SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT

METAZINE® SYRUP

Strength

Each 5ml contains:

Promethazine Hydrochloride BP…… 5mg

Pharmaceutical/Dosage form

Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Promethazine Hydrochloride BP…… 5mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

A clear, light-yellow syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Metazine syrup is indicated in the following:
Symptomatic treatment of allergic reactions such as in perennial and seasonal rhinitis, vasomotor rhinitis, urticaria, conjunctivitis and pruritic skin disorders.
Prevention and control of nausea and vomiting.
Treatment and prevention of motion sickness.
Sedation in children and adults for relief of apprehension and production of light sleep from which the patient can easily be aroused.

4.2 Posology and method of administration

Route of administration: Oral.

As an antihistamine in allergy:

Children 2-5 years	5–15 mg as a single dose. Or 5 mg bd. Maximum daily dose 15 mg.
Children 5-10 years	10–25 mg as a single dose. Or 5-10 mg bd. Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly)	Initially 10 mg bd. Increasing to a maximum of 20 mg tds as required.

As an antiemetic:

Children 2-5 years	5 mg to be taken the night before the journey. To be repeated after 6–8 hours as required.
Children 5-10 years	10 mg to be taken the night before the journey. To be repeated after 6–8 hours as required.
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	15 or 20 mg as a single nighttime dose.
Children 5-10 years	20 or 25 mg as a single nighttime dose.
Children over 10 years and adults (including elderly)	25 or 50 mg as a single nighttime dose. The use of Metazine tablets to provide these doses is recommended.

4.3 Contraindications

Metazine should not be used in patients in coma or suffering from CNS depression of any cause.

Metazine should not be given to patients with a known hypersensitivity to promethazine or to any of the excipients.

Promethazine is contraindicated for use in premature infants and neonates because of the potential for fatal respiratory depression.

Metazine should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.4 Special warnings and precautions for use

Metazine 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.

Metazine Syrup contains sodium sulphite anhydrous and sodium metabisulphite these may rarely cause severe hypersensitivity reaction and bronchospasm.

Phenothiazine derivatives may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated in the presence of bradycardia, hypokalaemia, and acquired (i.e. drug induced) QT prolongation. If the clinical situation permits, medical and laboratory evaluations should be performed to rule out possible risk factors before initiating treatment with a phenothiazine derivative and as deemed necessary during treatment (see section 4.8).

Benzoic acid

Metazine Syrup contains 5mg sodium benzoate in each 5ml dose, which is equivalent to 1mg/ml.

Sodium benzoate may increase bilirubinemia in newborn babies (up to 4 weeks old).

4.5 Interaction with other medicinal products and other forms of interaction
Metazine will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Metazine may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results. Metazine should be discontinued at least 72 hours before the start of skin tests as it may inhibit the cutaneous histamine response thus producing false-negative results.

Special caution is required when promethazine is used concurrently with drugs known to cause QT prolongation (such as antiarrhythmics, antimicrobials, antidepressants, antipsychotics) to avoid exacerbation of risk of QT prolongation.

4.6 Fertility, pregnancy and lactation
Metazine Syrup should not be used in pregnancy unless the physician considers it essential. The use of Metazine is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonatal irritability and excitement.

4.7 Effects on ability to drive and use machines
Because the duration of the action may be up to 12 hours, patients should be advised that if they feel drowsy, they should not drive or operate heavy machinery.

4.8 Undesirable effects
The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 00 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from the available data).

Side effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness, and disorientation. Anticholinergic side effects such as blurred vision, dry mouth and urinary retention occur occasionally. Infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability. The elderly are particularly susceptible to the anticholinergic effects and confusion due to promethazine. Other side effects include urticaria, rash, pruritus, anorexia, gastric irritation, palpitations, hypotension, arrhythmias, QT prolongation, torsade de pointes, extrapyramidal effects, Restless Legs Syndrome, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasia, including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

The preservatives used in Metazine Syrup have been reported to cause hypersensitivity reactions, characterised by circulatory collapse with CNS depression in certain susceptible individuals with allergic tendencies.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose
Symptoms of severe overdosage are variable. They are characterised in children by various combinations of excitation, ataxia, incoordination, athetosis and hallucinations, while adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children: coma or excitement may precede their occurrence. Tachycardia may develop. Cardiorespiratory depression is uncommon. High doses (supratherapeutic doses) can cause ventricular arrhythmia including QT prolongation and torsade de pointes (see section 4.8). If the patient is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used.

Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or other suitable anticonvulsants.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihistamines for systemic use; Phenothiazine derivatives,

Potent, long acting, antihistamine with additional anti-emetic central sedative and anti-cholinergic properties.

5.2 Pharmacokinetic properties
Promethazine is distributed widely in the body. It enters the brain and crosses the placenta. Promethazine is slowly excreted via urine and bile. Phenothiazines pass into the milk at low concentrations.

5.3 Preclinical safety data
No additional preclinical data of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%), Sucrose, Citric Acid Anhydrous, Sodium Citrate, Sodium Sulphite, Sodium Metabisulphite, Ascorbic Acid, Caramel Colour, Sodium Benzoate, Orange Flavour, Purified Water.

S.NO	Composition	Reference
1.	Ethanol (96%),	BP
2.	Sucrose	BP
3.	Citric Acid Anhydrous	BP
4.	Sodium Citrate	BP
5.	Sodium Sulphite	BP
6.	Sodium Metabisulphite	BP
7.	Ascorbic Acid	BP
8.	Caramel Colour	USP
9.	Sodium Benzoate	BP
10.	Orange Flavour	IHS
11.	Purified Water	BP

6.2 Incompatibilities
None stated.

6.3 Shelf life
36 months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

Keep out of the reach of children.

6.5 Nature and contents of container
Amber Pet bottle capped with an ROPP cap in pack sizes of 60ml and 100 ml.

6.6 Special precautions for disposal and other handling
No special requirements.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
Ogun State, Nigeria.
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9. NAFDAC REGISTRATION NUMBER(S)

04-7921.

10. DATE OF REVISION OF THE TEXT

22/02/2028