

1. למה מיוחדת התרופה?
פרטאיזון הינו תכשיר אנטיהיסטימי בעל פעילות מרגיעה למניעה והקלה של תגובות אלרגיות. הלארעה במצבי חדרה ואי שקט וכן משמש נגד הקאות ובחילות.
קבוצה תרופתית: החומר הפעיל שייך לקבוצת האנטי-היסטמינים (פנותיאינים).

✖ אין להשתמש בתרופה אם:

- הינן מניקה או שבעיים בסמוך למועד לידה משוער (ראי גם "הריון והנקה").
- גילו של המטופל מתחת לשנתיים.
- אתה רגיש (אלרגי) לחומר הפעיל או לכל אחד מהמרכיבים הנוספים אשר מכילה התרופה (ראו סעיף 6 "מידע נוסף").
- הנך נוטל תרופות המעכבות מנווומין אוקסידאז (לטיפול בדיכאון) או במשך שבועיים לאחר סיום טיפול במעכבי מנווומין אוקסידאז.
- אתה נוטל או נטלת מינון גבוה של מדכאי מערכת העצבים המרכזית (לטיפול בחרדה, הפרעות שינה).
- המטופל מחוסר הכרה או שרירי בקוהה או סובל מתופעות חמורות של סחרחורת, נמנום או כאב ראש.
- אתה סובל מצהבת.



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**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed with a doctor's prescription only

Prothiazine Syrup
Each teaspoonful (5 ml) contains:
Promethazine Hydrochloride 5 mg
Prothiazine Tablets
Each tablet contains: Promethazine Hydrochloride 25 mg
For inactive ingredients in the preparation – see section 6.
Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.
This medicine is not intended for children under 2 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?
Prothiazine is an antihistaminic and tranquilizing agent, for the prevention and relief of allergic reactions, for sedation in anxiety states and agitation. It is also used against vomiting and nausea.

Therapeutic group: The active ingredient belongs to the antihistamine group (phenothiazines).

2. BEFORE USING THE MEDICINE:

- ☒ **Do not use this medicine if:**
 - you are breastfeeding or you are two weeks before your estimated date of birth (see also "Pregnancy and breastfeeding").
 - the patient is under 2 years of age.
 - you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6 "further information").
 - you are taking monoamine oxidase inhibitors (for treatment of depression) or are within two weeks of completing treatment with monoamine oxidase inhibitors.
 - you are taking, or you took, a high dosage of central nervous system depressants (for treatment of anxiety, sleeping disturbances).
 - the patient is unconscious or in a coma or suffering from severe effects of dizziness, drowsiness or headache.
 - you are suffering from jaundice.

Special warnings regarding use of the medicine:

- Consult the doctor if you are suffering, or have suffered in the past, from impaired function of the respiratory system (e.g., asthma, bronchitis,

wheezing), from epilepsy, severe heart and blood vessel problems, blood pressure problems, liver or kidney problems, gastric ulcer, bladder problems, prostate problems, digestive or urinary system blockages, hearing problems, high intraocular pressure (glaucoma), Rey's Syndrome.

- Consult the doctor if you are pregnant or planning to become pregnant (see also "Pregnancy and breastfeeding").
- Inform the doctor if you are due to undergo surgery.
- Inform the doctor before taking the medicine, if you are sensitive to any food, food coloring, preservatives or any medicine, especially phenothiazines.
- The elderly and children must be under medical supervision, due to the fact that they are more sensitive to side effects.
- Prothiazine may cause your skin to become more sensitive to the sun. Therefore, avoid exposure to direct sun.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor of pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

- Tranquilizers and hypnotics (e.g., diazepam, zolpidem)
- Antidepressants of the tricyclic (e.g., amitriptyline, amoxapine) and monoamine oxidase inhibitor group
- Opiate analgesics
- Other antihistamines

Prothiazine may increase the tranquilizing effect of these medicines.

Do not use this medicine if you are taking a high dosage of central nervous system depressants, e.g., methyldopa, metoclopramide, pimizide; see also "Do not use this medicine if".

