

PROTAZINE TABLET

Prochlorperazine Maleate (5mg)

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This leaflet answers some common questions about PROTAZINE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PROTAZINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PROTAZINE is used for

PROTAZINE is used to treat nausea vomiting due to various causes including migraine (severe headache); dizziness due to Meniere's syndrome (an inner ear disorder that affects balance and hearing); labyrinthitis (involves irritation and swelling of the inner ear) and other causes.

How PROTAZINE works

PROTAZINE belongs to a group of medicines called phenothiazines. It helps to correct chemical imbalances in the brain, allowing it to function correctly.

These chemicals may also affect the parts of the brain which control nausea (feeling sick) and vomiting.

Your doctor may have prescribed PROTAZINE for another reason. Ask your doctor if you have any questions about why PROTAZINE has been prescribed for you.

PROTAZINE is not recommended for use in children (under the age of 2 years or children under 10kg in weight).

Before you use PROTAZINE

- When you must not use it

Do not take PROTAZINE if you have an allergy to:

- PROTAZINE
- The group of medicines called Phenothiazines
- Any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to PROTAZINE may include:

- Shortness of breath, wheezing or difficulty in breathing.
- Swelling of the face, lips, tongue or other parts of the body.
- Rash, itching or hives on the skin.

You should not take PROTAZINE if you have any of the following medical conditions:

- Disease of the blood with a low number of blood cells.
- Yellowing of the skin and/or eye, also called jaundice.
- Bone marrow depression
- Circulatory collapse (a sudden loss of effective blood flow)

PROTAZINE must not be given to anyone who is unconscious or in a coma.

Do not take any medicines that cause drowsiness while you are taking PROTAZINE.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking PROTAZINE, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant. Like most phenothiazine medicines, PROTAZINE is not recommended for use during pregnancy.

If there is a need to take PROTAZINE during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

It is recommended that you do not breastfeed while taking PROTAZINE, as it is not known whether PROTAZINE passes into breast milk.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- Pheochromocytoma a rare tumour of the adrenal glands which sit near the kidneys.
- Parkinson's disease, a disease of the brain affecting movement which causes rigid posture, trembling, slow movement and unbalanced walk.

- Myasthenia gravis, a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs.
- Kidney problems
- Low blood pressure
- Liver disease
- Prostate problems
- Epilepsy, seizures or fits
- Low blood calcium levels
- Decreased thyroid activity

Tell your doctor if you are about to have any surgery which requires a general anaesthetic (an agent used to cause a loss of consciousness so that you are unaware of surgery).

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking PROTAZINE.

- Taking other medicines

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

Some medicines and PROTAZINE may interfere with each other. These include:

- Some medicines used to control depression.
- Alcohol.
- Desferrioxamine, a medicine used in iron overdose.
- Procarbazine, an anticancer medicine
- Some medicines used to control epilepsy.
- Medicines used to treat Parkinson's disease
- Anticholinergic medicines which are used to relieve stomach cramps, spasms and travel sickness.
- Some oral medicines used to prevent your blood from clotting.
- Medicines used to treat high blood pressure and fluid build-up in your body.
- Medicines that can reduce potassium levels in the blood e.g. diuretics.

These medicines may be affected by PROTAZINE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking PROTAZINE.

How to use PROTAZINE

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Your doctor or pharmacist will tell you how much PROTAZINE you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

Nausea and vomiting

Adult dose: 5 or 10 mg two or three times daily. For acute attacks 20mg at once followed, if necessary, by 10 mg 2 hours later.

Children: If it is considered unavoidable to use prochlorperazine for a child, the dosage is 250 micrograms/ kg bodyweight two or three times a day.

Prochlorperazine has been associated with dystonic (a neurological movement disorder, ie faulty signals from the brain cause involuntary muscle contractions) reactions particularly after a cumulative dosage of 500 micrograms / kg. It should therefore be used cautiously in children.

Prochlorperazine is not recommended for children weighing less than 10 kg.

When treating children, it is recommended that the 5 mg tablets are used.

Vertigo and Meniere's disease

Adult dose: 5 -10mg three to four times daily. Dosage may be reduced gradually after several weeks to a maintenance dosage of 5 or 10mg daily.

