

PRONERGAN TABLET

Promethazine Hydrochloride (12.5 mg)

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What Pronergan Tablet is used for

Used for allergic reactions, motion sickness, nausea and vomiting.

How Pronergan Tablet works

Pronergan tablet contains promethazine hydrochloride which belongs to a group of medicine called antihistamine. It works by blocking a substance called histamine that your body makes during an allergic reaction. Promethazine also works directly on the brain to help you feel more relaxed.

Before use Pronergan Tablet

-When you must not use it:

Do not use Pronergan Tablet if you:

- are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of this medicine (listed in Product Description)

- Before you start to use it:

Tell your doctor or pharmacist before you take this medicine if you:

- are sensitive to medicines in the same class as promethazine such as methdilazine and trimeprazine.
- have bladder blockage
- have prostate gland enlargement
- have urinary retention
- have bone marrow depression (reduced production of blood cells)
- have heart disease
- have seizures
- have glaucoma, (eye disorder)
- have liver disease or jaundice

- have Reye's syndrome, (rare disorder that can cause serious liver and brain damage)

Do not use in newborn or premature infants as it may cause convulsions.

Do not use this medicine for a prolonged period as it may cause dental problems such as tooth decay, gum disease, oral fungal disease and discomfort.

Do not give to children below 2 years of age.

Pregnancy and breast-feeding

Do not take promethazine 2 weeks before giving birth.

Do not take Promethazine if you are breastfeeding as promethazine may pass into mother's milk and this may be harmful to the baby.

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

-Taking other medicines:

Talk to your doctor if you are taking the following:

- alcohol
- medicines to treat depression such as Monoamine Oxidase (MAO) inhibitors, maprotiline and tricyclic antidepressants.
- medicines to treat attention deficit hyperactivity disorder (ADHD) such as amphetamines
- medicines to treat seizure such as barbiturates
- medicines to suppress appetite
- medicines to treat high blood pressure such as propranolol
- medication to treat Parkinson such as bromocriptine, levodopa and selegiline
- medicines to treat low blood pressure such as dopamine, ephedrine, metaraminol and methoxamine
- medicines to treat severe allergic reactions such as epinephrine
- medicines that causes movement disorders

- medicines to treat high blood pressure such as guanadrel or guanethidine.
- medications that can cause injury or liver damage
- medication that causes low blood pressure
- medicines used for radiologic test such as Metrizamide
- medicines used to treat bacterial infections such as furazolidone
- medicines used to treat Hodgkin's disease (a type of blood cancer) such as procarbazine
- medication that may cause damage to the ear
- medicines to treat irregular heart beat such as quinidine
- health supplement such as riboflavin (Vitamin B2)

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to take Pronergan Tablet

- How to use it

Adult : Take 1 tablet, 4 times a day

Children (6 - 12 yrs) : Give half or one tablet, 2 or 3 times a day

-When to take it :

Use as directed by your doctor or pharmacist.

-How long to take it :

Use Pronergan Tablet for the duration that the doctor recommends.

-If you forget to take it :

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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-If you take too much (overdose):

If you or your child takes more Promethazine Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you.

This is so the doctor knows what you or your child has taken.

The following effects may occur:

- In children:
 - clumsiness or unsteadiness; severe drowsiness; severe dryness of mouth, nose, or throat; flushing or redness of face; shortness of breath or troubled breathing
 - hallucinations; seizures; trouble in sleeping
- In Adult:
 - muscle spasms, especially of neck and back; restlessness; shuffling walk; jerky movements of head and face; trembling and shaking of hands
 - Low blood pressure feeling faint

While you are taking Pronergan Tablet

-Things you must do :

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Pronergan Tablet.

Tell your doctor immediately if you become pregnant while using this medication.

-Things you must not do :

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Pronergan Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of:

Promethazine Tablet contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor or pharmacist before taking Promethazine.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel dizzy or sleepy, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, promethazine can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor or go to a hospital straight away if you notice any of the following side effects:

Incidence more frequent

- Drowsiness
- Thickening of mucus

Incidence less frequent or rare

- Blood disorders (sore throat; fever; unusual bleeding or bruising; unusual tiredness or weakness)
- Blurred vision or any change in vision
- Confusion
- Difficult or painful urination
- Dizziness
- Dryness of mouth, nose, or throat
- Low blood pressure (feeling faint)
- Increased sweating
- Loss of appetite
- Paradoxical reaction (nightmares; unusual excitement, nervousness, restlessness, or irritability)
- Photosensitivity (increased sensitivity of skin to sun)
- Ringing in ears
- Skin rash
- fast heartbeat

If you experience any of the above effects or react badly to the tablet in any other way not listed in this leaflet, tell your doctor or pharmacist immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Pronergan Tablet

-Storage

Store below 30°C in a dry place, protected from direct sunlight.

Keep out of reach of children.

-Disposal

Do not use the tablets after the expiry date, which is stated on the carton and blister packs. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

White coloured round flat tablet with "TPI" score on one side and "J/61" embossed on the other side.

- Ingredients

-Active Ingredient(s)

Promethazine hydrochloride

-Inactive Ingredients

Magnesium stearate, croscarmellose sodium, corn starch, PVP-K90, lactose

-MAL Number:

MAL19872194ACZ

Manufacturer

Terapeutics Sdn. Bhd. (590500-W)
Lot 10 & 11, PERDA Industrial Park
Lorong IKS Simpang Ampat B, 14100
Simpang Ampat, Pulau Pinang, Malaysia

Product Registration Holder

Zontron Pharmaceuticals Sdn. Bhd.
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