- Anticholinergic medicines – including medicines to treat irritable bowel syndrome, to treat asthma or to treat a weak bladder, may increase the risk of dizziness, dry mouth and blurred vision (e.g., atropine and its derivatives).
- Medicines such as aspirin (for treatment of arthritis and joint pains); Prothiazine may mask the side effects of this medicinal treatment.

Use of the medicine and food: This medicine can be taken with or without food.

Use of the medicine and alcohol consumption: Do not drink wine or alcoholic beverages during the course of treatment with this medicine. This medicine increases the hypnotic and tranquilizing effects of alcohol.

Pregnancy and breastfeeding: Do not take this medicine in the two weeks before your estimated date of birth or if you are breastfeeding. Prothiazine is secreted into breast milk, which may be harmful to your baby. If you

are pregnant or planning to become pregnant, consult the doctor before using this medicine.

Driving and use of machines: This preparation may cause sleepiness and drowsiness. Be cautious when driving and/or operating machines that require alertness. Children should be warned about riding bicycles or playing near roads and the like.

Important information regarding some of the ingredients of the medicine: Prothiazine tablets contain lactose and may cause allergy among people sensitive to lactose.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure. The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally:

For treatment of allergies: Children aged 2-5 years: 5-15 ml of syrup in one dose, to be taken at night or 5 ml two to three times a day. Do not administer more than 15 ml per day. Children aged 6-12 years: 10-25 ml of syrup in one dose to be taken at night, or 10 ml twice a day. Do not administer more than 25 ml per day. Children above the age of 12 and adults: begin treatment by taking one tablet at night. The dosage can be increased to a maximum of one tablet twice a day, as required.

For treatment and prevention of nausea and vomiting: Children aged 2-5 years: 5 ml of syrup every 4-6 hours up to a maximum of 15 ml per day. Children aged 6-12 years: A dose of 10 ml of syrup; wait 4-6 hours before administering another dose. Up to two doses per day can be administered (a total of 20 ml per day). Children above the age of 12 and adults: one tablet every 4-6 hours, up to a maximum of 4 tablets per day.

For short-term use as a sedative, with the doctor's instruction only: Children aged 2-5 years: 5-15 ml of syrup as a single dose to be taken at night, at bedtime. Children aged 6-12 years: 10-20 ml of syrup as a single dose to be taken at night, at bedtime. Children above the age of 12 and adults: one to three tablets as a single dose, to be taken at night, at bedtime. Do not exceed the recommended dose. **Tablets:** Swallow the tablet with a full glass of water. If necessary, the tablet can be crushed.

When using the syrup use the measuring cup/spoon, syringe or dropper designated for measuring the proper amount of the medicine. If a cup/teaspoon or other measuring tool has not been provided with the package, consult the pharmacist. Do not use a household teaspoon for measuring the amount of the medicine. Household teaspoons differ in their sizes and you may not get the proper amount of medicine.

Do not take this preparation for more than 7 consecutive days. If the symptoms worsen or if there is no improvement in your health after 7 days, discuss it with the attending doctor. If you feel that the effect of the medicine is too weak or too strong, do not change the dose on your own.

Consult the attending doctor. If you are above the age of 65 years, discuss the recommended dose with the doctor, as there is a higher possibility of side effects when taking this preparation.

Tests and follow-up: Taking this medicine may affect certain tests, including pregnancy tests and allergy skin tests. Stop taking this medicine at least three days before starting an allergy skin test.

If you took an overdose: or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of this medicine with you. Effects of overdose: in children: restlessness, unsteadiness, involuntary movements, particularly of the hands and legs, hallucinations, convulsions/trembling, loss of consciousness, irregular heart rate, high fever and difficulty breathing. Adults: sleepiness, convulsions/trembling, loss of consciousness, anxiety, hallucinations, irregular heart rate, difficulty breathing and shortness of breath.

If you forgot to take this medicine at the required time, do not take a double dose. When treating allergy – take the dose as soon as you remember and continue the treatment regimen as before. If you are taking the medicine as a sedative – skip the dose and take the dose the next evening, as usual. Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor or pharmacist. Do not take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them. If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:
As with any medicine, use of Prothiazine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them. **Discontinue treatment with the medicine and immediately refer to the doctor or proceed to a hospital if the following occurs:** an allergic reaction. The symptoms may include: rash, swallowing or breathing problems, swelling of the lips, face, neck or tongue (or other parts of the body); liver problems which may cause the eyes or skin to go yellow/appear yellow (jaundice); trembling or muscle stiffness; lack of control of the head or facial muscles; unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling; very rapid, strong and irregular heartbeats (palpitations); tiredness which lasts for a long time – which may be due to blood problems such as anemia; hyperactivity in children.

