

AXCEL PROCHLORPHERAZINE TABLET

Prochlorperazine Maleate (5mg)

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WHAT AXCEL PROCHLORPHERAZINE TABLETS IS USED FOR

Axcel Prochlorperazine Tablets is used for the treatment of:

- Migraine.
- Meniere's disease (an inner ear disorder that affects balance and hearing).
- Nausea.
- Vomiting.
- Vertigo.
- Minor mental and emotional disturbances.
- Schizophrenia.
- Other psychotic disturbances.

HOW AXCEL PROCHLORPHERAZINE TABLETS WORKS

Prochlorperazine Maleate has an activity of depressant actions on the central nervous system and its alpha-adrenagic blocking agent and weaker anticholinergic activities. It possesses sedative and tranquilising properties. It is used in the psychiatric states for the control of symptoms including anxiety, tension, agitation and other psychomotor disturbances in schizophrenic patients. It has powerful anti-emetic (effective against vomiting and nausea) properties.

BEFORE YOU USE AXCEL PROCHLORPHERAZINE TABLETS

When you must not use it

Do not take Axcel Prochlorperazine Tablets if:

- If you are allergy or hypersensitive to ingredients in the product.
- If it is not prescribed by a qualified doctor or pharmacist for you.
- If you are having blood dyscrasias (abnormal blood quantity), bone-marrow depression or known liver damage.
- Do not take Axcel Prochlorperazine Tablets if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Prochlorperazine Tablets if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Tell your doctor if:

- If you are taking any other medicines (including those not prescribed by your doctor).
- If you are pregnant or nursing babies.
- If you are having cardiovascular (heart / blood vessels) disease, phaeochromocytoma (rare tumor of adrenal gland tissue), liver dysfunction and parkinsonism.
- If you are having kidney dysfunction, epilepsy, hypothyroidism (low level of thyroid hormone), myasthenia gravis (weakness and rapid fatigue of any of the muscles under voluntary control) and prostate hypertrophy (enlargement of the prostate).

Taking other medicines

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 USE AXCEL PROCHLORPHERAZINE TABLETS

How much to use

For oral administration.

As an antiemetic (effective against vomiting and nausea): Adult and children over 12 years: 1-2 tablets three times daily.

Children 6-12 years: 1 tablet two to three times daily.

Children 1-5 years: ½ tablet twice daily.

In psychiatric states: 3-20 tablets daily in divided doses.

When to use it

Your doctor will decide when it is appropriate for you to use Axcel Prochlorperazine Tablets according to the type of condition you have.

How long to use it

Continue taking Axcel Prochlorperazine Tablets for as long as doctor recommends.

If you forget to use 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.

If you use too much (overdose)

Symptoms of overdosage include:

- Extrapyramidal disorder (disturbances of muscular movement)
- Hypotension (low blood pressure)

It is advisable for you to contact and inform your doctor if you did take Axcel Prochlorperazine Tablets too much.

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WHILE YOU ARE USING IT

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Prochlorperazine Tablets.
- Tell your doctor immediately if you become pregnant while talking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Prochlorperazine Tablets to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Avoid prolonged treatment with high dosage.
- Caution while using in elderly and debilitated and in children with an acute illness.
- Avoid activities that require mental alertness.

SIDE EFFECTS

Like all medicines, Axcel Prochlorperazine Tablets can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

Common side effects

- Drowsiness, dizziness, skin reaction, dry mouth.
- Neuroleptic malignant syndrome (hyperthermia (elevated body temperature), rigidity, autonomic dysfunction and altered consciousness).

Rare side effects

- Hypotension (low blood pressure), insomnia (sleep disorder) and agitation.

- Jaundice.
- Blood dyscrasias (pathologic conditions or disorders in which the constituents of the blood are abnormal or are present in abnormal quantity).

Very rare side effects

- Hyperprolactinaemia (a raised level of prolactin hormone in the blood).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

STORAGE AND DISPOSAL OF AXCEL PROCHLORPERAZINE TABLETS

Storage

Keep Axcel Prochlorperazine Tablets out of reach of children. Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Prochlorperazine Tablets after the expiry date which is stated on the carton.

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

Axcel Prochlorperazine Tablets is light green, biconvex, round tablets, 8mm in diameter with a single score-line on one side and marked KOTRA logo on the other side.

Ingredients

Active Ingredient:

Prochlorperazine Maleate

Inactive Ingredients:

Lactose, Corn Starch, PVP K90, Magnesium Stearate, Brilliant Blue

Dye, Quinoline Yellow and Purified Water.

MAL Number

MAL19921471A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
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DATE OF REVISION

04/12/2014

SERIAL NUMBER

BPFK(R4/1)271114/00060