Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Promethazine hydrochloride 25 mg Film-coated Tablets

promethazine hydrochloride

PL 44041/0236 - 0237

NOUMED LIFE SCIENCES LIMITED

LAY SUMMARY

Promethazine hydrochloride 25 mg Film coated Tablets
promethazine hydrochloride

This is a summary of the Public Assessment Report (PAR) for Promethazine hydrochloride 25 mg Film-coated Tablets. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Promethazine Hydrochloride Tablets in this lay summary for ease of reading.

For practical information about using Promethazine Hydrochloride Tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Promethazine Hydrochloride Tablets and what are they used for?
These applications are the same as Promethazine hydrochloride 25 mg Film-coated Tablets (PL 44041/0171) which is already authorised. The company responsible for Promethazine hydrochloride 25mg Film-coated Tablets (PL 44041/0171) is the same company that is the holder of Promethazine hydrochloride 25 mg Film-coated Tablets (PL 44041/0236 - 0237).

Promethazine Hydrochloride Tablets are used to treat the following conditions:
- For short term use: to treat adults with difficulty sleeping (insomnia).
- To treat allergic conditions such as hay fever or rashes (like nettle rash or hives).
- To treat or stop the patient feeling sick (nausea) or being sick (vomiting) such as travel sickness.
- For short term use: as a sedative for children aged 5 years and above.

How do Promethazine Hydrochloride Tablets work?
Promethazine Hydrochloride Tablets contain a medicine called promethazine hydrochloride. This belongs to a group of medicines called phenothiazines. It works by blocking a natural substance (histamine) that the body makes during an allergic reaction. It also works directly on the brain to help the patient feel more relaxed.

How are Promethazine Hydrochloride Tablets used?
The pharmaceutical form of these medicines is a film-coated tablet, and the route of administration is oral (by mouth).

Taking these medicines
- These medicines should be taken by mouth.
- The patient should *not* take these medicines for longer than 7 days. If their symptoms worsen or do not improve after 7 days, they or the caregiver should talk to their doctor or pharmacist.
- If the patient feels the effect of their medicine is too weak or too strong, they or the caregiver should *not* change the dose themselves without consulting the doctor.

The amount of Promethazine Hydrochloride Tablets the patient needs to take depends on the reason they are taking these medicines.

The recommended dose is:

For allergies (such as hay fever, rashes and hives)
Children 2-5 years:

- Other forms of these medicines may be more suitable for children in this age group; the caregiver should ask the child's doctor or pharmacist.

Children 5-10 years:

- A single tablet (25 mg) should be given at night.
- The caregiver should *not* give the child more than 25 mg each day.

Children over 10 years and adults (including the elderly):

- Start with one tablet (25 mg) taken at night.
- This may be increased to a maximum of one tablet (25 mg) twice a day if necessary.

For treatment and prevention of feeling sick or being sick (such as travel sickness)
Children 2-5 years:

- Other forms of these medicines may be more suitable for children in this age group; the caregiver should ask the child's doctor or pharmacist.

Children 5-10 years:

- Promethazine Hydrochloride 10 mg Tablets or other forms of these medicines may be suitable for this age group; the caregiver should ask the child's doctor or pharmacist.

Children over 10 years and adults (including the elderly):

- A single tablet (25 mg) to be taken the night before the journey.
- This may be repeated after 6-8 hours if necessary.

As a short-term paediatric sedative for children and for short term treatment of insomnia in adults
Children 2-5 years:

- Other forms of these medicines may be more suitable for children in this age group; the caregiver should ask the child's doctor or pharmacist.

Children 5-10 years:

- A single tablet (25 mg) given at night.

Children over 10 years and adults (including the elderly):

- One or two tablets (25 mg-50 mg) taken at night.

These medicines should only be used as recommended. The patient should *not* exceed the recommended dose of these medicines.

For further information on how Promethazine Hydrochloride Tablets are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines 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 Promethazine Hydrochloride Tablets have been shown in studies?
Promethazine Hydrochloride Tablets are considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Promethazine Hydrochloride Tablets; however, reference is made to the studies for Promethazine Hydrochloride 25 mg Film-coated Tablets (PL 44041/0171).

What are the possible side effects of Promethazine Hydrochloride Tablets?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs 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.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Promethazine Hydrochloride Tablets are considered to be identical to the previously authorised product with the same benefits and risks.

Why were Promethazine Hydrochloride Tablets approved?
The MHRA decided that the benefits of Promethazine Hydrochloride Tablets are greater than the risks and recommended that these medicines are approved for use.

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

The following safety concerns have been recognised for Promethazine Hydrochloride Tablets:

Summary of safety concerns	
Important identified risks	• Use in pregnancy and breast-feeding • Photosensitivity
Important potential risks	• None
Missing information	• Fertility

The information included in the SmPCs 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 Promethazine Hydrochloride 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 these applications and are satisfactory.

Other information about Promethazine Hydrochloride Tablets
Marketing Authorisations were granted in the UK on 11 June 2024.

The full PAR for Promethazine Hydrochloride Tablets follows this summary.

This summary was last updated in June 2024.

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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 applications for Promethazine hydrochloride 25 mg Film coated Tablets (PL 44041/0236 - 0237) could be approved.

These products are approved for the following indications:

- As symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis, urticaria and anaphylactic reactions to drugs and foreign proteins.
- As an antiemetic.
- For short term use:
  - Treatment of insomnia in adults.
  - As a paediatric sedative.

The active substance, promethazine hydrochloride is a potent, long acting, antihistamine with additional anti-emetic central sedative and anti-cholinergic properties.

These are national abridged applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross-refers to the reference product, Promethazine Hydrochloride 25 mg Film-coated Tablets (PL 44041/0171).

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

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions 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 these products at all sites responsible for the manufacture, assembly and batch release of these products.

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

National marketing authorisations were granted in the UK on 11 June 2024.

II EXPERT REPORT

The applicant cross-refers to the data for Promethazine Hydrochloride 25 mg Film-coated Tablets (PL 44041/0171), Noumed Life Sciences Limited, to which these applications are claimed to be identical. This is acceptable.

III ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)

The SmPCs are in line with those for Promethazine Hydrochloride 25 mg Film-coated Tablets (PL 44041/0171), dated 19 January 2024.

PATIENT INFORMATION LEAFLET

Leaflet text and mock-up has been provided which has been aligned with that for Promethazine Hydrochloride 25 mg Film-coated Tablets (PL 44041/0171), dated for December 2023.

LABEL

Label texts and mock-ups have been provided.

IV QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specifications

The sources of the active substances are 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 Products

Name

These products have been named in line with current requirements.

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

Promethazine Hydrochloride 25 mg Film coated Tablets are packaged in white opaque PVC-PVDC 250 microns/20 microns Aluminium foil coated with VMCH in blisters and are available in pack-sizes of 28, 56, 84 and 100 tablets.
Not all pack sizes may be marketed.

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

The proposed shelf life of the products is 3 years with the recommended storage conditions, 'Store below 30°C. Store in the original package in order to protect from light'.

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

Legal status

Pharmacy (P) medicine

Manufacturers

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

Qualitative and quantitative compositions

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

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.

The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

These products do not contain or consist of genetically modified organisms (GMO).

V NON-CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-clinical data have been supplied and none are required.

VI CLINICAL ASPECTS
As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) 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) was provided with the application in accordance with legal requirements, including user consultation.

IX OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference products and positive.

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

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

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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**