Refer to a doctor as soon as possible if the following occur: fever or sore throat; tinnitus – buzzing, hissing, ringing or other persistent noise in the ears; hallucinations or nightmares; nervousness and restlessness; anxiety; seizures; irregular bleeding or occurrence of internal

hemorrhages; disturbance in passing urine.

Similarly, refer to a doctor if the following side effects worsen or persist for more than a few days: dry mouth blurred vision; feeling drowsy, sleepy, tired, disorientation/confusion, nightmares, headaches, restlessness; loss of appetite and indigestion; feeling dizzy and faint (drop in blood pressure); confusion, particularly in adults above the age of 65; increased sensitivity to exposure to the sun. If you experience this effect, avoid direct exposure to the sun and avoid using sun lamps; nausea or vomiting; diarrhea or constipation; dryness in the nose and throat.

If any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor. Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Tablets – store at a temperature below 25°C.
Syrup – store at a temperature below 25°C. Discard 22 days after opening.
Store in the original package.

6. FURTHER INFORMATION:
In addition to the active ingredient, Prothiazine syrup also contains: Sucrose, Sorbitol solution, Liquid glucose, Disodium hydrogenphosphate, Ethanol, Ascorbic acid, Citric acid, Orange flavour 926, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sunset yellow, Purified water.

Each 5 ml (teaspoonful) of Prothiazine syrup contains 2.7 g sucrose and about 3.8 mg sodium.

In addition to the active ingredient, Prothiazine tablets also contain: Lactose, Maize starch, Methocel E5, Povidone 25, Purified talc, Magnesium stearate, Diethyl phthalate, Propylene glycol, Polyvinyl acetate phthalate, Colloidal silicone dioxide, Titanium dioxide, Indigo carmine, Ponceau 4R.

Each Prothiazine tablet contains 38.9 mg lactose. What the medicine looks like and the contents of the package: Prothiazine syrup is a clear orange-colored liquid. Each package contains one glass bottle of 110 ml. Prothiazine tablets are purple, round, and biconvex. Each package contains 30 tablets.

License holder and address: CTS Chemical Industries Ltd., Kiryat Malachi.
Manufacturer and address: CTS Chemical Industries, Ltd., 3 Hakidma St., Kiryat Malachi.
This leaflet was checked and approved by the Ministry of Health in August 2014.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: Prothiazine Syrup - 1157323131
Prothiazine tablets - 1094625265

خاصة لدى المسنين فوق عمر ٦٥ سنة؛ حساسية زائدة في التعرض للشمس، إذا كنت تعاني من هذا العرض الجانبي يجب تجنب التعرض المباشر للشمس وإستعمال مصابيح الشمس؛ غثيان أو قيء؛ إسهال أو إمساك؛ جفاف في الأنف والحجرة. إذا تفاقت إحدى الأعراض الجانبية، أو عندما تعاني من عرض جانبي لم يذكر في هذه النشرة، عليك إستشارة الطبيب.

4. كيفية تخزين الدواء؟
تجنب التسمم! يجب حفظ هذا الدواء وكل دواء في مكان مغلق بعيداً عن متناول أيدي الأطفال و/ أو الرضع وذلك لتفادي إصابتهم بالتسمم. لا تسيب النقيو من دون تعليمات واضحة من الطبيب. لا يجوز استخدام الدواء بعد تاريخ إنتهاء الصلاحية (Exp. Date) الذي يظهر على العبوة.

يشير تاريخ إنتهاء الصلاحية إلى اليوم الأخير من نفس الشهر. إذا كان عمرك ما فوق ٦٥ سنة، يجب مناقشة الطبيب بشأن الجرعة الموصى بها لأن هناك احتمال أعلى لأعراض جانبية في تناول هذا المستحضر.

