexyphenidyl has a direct anti-spasmodic effect on smooth muscles and in small doses depresses the Central Nervous System but larger doses may cause cerebral excitation.
ATC Code: N04A A01. Classification: Anticholinergic agents, Tertiary amines.

5.2 Pharmacokinetic properties

Trihexyphenidyl is absorbed in the gastro-intestinal tract with an onset of action of 1 hour and duration of action of 6 to 12 hours.

5.3 Pre clinical safety data

No additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Pregelatinised maize starch
Sodium starch glycollate
Magnesium Stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years (36 months).

6.4 Special precautions for storage

Do not store above 25° C in a dry place.

Protect from light.

6.5 Nature and contents of container

Polypropylene container and lid with polyurethane/polythene inserts. Pack sizes: 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Dr. Reddy's Laboratories (UK) Limited
6 Riverview Road, Beverley
HU17 0LD
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

08553/0069

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/11/2006

10 DATE OF REVISION OF THE TEXT

15/11/2006

PRODUCT INFORMATION LEAFLET

TXP0102PI-1

TRIHEXYPHENIDYL 2mg & 5mg TABLETS
Patient Information Leaflet

Please read this leaflet carefully before you start taking this medicine. Keep this leaflet until you have finished all the prescribed course of Trihexyphenidyl. If you have any questions concerning your medicine ask your doctor or pharmacist.

What is in your medicine?
The name of this medicine is Trihexyphenidyl 2mg Tablets or Trihexyphenidyl 5mg Tablets. Your medicine contains a substance called Trihexyphenidyl hydrochloride BP.

The active ingredient in this medicine is Trihexyphenidyl Hydrochloride. This is the new name for Benzhexol Hydrochloride. The ingredient itself has not changed.

Trihexyphenidyl is available in two strengths. The 2mg tablets contain 2mg Trihexyphenidyl hydrochloride and the 5mg tablets contain 5mg Trihexyphenidyl hydrochloride. Your tablets also contain the ingredients lactose monohydrate, maize starch, pre-gelatinised maize starch, sodium starch glycollate, magnesium stearate.

The tablets are round, white and flat with a bevelled-edge. Both strengths are available in containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000 tablets. The 5mg tablets are scored. The 2mg tablets are unscored.

Marketing Authorisation holder and manufacturer:
Dr. Reddy's Laboratories (UK) Limited
6 Riverview Road
Beverley
HU17 0LD
UK

How does Trihexyphenidyl work?
Trihexyphenidyl belongs to a group of medicines known as the anti-spasmodics that act on the central nervous system to control certain involuntary muscular movements such as spasm of muscles causing contractions, involuntary movements and troublesome restlessness. Trihexyphenidyl also reduces muscular stiffness and saliva production. This medicine also reduces the rigidity (stiffness) of muscle spasm.

Why have you been prescribed Trihexyphenidyl?
Trihexyphenidyl is used in the management of Parkinson's Disease and also to control certain types of disorder such as muscular rigidity, stiffness, tremor (fine shaking of the hands), spasm which may be caused by certain drugs acting on the central nervous system of which the phenothiazine drugs and reserpine are examples.

If you are not sure why you have been prescribed Trihexyphenidyl then please ask your doctor.

Before taking this medicine
Before taking these tablets, tell your doctor if you have ever had any unusual or allergic reactions to Trihexyphenidyl or any of the other ingredients of these tablets.

Tell your doctor if you are pregnant, planning a pregnancy, or are breast-feeding.

Also tell your doctor or pharmacist if you are allergic to any other substances such as food, preservatives or dyes.

Do not use Trihexyphenidyl if you have suffered or suffer from:
- Glaucoma (increased eyeball pressure),
- Obstructive disease of the urinary tract,
- Obstructive disease of the gastro-intestinal tract,
- If you have a condition known as enlargement of the prostate,
- If you suffer from high blood pressure, heart, liver or kidney disorders then you should be regularly checked by your doctor.

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, please contact your doctor before taking this medicine.

Use in pregnancy and lactation
Trihexyphenidyl should not be used when pregnant, or if planning a pregnancy. Trihexyphenidyl should also be avoided when breast-feeding.

Taking other medicines
It is important that your doctor is aware of any other medication you are taking, whether it is prescribed or bought without a prescription. Your doctor will be able to identify medicines which you should not take with Trihexyphenidyl.

Also tell your doctor if you are or have been taking any of the phenothiazine drugs or reserpine (to treat high blood pressure) or imipramine (to treat anxiety).

Taking your medicine
Take this medicine by mouth and only in the doses prescribed by your doctor. Do not take more of it and do not take it more often or for a longer time than your doctor ordered.

Dosage
This medicine is to be taken by mouth. Treatment should be initiated at 2mg and subsequent doses up to 20mg as recommended by the physician.

The usual dosage for Parkinsonism is 6-10 mg per day, however patients, particularly those in the post-encephalitic group may require on average a daily dose of 12-15 mg. This should be given at mealtimes either three or four times a day.
On drug-induced Parkinsonism the normal dose usually lies between 5 mg and 15 mg per day. Some patients have been controlled by as little as 1 mg daily.