Children: same as for nausea and vomiting.

Elderly

Dosages in the lower range are sufficient for most elderly

Impaired liver function

Dosage reduction may be necessary since prochlorperazine is extensively metabolized by the liver.

- When to use it

If you are not sure what to do, ask your doctor or pharmacist.

- How long to use it

Continue taking PROTAZINE for as long as your doctor tells you.

- If you forget to use it

Do not take a double dose of PROTAZINE to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to the nearest hospital if you think that you or anyone else may have taken too much PROTAZINE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include the following:

- Drowsiness
- Coma

- Restlessness, shaking, muscle twitching, muscle weakness, spasm.
- Confusion
- Low blood pressure
- Fast heart beat
- Decrease in body temperature
- Pupil in the eye becomes smaller
- Difficulty in swallowing or breathing
- Abnormal blue discoloration of the skin and mucous membranes

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

While you are using it

- Things you must do

Tell your doctor immediately if you notice any uncontrolled movements of the tongue, face, mouth or jaw.

These are symptoms of a very rare condition called tardive dyskinesia, which may develop in people taking phenothiazine medicines, including PROTAZINE.

The condition is more likely to occur during long term treatment with PROTAZINE, especially in elderly women. In very rare cases, this may be permanent.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking PROTAZINE.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking PROTAZINE.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking PROTAZINE.

If you become pregnant while taking PROTAZINE, tell your doctor immediately.

- Things you must not do

Do not give PROTAZINE to anyone else, even if they have the same condition as you.

Do not take PROTAZINE to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking PROTAZINE, or lower the dosage, even if you are feeling better, without checking with your doctor.

- Things to be careful of

Be careful of driving or operating machinery until you know how PROTAZINE affects you.

As with other medicines, PROTAZINE may cause light headedness, dizziness, tiredness, drowsiness in some people.

Make sure you know how you react to PROTAZINE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded. If this occurs do not drive.

If PROTAZINE makes you feel lightheaded, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help.

Be careful when drinking alcohol while taking PROTAZINE. Combining PROTAZINE and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with PROTAZINE.

PROTAZINE may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching or redness. If your skin does appear to be burning, tell your doctor.

Make sure you keep cool in hot weather and keep warm in cool weather. PROTAZINE may affect the way your body reacts to temperature changes.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PROTAZINE.

All medicines can have side effects. PROTAZINE helps most people but it may have unwanted side effects in a few people.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have. If you get any side effects, do not stop taking PROTAZINE without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Constipation
- Dry mouth
- Drowsiness
- Restlessness
- Trembling, rigid posture, slow movements and unbalanced walk.
- Blurred vision

The following side effects are less common:

- Low blood pressure
- Changes in heart beats
- Swelling of the hands, ankles or feet.
- Skin rash
- For females: unusual secretion of breast milk, irregular periods
- For males: breast enlargement, difficulty in ejaculating
- Difficulty passing urine
- Yellowing of the skin and/or eyes
- Headache
- Insomnia
- Seizures
- Difficulty in breathing

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website portal.bpfk.gov.my (*Consumers-Reporting*).

Storage and disposal of PROTAZINE

- Storage

Keep PROTAZINE tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Keep your PROTAZINE in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Do not store PROTAZINE or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and a half metres above the ground is a good place to store medicines.

- Disposal

If your doctor or pharmacist tells you to stop taking PROTAZINE, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

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

GP: a 7mm round tablet, white in colour with markings 'd' on one side and a 'star' on the reverse side.

Tender: A 7mm round, scored tablet, white in colour with markings 'KKM' on one side and 'DUO 861' on the reverse side.

- Ingredients

Active Ingredient:
Each tablet of PROTAZINE Tablet contains 5 mg of Prochlorperazine maleate.

Inactive Ingredients

- Promigel
- Lactose
- Aerosil
- Cornstarch
- Magnesium Stearate

- MAL Number MAL19890019A

Manufacturer

DUOPHARMA (M) SDN BHD
(42491 M)
Lot 2599, Jalan Seruling 59 Kaw 3,
Taman Klang Jaya,
41200 Klang,
Selangor Darul Ehsan

Product Registration Holder

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