Public Assessment Report

Prochlorperazine 5mg Tablets

Prochlorperazine maleate

PL 08553/0091

Dr Reddy's Laboratories

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Lay Summary

The MHRA today granted Dr Reddy's Laboratories (UK) Ltd a Market Authorisation (licence) for the medicinal product Prochlorperazine 5mg Tablets. This is a prescription only medicine (POM) for the treatment of vertigo due to Meniere's syndrome, labyrinthine and other causes, nausea and vomiting from whatever cause. It is also used to treat migraine, schizophrenia and other psychotic disorders, and for the short-term management of anxiety.

This product contains the active ingredient prochlorperazine maleate. No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Prochlorperazine 5mg Tablets outweigh the risks hence a Marketing Authorisation was granted.

Scientific Discussion

INTRODUCTION

This Public Assessment Report is based on the assessment report on a National application for a Marketing Authorisation in the UK submitted under Directive 2001/83/EC, Art 10c for a product claimed to be essentially similar to Prochlorperazine 5 mg Tablets, PL 02463/5024R, granted to Wallis Laboratory (Sales) Ltd in August 1990.

A satisfactory letter of access was submitted. Appropriate declarations confirm that the applicant has full access to pre-clinical and clinical data and have all the necessary quality data in their possession to support the application.

The Pre-clinical, Pharmaceutical and Clinical Expert reports are provided by suitably qualified experts and confirm that the chemical, pharmaceutical, biological and clinical documentation included in the cross-reference product dossier are directly applicable and relevant to this specified marketing authorisation application.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

The drug substance specification is identical to that approved for the cross reference product. The active substance manufacturers are the same as previously authorised for the cross-referenced product.

DRUG PRODUCT

Composition

The qualitative composition of the finished product is

- Lactose
- Maize starch
- Pregelatinised maize starch
- Sucrose
- Sodium starch glycolate
- Magnesium stearate
- Purified water

Magnesium stearate is of vegetable origin and a current TSE certificate was provided for lactose.

Manufacturers

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

Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

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

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

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

PRODUCT LITERATURE

Minor changes to the SPC were made to bring it in to line with the reference product and subsequent minor changes were made to the Patient Information Leaflet. Labels were found to be satisfactory after minor amendments.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY AND ADVICE

A Marketing Authorisation was granted.

PRE-CLINICAL ASSESSMENT

No new pre-clinical data was submitted for this application and none were required.

MEDICAL ASSESSMENT

No new clinical data was submitted for this application and none were required.

Overall Conclusion and Risk/Benefit Analysis

Quality

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

Pre-Clinical

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

Clinical

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

Risk/Benefit Analysis

The quality of the product, Prochloroperazine 5mg Tablets, is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The risk benefit is therefore considered to be positive.

Steps Taken During Assessment

1	The MHRA received the application on 19th June 2003.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 5th August 2003.
3	Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 30th April 2004, 11th March 2005
4	The applicant provided further information in regard to the quality assessment on and 13th December 2005
5	The application was determined on 6th August 2007.

Steps Taken after Assessment

None

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Prochlorperazine 5mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg Prochlorperazine Maleate
See 6.1 for excipients.

3. PHARMACEUTICAL FORM

Tablet
Almost white or pale buff coloured tablets; flat, bevelled and scored.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Vertigo due to Meniere's syndrome, labyrinthine and other causes, nausea and vomiting from whatever cause. Migraine, schizophrenia and other psychotic disorders, short-term management of anxiety.

4.2. Posology and method of administration

For oral administration

Adults:
Prevention of nausea and vomiting: 5-10 mg b.d or t.d.s

Treatment of nausea and vomiting: 20 mg stat. followed if necessary by 10 mg two hours later.

Vertigo and Meniere's syndrome: 5 mg t.d.s increasing if necessary to 30mg daily. Dosage may be reduced gradually to 5-10 mg daily.

Adjunct in the short-term management of anxiety: 15-20 mg daily in divided doses initially but this may be increased if necessary to a maximum of 40 mg daily in divided doses.

Schizophrenia and other psychotic disorders: Usual effective daily oral dosage is 75-100 mg. Amounts as small as 50 mg or 25 mg have been found to be effective. Initially 12.5 mg twice daily for seven days, the daily amount being subsequently increased by 12.5 mg at four to seven day intervals until a satisfactory response is obtained. An attempt should be made to reduce this dosage after some weeks at the effective dosage.

Children:
Prevention and treatment nausea and vomiting: The dosage is 25 micrograms/kg bodyweight two or three times a day.
It is recommended that the 5 mg tablet should be used.
Not recommended for children weighing less than 10 kg.

Elderly:
Prochlorperazine should be used cautiously in this group of psychotic disorders.

Lower initial dosage is recommended. Care should also be taken not to confuse adverse effects of Prochlorperazine Maleate, e.g. orthostatic hypotension, with effects due to the primary disorder.

4.3. Contraindications

In patients with renal or liver dysfunction, epilepsy, Parkinson's disease, hypothyroidism, phaeochromocytoma, myasthenia gravis and prostate hypertrophy. Pregnancy.

4.4. Special warnings and precautions for use

Prochlorperazine should be avoided in patients known to be hypersensitive to phenothiazines or with a history of narrow angle glaucoma. It should be used with caution in the elderly, particularly during very hot or very cold weather (risk of hyper-/hypothermia).
These tablets contain lactose and sucrose. Patients with rare hereditary problems of fructose or galactose intolerances, the Lapp lactase deficiency or glucose-galactose malabsorption or sucrase-isomaltase insufficiency, should not take this medicine.

4.5. Interactions with other medicinal products and other forms of interaction

The depressant actions of the drug may be intensified by alcohol, barbiturates, and other sedatives. Respiratory depression may occur.

The hypotensive effect of most antihypertensive drugs, especially alpha adrenoceptor blocking agents, may be exaggerated.

The mild anticholinergic effect may be enhanced by other anticholinergic drugs and this may lead to heat stroke, constipation, etc.

The action of certain drugs may be opposed and these include amphetamine, laevodopa, clonidine, guanethidine, adrenaline.

Anticholinergic agents may reduce the antipsychotic effect.

Drugs interfering with absorption include antacids, anti-Parkinson, lithium. Increases or decreases in the plasma concentration of a number of drugs, e.g. propranolol, phenobarbitone, have been reported but are of no clinical significance.

High doses of Prochlorperazine reduce the response to hypoglycaemic agents and accordingly the dosage of these may have to be raised.

4.6. Pregnancy and lactation

Prochlorperazine is contraindicated in pregnancy. There is inadequate evidence of the safety of Prochlorperazine in human pregnancy, but it has been widely used for many years without apparent ill consequence. There is evidence of harmful effects in animals.

Possible adverse effects on the neonate include lethargy or paradoxical hyperexcitability, tremor and low Apgar score.

It may occasionally prolong labour and at such time should be withheld until the cervix is dilated 3-4 cm. It may be excreted in breast milk, breast-feeding should be suspended during treatment.

4.7. Effects on ability to drive and use machines

Patients should be warned about drowsiness, particularly during the early days of treatment, and should be advised not to drive or operate machinery.

4.8. Undesirable effects

Cardio-respiratory: Hypotension, usually postural, occurs commonly. The elderly are particularly susceptible.

Cardiac arrhythmias, including auricular arrhythmia A-V block, ventricular tachycardia and fibrillation have been reported. This may be related to dosage.

Pre-existing cardiac disease, old age, hypokalaemia and concurrent tricyclic antidepressants may predispose cardiac arrhythmias. ECG changes include widened QT interval, ST depression, U-waves and T-wave changes. Respiratory depression is possible in susceptible patients.

Blood dyscrasias: Mild leukopaenia occurs in up to 30% of patients on prolonged high dose therapy. Agranulocytosis may occur rarely. Any occurrence of unexplained infections or fever require haematological investigation.

Extrapyramidal: Acute dystonias or dyskinesias, usually transitory are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases.

Akathisia occurs after large initial doses.

Parkinsonism is commoner in adults and the elderly. It usually develops after weeks or months of treatment. One or more of the following may be seen: tremor, rigidity, akinesia or other features of Parkinsonism. Commonly just tremor.

Tardive dyskinesia: If this occurs it is usually, but not necessarily, after prolonged or high dosage. It can even occur after treatment has been stopped. Dosage should therefore be kept low whenever possible.

Skin and eyes: Contact skin sensitisation is a serious but rare complication, the greatest care must be taken to avoid contact of the drug with the skin. Skin rashes may also be seen in patients treated with the drug. Patients on high dosage should be warned that they may develop photosensitivity in sunny weather and should avoid exposure to direct sunlight. Ocular changes and the development of metallic greyish mauve coloration of exposed skin have been noted in some individuals, mainly females, who have received chlorpromazine continuously for long periods (4-8 years) and that this could possibly happen with Prochlorperazine.

Jaundice, usually transient, occurs in a very small percentage of patients. A premonitory sign may be a sudden onset of fever after one to three weeks of treatment followed by the development of jaundice. Neuroleptic jaundice has the biochemical and other characteristics of obstructive jaundice; the frequent presence of an accompanying eosinophilia indicates the allergic nature of this phenomenon. Treatment should be withheld on the development of jaundice.

Minor side effects of neuroleptics are nasal stuffiness, dry mouth, insomnia, agitation.

Endocrine: hyperprolactinaemia which may result in galactorrhoea, gynaecomastia, amenorrhoea, impotence.

Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) may occur with any neuroleptic.

4.9. Overdose

Symptoms of overdose include drowsiness or loss of consciousness, hypotension, tachycardia, E.C.G. changes, ventricular arrhythmias and hypothermia. Severe extra-pyramidal dyskinesias may occur.

If the patient is seen up to 6 hours after ingestion of a toxic dose, gastric lavage may be attempted. Activated charcoal should be given. There is no specific antidote. Treatment is supportive.

Volume expansion by intravenous fluids may be needed; infusion fluids should be warmed before administration in order not to aggravate hypothermia.

Positive inotropic agents such as dopamine may be tried if fluid replacement is insufficient to correct the circulatory collapse. Avoid the use of adrenaline.

Ventricular or supraventricular tachy-arrhythmias usually respond to restoration of normal body temperature and correction of circulatory or metabolic disturbances. Appropriate anti-arrhythmic therapy may be considered. Avoid lignocaine and, as far as possible, long acting anti-arrhythmic drugs.

Pronounced Central Nervous System depression requires airway maintenance or, in extreme circumstances, assisted respiration. Severe dystonic reactions usually respond to procyclidine (5-10mg) or orphenadrine (20-40mg administered intramuscularly or intravenously.
Convulsions should be treated with intravenous diazepam.

Neuroleptic malignant syndrome should be treated with cooling. Dantrolene sodium may be tried.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Prochlorperazine has a wide range of activity arising from its depressant actions on the Central Nervous System and its alpha-adrenergic blocking and weaker anticholinergic activities. It is a dopamine inhibitor; it inhibits prolactin-release-inhibitory factory, considered to be dopamine, thus stimulating the release of prolactin. The turnover of dopamine in the brain is also increased.

It has anti-emetic, antipruritic, serotonin-blocking and weak antihistamine properties and slight ganglion-blocking activity. It inhibits the heat regulating centre so that the patient tends to acquire the temperature of his surroundings. It is analgesic and can relax skeletal muscle. Its actions on the autonomic system produce vasodilation, hypotension and tachycardia. Salivary and gastric secretions are reduced.

5.2. Pharmacokinetic properties

Prochlorperazine is readily absorbed from the gastro-intestinal tract but is subject to considerable first-pass metabolism in the gut wall. It is also extensively metabolised in the liver and is excreted in the urine and faeces in the form of numerous active and inactive metabolites; there is evidence of enterohepatic recycling.

Although the plasma half-life has been reported to be only a few hours, it has a very prolonged terminal elimination phase of up to about 3 weeks. Its duration of therapeutic effect can range from a few days to several weeks or possibly longer.
It is very extensively bound to plasma proteins. It is widely distributed in the body and crossed the blood-brain barrier to achieve higher concentrations in the brain than in the plasma. Its metabolites also cross the placental barrier and are excreted in breast milk.

5.3. Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose
Maize starch
Pregelatinised maize starch
Sucrose
Sodium starch glycollate
Magnesium stearate
Purified water

6.2. Incompatibilities

None known.

6.3. Shelf life

Polystyrene/polypropylene containers:	3 years
PVC/Aluminium blister-packs:	2 years

6.4. Special precautions for storage

Polystyrene/polypropylene containers: Do not store above 25° C. Keep in the original container. Keep the container tightly closed.

PVC/Aluminium blister-packs: Do not store above 25° C. Keep in the original packaging. Keep the blister in the outer carton.

6.5. Nature and contents of container

High density polystyrene with a polythene lid and/or polypropylene containers with polypropylene or polythene lid, and polyurethane/polythene inserts.
Packs of 28, 30, 56, 60, 84, 90, 100, 500 and 1,000.

PVC/Aluminium blister-packs.
Packs of 28 and 84.

6.6. Instruction for Use/Handling

Not applicable.

Administrative Data

7. MARKETING AUTHORISATION HOLDER

Dr Reddy's Laboratories (UK) Ltd
6 Riverview Road
Beverley
East Yorkshire
HU17 0LD

8. MARKETING AUTHORISATION NUMBER

PL 08553/0091

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/08/2007

10 DATE OF REVISION OF THE TEXT

06/08/2007

Labels and Leaflet

Component code

PROCHLORPERAZINE 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 Prochlorperazine. If you have any questions concerning your medicine ask your doctor or pharmacist for more information.

What you need to know about your medicine
The name of your medicine is Prochlorperazine 5mg Tablets.

Each tablet contains prochlorperazine maleate 5mg. The tablets also contain lactose, maize starch, pre-gelatinised maize starch, sodium starch glycollate, sucrose and magnesium stearate.

The tablets are almost white or pale buff coloured tablets; flat, bevelled and scored, and are available in plastic containers of 28, 30, 56, 60, 84, 90, 100, 500 and 1,000 and in blister packs of 28 and 84 tablets.

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

How does Prochlorperazine work?
Prochlorperazine belongs to a group of medicines known as phenothiazines. This group of drugs act on the Central Nervous System (C.N.S.). In adults, Prochlorperazine is used for the prevention and treatment of nausea and vomiting. The medicine is also used for the treatment of vertigo (dizziness) and Meniere's syndrome (falling to one side). Prochlorperazine is used as an aid in the short-term management of anxiety and for the treatment of schizophrenia and other mental (psychotic) disorders. In children, Prochlorperazine is used for the prevention and treatment of nausea and vomiting. If you are not sure why you have been prescribed Prochlorperazine, then ask your doctor.

Before taking this medicine
Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Prochlorperazine, or any of the other ingredients, or other phenothiazine medicines. Also tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes.
The presence of other medical problems may affect the use of this medicine.

Make sure, therefore, to tell your doctor if you have any other medical problems, especially:
- Parkinson's disease,
- Any liver or kidney problems for which you have or are receiving treatment,
- Epilepsy,
- Reduced function of your thyroid gland,
- Myasthenia gravis (muscle weakness particularly after exercise),
- Enlargement of the prostate gland,
- Phaeochromocytoma (a tumour of the medulla of the adrenal gland, leading to elevated blood pressure)
- Glaucoma (raised eyeball pressure).

Taking other medicines
You can take these tablets with other medicines but there are some medicines which interfere with Prochlorperazine Tablets.
It is very important to tell your doctor or pharmacist about all the medicines which you are taking, whether prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. This includes medicines such as amphetamines, adrenaline, clonidine (used to treat migraine and high blood pressure), antacids (used to reduce stomach acid), lithium and treatments for raised blood pressure, diabetes (raised blood sugar) and Parkinson's disease.

This medicine will add to the effects of alcohol, and other medicines that tend to cause drowsiness such as anti-histamines (medicines for hay-fever and other allergies), sedatives such as barbiturates tranquillisers (for anxiety), medicines to help you sleep and pain relieving medicines.

Use in pregnancy and breast-feeding
It is important that you tell your doctor if you are pregnant, likely to become pregnant, or are breast-feeding. Do not use this medicine during pregnancy, unless your doctor considers it essential. Because this medicine may pass into the breast milk, its use should be avoided during breast feeding.

Driving or operating Machinery
Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert. Please remember that alcohol may intensify these effects and should be avoided during treatment.

Taking your medicine
Take this medicine by mouth and only in the doses prescribed by your doctor. Do not exceed this dose. Your doctor will prescribe the lowest dose necessary to control your symptoms.

Dosage
Adults:

Prevention of nausea and vomiting: 5-10 mg two or three times a day. Treatment of nausea and vomiting: 20 mg followed if necessary by 10 mg two hours later.

Vertigo and Meniere's syndrome: 5 mg three times daily, increased if necessary to 30 mg daily. Dosage may be reduced gradually to 5-10 mg daily.

Aid in the short-term management of anxiety: Initially 15-20 mg daily in divided doses. This may be increased if necessary to a maximum of 40 mg daily in divided doses.

Schizophrenia and other psychotic (mental) disorders: The usual dose is 12.5 mg twice daily for 7 days. The dose is then increased by 12.5 mg at 4-7 day intervals until it has a satisfactory effect. After you have been on an effective dose for some weeks, your doctor may advise you to try to reduce the dosage.

Children:
For the prevention and treatment of nausea and vomiting: The dosage is 25 micrograms per kilogram bodyweight two or three times a day. It is recommended that the 5mg tablet should be used. Not recommended for children weighing less than 10 kilograms.

Elderly: Prochlorperazine should be used cautiously in this group of psychotic disorders. Lower initial dosage is recommended.

Overdose
If you accidentally take more tablets than recommended, contact your doctor or nearest hospital casualty department. Take any remaining tablets or packaging so that they can be identified.

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

What side effects can Prochlorperazine cause?
If after taking your medicine you have any problems consult your doctor. The following side effects have been reported:

Nasal stuffiness, dry mouth, insomnia, agitation, dizziness when standing from a lying or sitting position, changes in heart rate, slowing of breathing in certain individuals.

Abnormal movement, tremors and muscle stiffness, and, usually in young patients, an inability to control certain muscles of the body such as tongue, mouth, arms and legs. You may experience extreme restlessness or agitation. These symptoms usually disappear after treatment with Prochlorperazine is discontinued.

A combination of high-temperature, pale complexion, muscle stiffness and changes in levels of alertness are symptoms of a serious condition called 'neuroleptic malignant syndrome'. If these symptoms develop, you should inform your doctor **immediately**.

After weeks or months of treatment it is possible that uncontrolled shaking of the hands or limbs and muscle stiffness may occur.

Disorders of the blood may occur during prolonged treatment or with high doses. If you develop a fever or experience an unusually bad sore throat or bruising, this could be a symptom of a blood disorder and you should tell your doctor **immediately**.

Jaundice (yellowing of the skin and whites of the eyes) may occur, sometimes preceded by a sudden onset of fever, 1-3 weeks after the start of treatment. If you develop jaundice, stop the treatment and inform your doctor **immediately**.

Do not crush the tablets or handle them more than you need to because you may develop a skin reaction. In sunny weather the skin may become sensitive to sunlight; therefore direct exposure to sunlight should be avoided. Visual changes and a greyish discoloration of exposed skin may develop, usually in women, but only after continuous, long term use of Prochlorperazine.

Swollen breasts can occasionally occur in men, but only after long term use. Unusual breast milk production, absence of menstrual periods and impotence can also sometimes occur.

If you experience any of the above reactions or side effects, or notice anything unusual which you are worried about, consult your doctor.

Storing your medicine
Plastic container: Do not store above 25°C. Keep in the original container. Keep the container tightly closed.
Blister pack: Do not store above 25°C. Keep in the original container. Keep the blister in the outer carton.

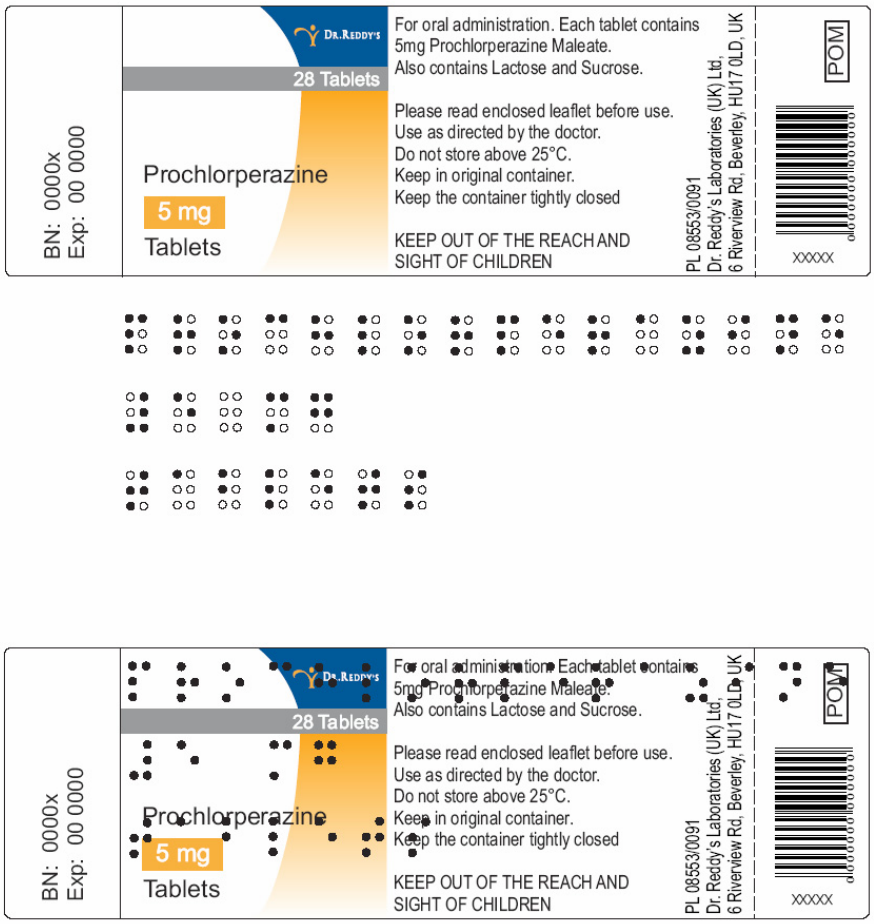
If the tablets show signs of discolouration then stop taking them and return them to your doctor or pharmacist.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

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 symptoms are 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.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Dr.Reddy's
28 Tablets
Prochlorperazine
5 mg
Tablets
For oral administration. Each tablet contains 5mg Prochlorperazine Maleate.
Also contains Lactose and Sucrose.
Please read enclosed leaflet before use.
Use as directed by the doctor.
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Keep the container tightly closed
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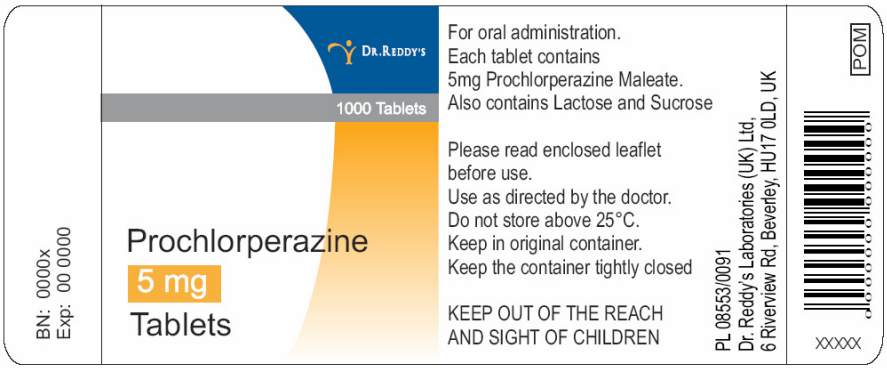
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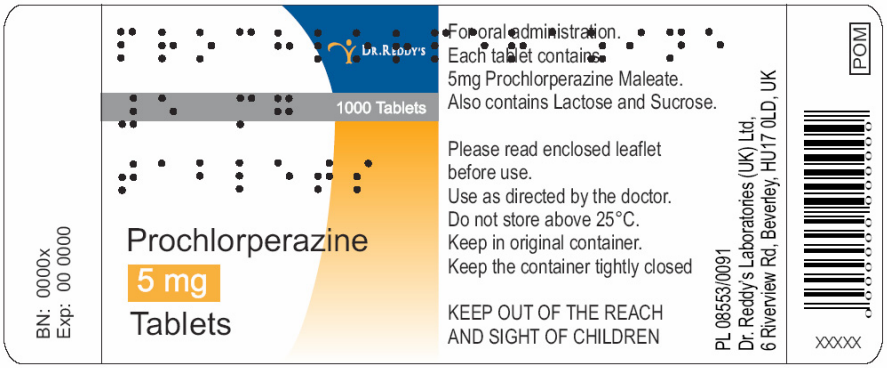
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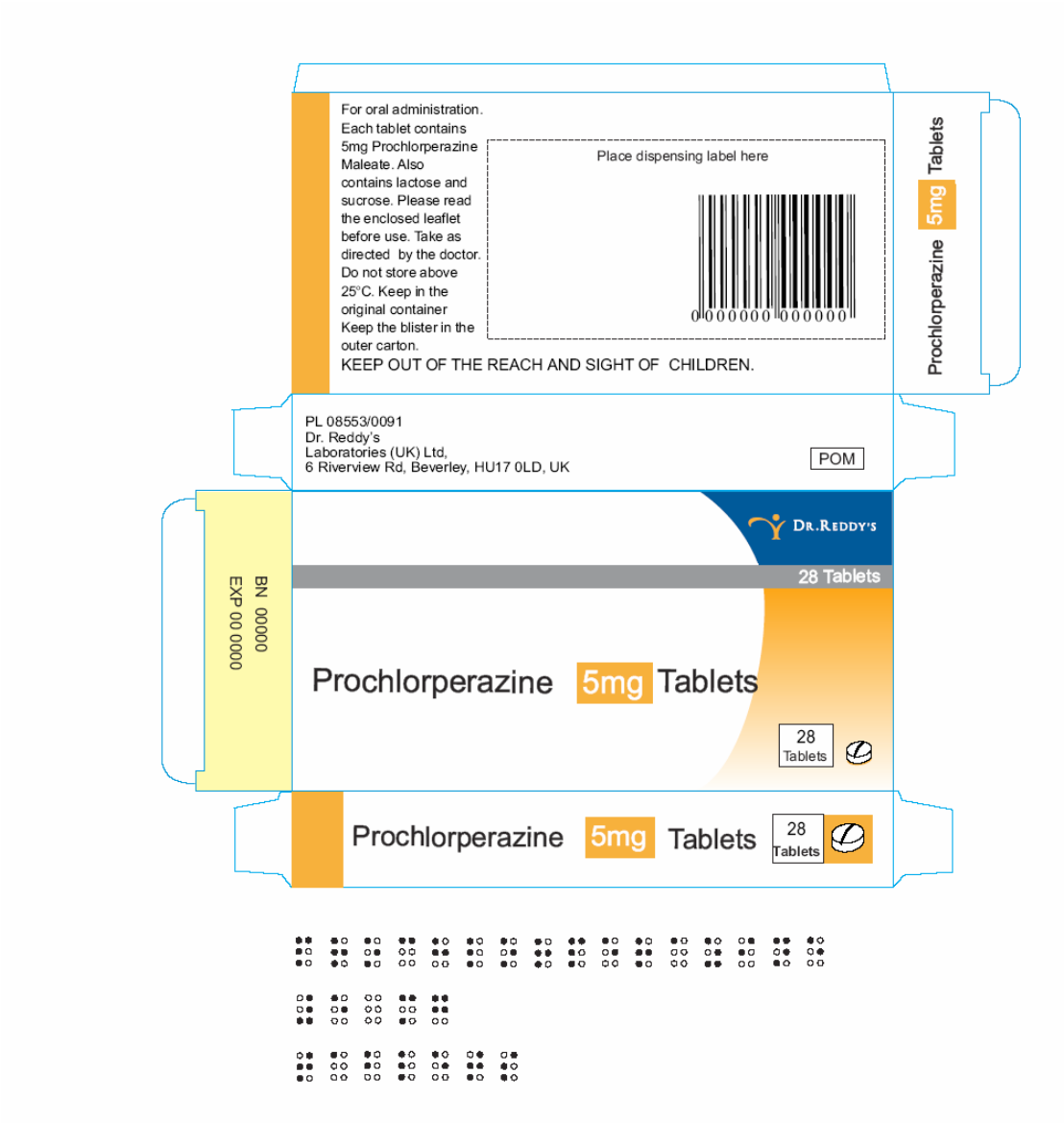
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Place dispensing label here
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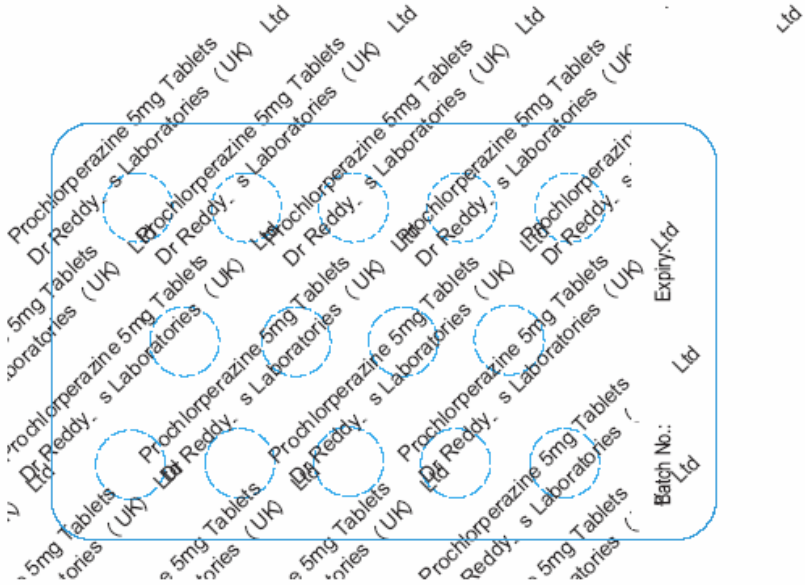
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