فحوص ومتابعة: إذا يؤثر تناول الدواء على نتائج فحوص معينة ومن ضمن ذلك فحوص حمل وفحوص الحساسية على الجلد. يجب التوقف عن تناول الدواء على الأقل ثلاثة أيام قبل البدء بفحوص الحساسية على الجلد.

إذا تناولت جرعة مفرطة: أو إذا لم يل طفل من الدواء بخطأ، توجه حالاً إلى الطبيب أو غرفة الطوارئ في المستشفى وأحضر عبوة الدواء معك. الأعراض الجانبية للجرعة المفرطة: لدى الأطفال: هيجان، عدم الثبات، حركات لا إرادية خاصة في اليدين أو الرجلين، هلوسة، تشنجات، رجفان، فقدان الوعي وتيرة قلب غير منتظمة، سخونة عالية وصعوبات في التنفس. لدى البالغين: الميل إلى النوم، تشنجات/ رجفان، فقدان الوعي، قلق، هلوسة، وتيرة قلب غير منتظمة، صعوبات في التنفس وضيق تنفس.

إذا تسببت تناول هذا الدواء في الوقت المطلوب، لا يجوز تناول جرعة مضاعفة. في علاج الجرعة - تناول الجرعة حال تذكرك وإستمر بالنظام العلاجي كما كان من قبل. إذا كنت تتناول الدواء للتهدئة - فرت الجرعة وتتناول الجرعة في المساء التالي كالمعتاد. يجب المراقبة على العلاج كما أوصى الطبيب. حتى ولو طرأ تحسن على حالتك الصحية، لا يجوز التوقف عن العلاج بالدواء من دون استشارة الطبيب أو الصيدلي. لا تتناول الدواء في العمة! يجب تشخيص طابع الدواء والتأكد من المقادير الدوائية في كل مرة تتناول فيها دواء. ضع النظارات الطبية إذا لزم الأمر ذلك. إذا كانت لديك أسئلة إضافية بخصوص إستعمال الدواء، إستشر الطبيب أو الصيدلي.

4. الأعراض الجانبية:
كما بكل دواء، إن إستعمال بروثيازين قد يسبب أعراضاً جانبية عند بعض المستعملين. لا تتدهش من قائمة الأعراض الجانبية، من الجائز ألا تعاني أيًا منها.

يجب التوقف عن استعمال الدواء والتوجه حالاً إلى الطبيب أو إلى المستشفى في حال ظهور: رد فعل الرجرج، قد تشمل الأعراض: طفح، صعوبة في البلع أو التنفس، إنتفاخ في الشفتين، الوجه، العنق أو اللسان (أو في أجزاء أخرى من الجسم)؛ مشاكل في الكبد التي قد تؤدي إلى اصفرار العينين أو الجلد؛ تبول مصفراً (يرقان)؛ رجفان أو تسلب في العضلات؛ قلة السيطرة على عضلات الرأس أو الوجه؛ حركات شاذة في اللسان؛ تشنجات عضلات الوجه؛ ترقاض العينين؛ (تعبيل العينين) ورجفان؛ دقت قلب سريعة جداً، قوّة وبغير منتظمة (خفقان)؛ تعب لفترة طويلة - يمكن أن ينبع هذا من مشاكل في الدم مثل فقر الدم؛ سلوك يميز بفرط النشاط لدى الأطفال.

يجب التوجه إلى الطبيب بأسرع وقت ممكن في حال ظهور: سخونة أو ألم في الحجرة؛ طنين - أزيز؛ صفير؛ رنين أو ضجة أخرى متواصلة في الأذنين؛ هلوسة أو كوابيس ليلية؛ عصبية وعدم هدوء؛ قلق؛ اختلاجات؛ نزف غير عادي أو ظهور أنزفة داخلية؛ اضطراب في التبول.

كذلك يجب التوجه إلى الطبيب في حال أن الأعراض الجانبية التالية تتفاقم أو تتواصل لأكثر من عدة أيام: جفاف في الفم؛ رؤية مشوشة؛ شعور بالغثاس، الميل إلى النوم، إرهاق، التوهان/إرتباك، كوابيس، صداع، عدم هدوء فقدان الشهية للطعام واضطرابات هضمية؛ شعور بالدوار والإغماء (إنخفاض في ضغط الدم)؛ إرتباك



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