In all patients alterations in dosage either upward or downwards should only be by small increments over a period of days. At the commencement of therapy the dose should be 1 mg on the first day, 2 mg on the second day and thereafter increments of 2 mg per day at 3-5 day intervals, continued until the optimum dose is reached.

The relationship of Trihexyphenidyl therapy with meals will vary according to the reaction of the patient. If when taken after meals thirst is induced this can be allayed by chewing gum, peppermints or drinking water. Should Trihexyphenidyl tend to dry the mouth excessively, it is wiser taken before meals unless nausea is troublesome.

Adults: Treatment should be initiated at a low level and gradually increased until an optimal dosage has been determined.

Children: Trihexyphenidyl is not recommended for children.

Elderly: Patients over 60 years of age will be more sensitive and therefore require smaller amounts of Trihexyphenidyl.

Overdose
If you think you may have taken too many of your tablets, either call your doctor straight away, or go to the nearest hospital casualty department. Always keep any remaining tablets in the container in which they were given to you so that the medicine can be identified by the doctor or pharmacist at the hospital.
Also tell them whether you have taken any other medicines.

Missed dose
If you miss a dose, skip the missed dose and go back to your regular dosing schedule. Do not take two doses at once.

If you feel this medicine is not working well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.

After taking your medicine
Dryness of mouth, blurring of vision, constipation, dizziness, mild feeling of sickness (nausea) or nervousness may occur. This is more frequent in the elderly but tends to become less pronounced as treatment continues.

Patients with arterial sclerosis (hardening of the arteries) or with unusual reactions to other drugs may develop mental confusion, agitation, euphoria, insomnia, restlessness, sickness and vomiting and very occasionally paranoid delusions have been reported. These have been more likely to occur in patients receiving higher than recommended doses. Under such circumstances, smaller doses with a gradual increase to an acceptable level may overcome this problem.

If you notice any of the above reactions or side effects, or if you notice other unusual or worrying changes contact your doctor.

Storing your medicine
- **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**
- Do not store above 25º C.
- Keep in original container.

If your doctor tells you to stop the treatment, return any remaining tablets to the doctor or pharmacist. On the label you will find the words "expiry date" followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date, but return it to your doctor or pharmacist.

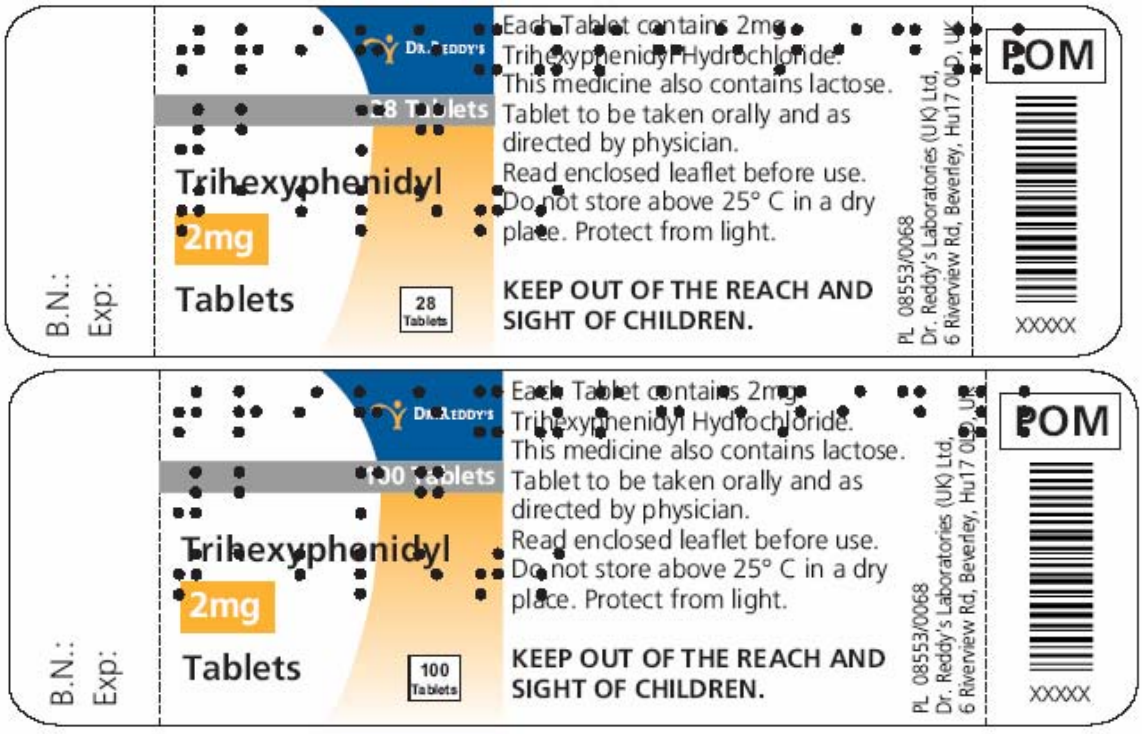
Remember: This medicine is for you. Never give it to someone else, even if their condition is the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

