

 Laboratory & Allied Ltd. Nairobi, Kenya.	BATCH PACKAGING RECORD		PAGES : 11 OF 44
	Product Name PROMETIN-25 TABLETS		
Batch Number 83324	Pack Code	P027	
Batch Size 1,200,000 Tablets	BPR No.	BPR/TAB/PRN/002	
Department	Production (General)	Edition No.	02
Shelf Life	36 Months	Supersedes Edition No.	01

4.3 LITERATURE / INSERTS APPROVAL:
 (Attach literature / insert here for approval)

PROMETIN®

Promethazine Hydrochloride Preparations

Elh 13/04/2023

COMPOSITION
Prometin® 25:
 Each film coated tablet contains: Promethazine hydrochloride BP 25mg.
Prometin® ELIXIR:
 Each 5ml contains : Promethazine hydrochloride BP 5mg.

PHARMACEUTICAL FORM
Prometin® 25: Pinkish-red film coated tablet
Prometin® ELIXIR: A Sweetened pleasantly flavored liquid.

CLINICAL PARTICULARS
Therapeutic 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.
 For short term use as a paediatric sedative.

Posology and method of administration
 Route of administration: Oral.
 Not recommended for children under 2 years.

As an antihistamine in allergy:

Children 2-5 years	5ml-15 ml as a single dose or 5ml twice a day. Maximum daily dose 15ml. Prometin® Elixir is recommended for this age group.
Children 5-10 years	10-25 mg as a single dose or 5-10 mg twice a day. Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly)	25 mg as a single dose or 10 mg twice a day. Increasing to a maximum of 25 mg twice a day as required.

As an antiemetic:

Children 2-5 years	5 ml to be taken the night before the journey. To be repeated after 6-8 hours as required. Prometin® Elixir is recommended for this age group.
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Children 5-10 years	10 ml or 10mg to be taken the night before the journey. To be repeated after 6-8 hours as required. Prometin® Elixir or 10 mg Tablets is recommended.
Children over 10 years and adults (including elderly)	25 mg to be taken the night before the journey. To be repeated after 6-8 hours as required.

As a paediatric sedative for short term use and for short term treatment of insomnia in adults:

Children 2-5 years	15ml or 20ml as a single night time dose. Prometin® Elixir is recommended for this age group.
Children 5-10 years	20-25 mg as a single night time dose.
Children over 10 years and adults (including elderly)	25 or 50 mg as a single night time dose.

Contraindications
 Not be used in patients in coma or suffering from CNS depression of any cause.
 Not be given to patients with a known hypersensitivity to promethazine or to any of the excipients.
 Contraindicated for use in children less than two years of age because of the potential for fatal respiratory depression.
 Should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Prometin® may thicken or dry lung secretions and impair expectoration. It should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis.
 Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency.
 Caution should be exercised in patients with bladder neck or pyloro-duodenal obstruction. The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.
 Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs e.g. salicylates. It may also delay the early diagnosis of intestinal obstruction or raised intracranial pressure through the suppression of vomiting.
 Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Note: Sign on the attached literature / insert as well as in the BPR.

Literature / Insert Approved By	Packing Supervisor	IPQA
Signature/ Date	<i>PM</i> 13/04/2023	<i>Elh</i> 13/04/2023

APPROVALS	PREPARED BY	CHECKED BY	APPROVED BY	AUTHORIZED BY
NAME	Peter Kinyua	Vipul Patel	Badi Saidi	Dr. Simon Mutgai
DESIGNATION	Asst. Manager-Prod.	Manager- Prod.	Asst. Manager- QA	Company Pharmacist
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	25/02/2023	23/02/2023	24/02/2023	24/02/2023