Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Prochlorperazine Maleate 5 mg Tablets

prochlorperazine maleate

PL 49565/0074

Rudipharm Limited

LAY SUMMARY

Prochlorperazine Maleate 5 mg Tablets
prochlorperazine maleate

This is a summary of the Public Assessment Report (PAR) for Prochlorperazine Maleate 5 mg Tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

For practical information about using Prochlorperazine Maleate 5 mg Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Prochlorperazine Maleate 5 mg Tablets and what are they used for?
This application is the same as Prochlorperazine Maleate 5 mg Tablets PL 21880/0121 which is already authorised.

The Company responsible for Prochlorperazine Maleate 5 mg Tablets (PL 21880/0121) has agreed that its scientific data can be used as the basis for the grant of an identical licence for Prochlorperazine Maleate 5 mg tablets.

Prochlorperazine Maleate 5 mg Tablets can be used to:
- treat balance problems or dizziness (vertigo). This includes problems of the inner ear such as 'Meniere's Syndrome' or 'labyrinthitis'
- stop patients feeling sick (nausea) or being sick (vomiting). This can be from any cause including migraines
- treat anxiety in the short-term, when used in addition to other medicines
- treat schizophrenia
- treat over-active behaviour or thoughts (mania).

How do Prochlorperazine Maleate 5 mg Tablets work?
Prochlorperazine maleate belongs to a group of medicines called 'phenothiazine antipsychotics'. It works by blocking the effects of a chemical in the brain.

How are Prochlorperazine Maleate 5 mg Tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (taken by mouth).

The tablets should be swallowed with water. Patients should not handle the tablets more than they need to as they may develop sore, red or blistered skin.

Doses
Adults
Dizziness (Vertigo)
5 mg three times a day, up to a maximum of 30 mg a day. The patient's doctor may gradually reduce to 5-10mg a day after several weeks.

Nausea and vomiting
Prevention: 5 – 10 mg two or three times a day.
Treatment: 20 mg immediately, followed if necessary, by 10 mg two hours later.

To help with the treatment of anxiety
15 – 20 mg a day (divided throughout the day). Up to a maximum of 40 mg a day (divided throughout the day).

Mental illness
75 – 100 mg a day, depending on response. Patients should start with 12.5 mg twice a day for seven days, rising by 12.5 mg every four to seven days.

Elderly
The patient's doctor may prescribe a lower dose.

Children
Not recommended to children under 12 years of age.

Exposure to sunlight
Prochlorperazine Tablets can cause the skin to be more sensitive to sunlight. Patients should avoid exposure to direct sunlight while taking this medicine.

Tests
The patient's doctor may do regular tests while they are taking this medicine. These might include blood tests and an ECG to check the heart is working properly.

For further information on how Prochlorperazine Maleate 5 mg Tablets are used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Prochlorperazine Maleate 5 mg Tablets have been shown in studies?
Prochlorperazine Maleate 5 mg Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Prochlorperazine Maleate 5 mg Tablets, however, reference is made to the studies for Prochlorperazine Maleate 5 mg Tablets (PL 21880/0121).

What are the possible side effects of Prochlorperazine Maleate 5 mg Tablets?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.ukor search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Prochlorperazine Maleate 5 mg Tablets are considered to be identical to the previously authorised product with the same benefits and risks.

Why were Prochlorperazine Maleate 5 mg Tablets approved?
The MHRA decided that the benefits of Prochlorperazine Maleate 5 mg Tablets are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Prochlorperazine Maleate 5 mg Tablets?
As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Prochlorperazine Maleate 5 mg Tablets. The RMP details the important risks of Prochlorperazine Maleate 5 mg Tablets, how these risks can be minimised, any uncertainties about Prochlorperazine Maleate 5 mg Tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Prochlorperazine Maleate 5 mg Tablets:

List of important risks and missing information	
Important identified risks	• Contrandicated with known hypersensitivity to Prochlorperazine or other ingredients. • Contraindicated in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption • Concomitant treatment with other neuroleptics barbiturates and other sedatives and consumption of alcohol. • QT interval prolongation and consequently Torsade de Pointes
Important potential risks	• Withdrawal syndrome • Interaction with other medicinal products (Adrenaline, desferrioxamine, antacids, anti-parkinsonian drugs and lithium) • Should be avoided in patients with liver or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, phaeochromocytoma, myasthenia gravis, prostate hypertrophy, narrow angle glaucoma or agranulocytosis. • Use with anticholinergics that may reduce antipsychotic effect and enhance its anticholinergic effect. • Close monitoring is required in patients with epilepsy or a history of seizures, as phenothiazines may lower the seizure threshold. • Use with caution in patients with risk factors for stroke and venous thromboembolism. • Breast-feeding • Close monitoring of the neonate exposed to it in 3rd trimester of pregnancy for extrapyramidal and withdrawal symptoms. • Use with caution in elderly as they are prone to hyper or hypothermia and postural hypotension, drug-induced Parkinsonism. • Use with caution in children due to risk of dystonic reactions.
Missing information	• Use during pregnancy.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Prochlorperazine Maleate 5 mg Tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Prochlorperazine Maleate 5 mg Tablets

A marketing authorisation was granted in the United Kingdom on 09 May 2023.

The full PAR for Prochlorperazine Maleate 5 mg Tablets follows this summary.
This summary was last updated in June 2023.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Prochlorperazine Maleate 5 mg Tablets (PL 49565/0074) could be approved.

The product is approved for the following indications:

- Vertigo due to Meniere's Syndrome, labyrinthis and other causes
- nausea and vomiting from whatever cause including that associated with migraine.

It may also be used for schizophrenia (particularly in the chronic stage), acute mania and as an adjunct to the short-term management of anxiety.

The active substance prochlorperazine is a potent phenothiazine neuroleptic.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers to the reference product Prochlorperazine Maleate 5 mg Tablets (PL 21880/0121).

No new non-clinical or clinical data have been supplied and none are required for this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A national marketing authorisation was granted in the United Kingdom on 09 May 2023

II. EXPERT REPORT

The applicant cross-refers to the data for Prochlorperazine Maleate 5 mg Tablets (Medreich Plc), to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Prochlorperazine Maleate 5 mg Tablets dated 09/01/2014.

PATIENT INFORMATION LEAFLET

A leaflet text and mock-up has been provided which has been aligned with that for Prochlorperazine Maleate 5 mg Tablets, dated for 09/01/2014. The bridging report submitted for PL 21880/0121 has been provided.

LABEL

Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications

The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Product

Name

The product has been named in line with current requirements.

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

Prochlorperazine Maleate 5 mg Tablets are available in Alu/PVC/PVdC blisters in a pack size of 28 and 84 tablets.

The appearance of the product is identical to that of the cross-reference product.

The proposed shelf life of the product is 3 years with the recommended storage condition "Do not store above 25 ºC. Store in the original package".

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

Legal status

Prescription only medicine (POM)

Manufacturers

The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative compositions

The composition of the proposed product is consistent with the details registered for the cross-reference product.

Manufacturing process & control of critical steps

The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

Finished product release/shelf life specifications

The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

TSE Compliance

With the exception of lactose monohydrate, no excipients of animal or human origin are used in the final products. A standalone declaration from the supplier has been provided.

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application), no new non-clinical data have been supplied and none are required.

VI. CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application), no new clinical data have been supplied and none are required.

VII. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Prochlorperazine Maleate 5 mg Tablets (PL 21880/0121; Medreich Plc). The bridging report submitted by the applicant is acceptable.

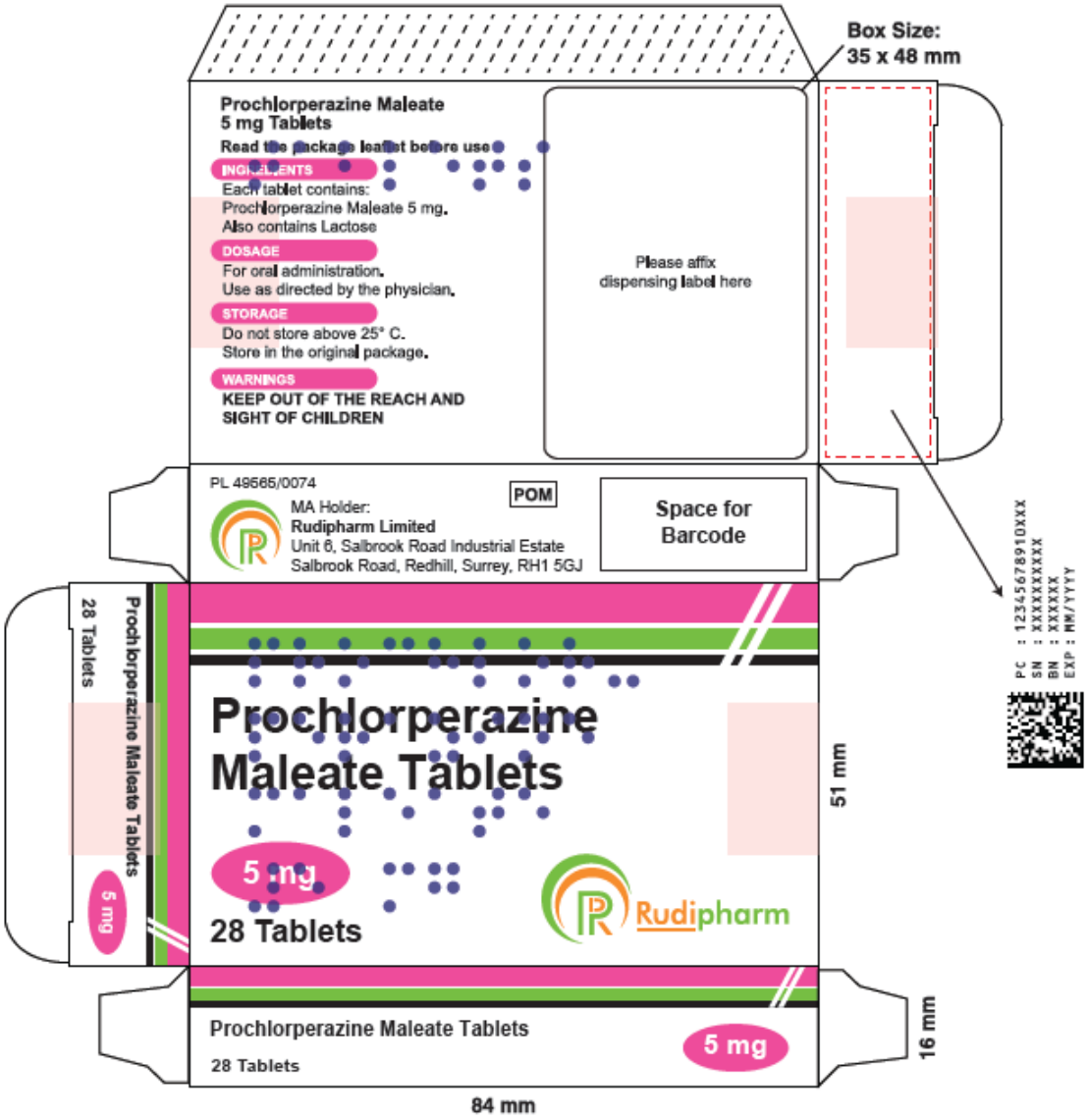
IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

Representative copies of the labels at the time of licensing are provided below.



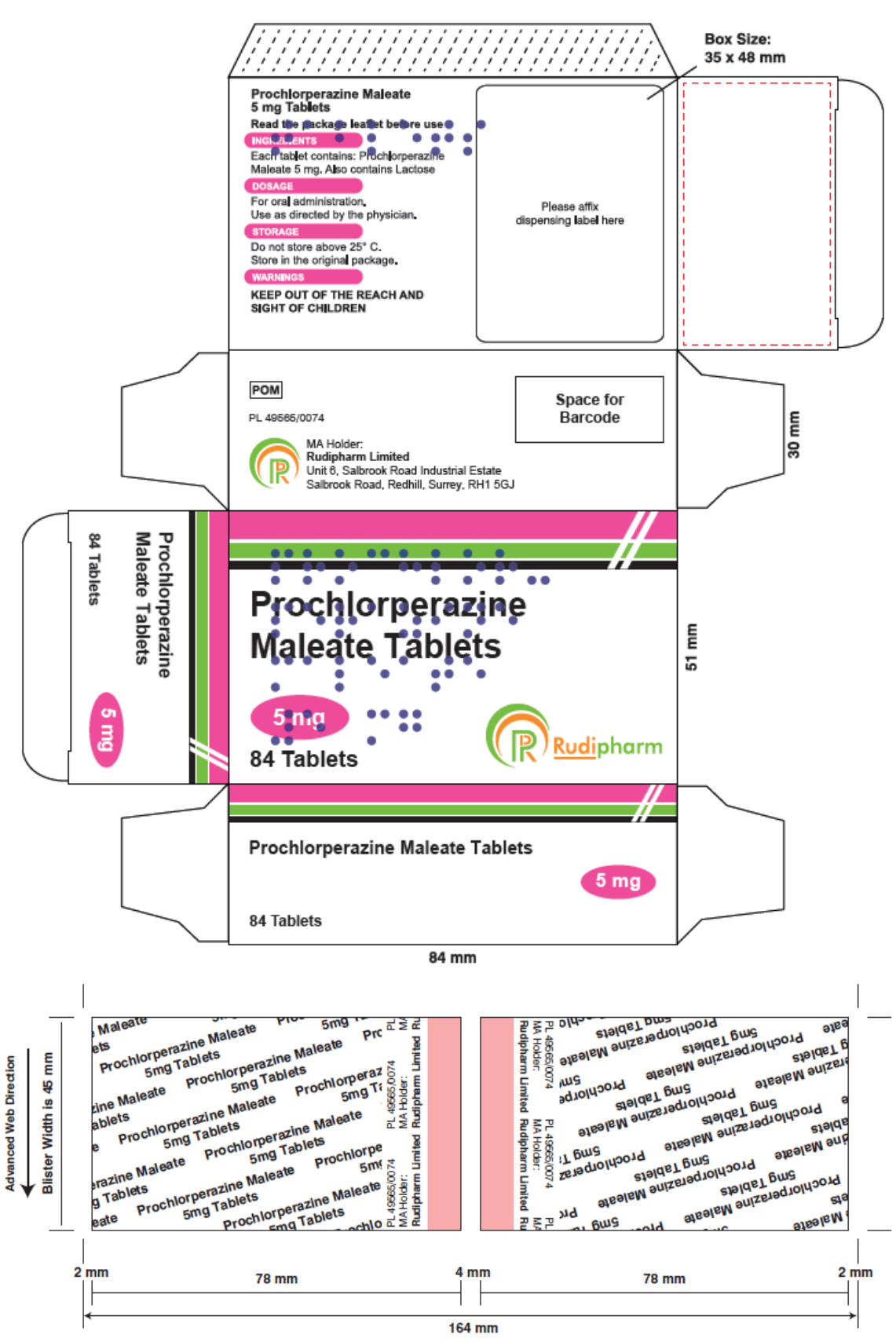

Box Size:
35 x 48 mm
Prochlorperazine Maleate
5 mg Tablets
Read the package leaflet before use
INGREDIENTS
Each tablet contains: Prochlorperazine Maleate 5 mg. Also contains Lactose
DOSAGE
For oral administration.
Use as directed by the physician.
STORAGE
Do not store above 25° C.
Store in the original package.
WARNINGS
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
Please affix dispensing label here
POM
PL 49565/0074
Space for Barcode
MA Holder:
Rudipharm Limited
Unit 6, Salbrook Road Industrial Estate
Salbrook Road, Redhill, Surrey, RH1 5GJ
30 mm
Prochlorperazine Maleate Tablets
84 Tablets
5 mg
Prochlorperazine Maleate Tablets
5 mg
84 Tablets
Rudipharm
51 mm
Prochlorperazine Maleate Tablets
5 mg
84 Tablets
84 mm
Advanced Web Direction
Blister Width is 45 mm
2 mm
78 mm
4 mm
78 mm
2 mm
164 mm

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**