Leaflet revision date: 26/09/2006
Trihexyphenidyl 2mg Tablets, PL 08553/0068
Trihexyphenidyl 5mg Tablets, PL 08553/0069

TXP0102PI-1

LABELLING


28 Tablets
Trihexyphenidyl
2mg
Tablets
28 Tablets
Each Tablet contains 2mg Trihexyphenidyl Hydrochloride.
This medicine also contains lactose.
Tablet to be taken orally and as directed by physician.
Read enclosed leaflet before use.
Do not store above 25° C in a dry place. Protect from light.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
PL 08553/0068
Dr. Reddy's Laboratories (UK) Ltd,
6 Riverview Rd, Beverley, Hu17 0LD, UK
POM
XXXXX
B.N.:
Exp:
100 Tablets
Trihexyphenidyl
2mg
Tablets
100 Tablets
Each Tablet contains 2mg Trihexyphenidyl Hydrochloride.
This medicine also contains lactose.
Tablet to be taken orally and as directed by physician.
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XXXXX
B.N.:
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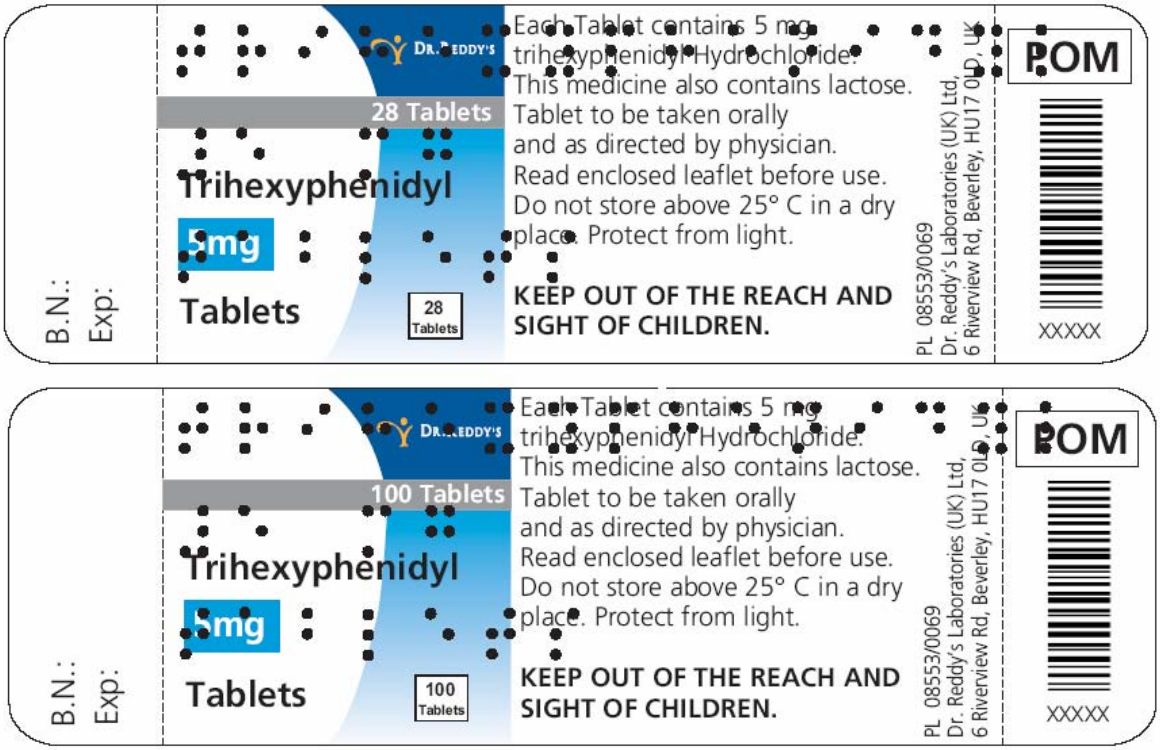
28 Tablets
Trihexyphenidyl
5mg
Tablets
28 Tablets
Each Tablet contains 5 mg trihexyphenidyl Hydrochloride.
This medicine also contains lactose.
Tablet to be taken orally and as directed by physician.
Read enclosed leaflet before use.
Do not store above 25° C in a dry place. Protect from light.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
PL 08553/0069
Dr. Reddy's Laboratories (UK) Ltd,
6 Riverview Rd, Beverley, HU17 0LD, UK
POM
XXXXX
B.N.:
Exp:
100 Tablets
Trihexyphenidyl
5mg
Tablets
100 Tablets
Each Tablet contains 5 mg trihexyphenidyl Hydrochloride.
This medicine also contains lactose.
Tablet to be taken orally and as directed by physician.
Read enclosed leaflet before use.
Do not store above 25° C in a dry place. Protect from light.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
PL 08553/0069
Dr. Reddy's Laboratories (UK) Ltd,
6 Riverview Rd, Beverley, HU17 0LD, UK
POM
XXXXX
B.N.:
Exp: