

PERMAX[®]

pergolide mesylate

Consumer Medicine Information (CMI)

PERMAX can cause the thickening of tissue (fibrotic reactions) in an organ such as the lungs. PERMAX can also damage the valves of the heart, causing them to leak. Please consult your doctor about regular monitoring for these possible conditions.

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about PERMAX. It does not contain all the available information and does not take the place of talking with your doctor.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What PERMAX is used for

PERMAX contains pergolide (as pergolide mesylate) as the active ingredient. It belongs to a group of medicines called ergot derivative dopamine agonists.

PERMAX is used to treat Parkinson's disease, a disease of the brain affecting movement. It works by directly stimulating dopamine receptors.

It is used in combination with other medicines that treat Parkinson's disease such as Sinemet[®] and Madopar[®].

It can also be used in patients who have tried unsuccessfully to use a non-ergot medicine.

The aim of treatment is to reduce the symptoms and problems associated with Parkinson's disease and to improve your ability to do normal everyday tasks.

Ask your doctor if you have any questions about why PERMAX has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no specific information available to recommend the use of this medicine in children.

PERMAX is only available with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take PERMAX if you have ever had an allergic reaction to:

- pergolide
- other ergot derivative medicines that are similar to PERMAX (e.g. medicines used to treat migraines such as Ergodryl[®] or Cafergot[®])
- any of the tablet ingredients listed at the end of this leaflet.

Signs of an allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

Do not take PERMAX if you have a history of:

- swelling or inflammation around the heart (pericarditis; pericardial effusion)

- heart valve disorder involving one or more valves
- swelling, inflammation or thickening of the lung (pleuritis; pleural fibrosis; pleural effusions)
- scarring and thickening in the lungs with shortness of breath (pulmonary fibrosis)
- abnormal formation of tissue outside the stomach wall (retroperitoneal fibrosis).

Do not take this medicine if the packaging is torn or shows signs of tampering.

Do not take PERMAX after the expiry date (EXP) printed on the pack.

If you are not sure whether you should start taking PERMAX, talk to your doctor.

Before you start to take it

A medical examination and some laboratory tests are usually performed before you begin therapy with PERMAX. They are usually repeated at regular intervals while you continue to take this medicine.

Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.

Tell your doctor if you have or have had any medical conditions, especially the following:

- irregular beating of the heart or any other heart problems
- kidney or liver disease
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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 may be affected by PERMAX or may affect how it works. These include:

- antihypertensives, medicines used to treat high blood pressure
- metoclopramide, a medicine used to treat nausea
- medicines used to treat psychoses
- warfarin, a medicine which thins the blood
- levodopa, a medicine used to treat Parkinson's disease.

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

Your doctor or pharmacist have a more complete list of medicines to be careful with or avoid while taking PERMAX.

How to take it

Carefully follow all directions given to you by your doctor. These may differ from the information contained in this leaflet.

How much to take

Always take the dose prescribed by your doctor.

The dose will depend on your condition, whether you are taking other medicines and your response to the treatment. Your dose will be maintained or gradually adjusted up

or down until a satisfactory response is noted.

PERMAX is not recommended for use above 3 mg per day due to the risk of tissues thickening.

How to take it

Swallow the tablet whole with a glass of water.

Do not crush tablets.

In the event of pergolide powder exposure to the eye, the affected eye should be flushed immediately with water and medical advice obtained. For nasal irritation, move to fresh air.

PERMAX tablets can be taken with or without food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

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

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember then go back to taking your medicine as you would normally.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else has taken too much PERMAX. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include vomiting, dizziness, agitation, hallucinations, severe uncontrollable movements, tingling sensations and fast or irregular heart beats.

While you are taking it

Things you must do

Take PERMAX exactly as your doctor has prescribed.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking PERMAX, especially if you are being started on any new medicines.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (e.g. heart and liver function, white blood cell count) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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

Abrupt discontinuation of PERMAX may cause serious side effects.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Things to be careful of

The most common side effects of PERMAX are nausea and hypotension (low blood pressure) especially when you first start taking this medicine or when the dose is increased. Hypotension may cause you to feel lightheaded or dizzy and is more likely to occur when getting up from a lying or sitting position. This effect lessens with continued use of PERMAX.

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

PERMAX may cause drowsiness or rarely, episodes of sudden onset of sleep, in some people. Make sure you know how you react to it before you drive a car, operate machinery or do anything else that could be dangerous.

Side effects

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

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

The following side effects have been reported in patients taking drugs like PERMAX for the treatment of Parkinson's disease, especially at high doses:

- compulsive behaviour such as gambling, increase in sex drive, shopping, eating, medication use and punding (repetitive purposeless activity).

Patients should seek help from their doctor if they, their family or their carer notice that their behaviour is unusual.

This possible behaviour may have serious financial and social consequences.

Tell your doctor if you notice any of the following side effects and they worry you:

- breathlessness at rest or exertion
- fatigue, difficulty in breathing, cough, chest pain and palpitations
- sharp chest pain and feeling of tightness in the chest which is worse when breathing in
- fast or irregular heart beat
- lightheadedness
- dizziness on standing up, especially when getting up from a lying or sitting position
- fainting
- fever
- trouble sleeping
- drowsiness or rarely, sudden onset of sleep
- confusion
- seeing, hearing or feeling things that are not there
- rash
- pain
- runny or blocked nose, sneezing, facial pressure or pain
- double vision
- pain behind the breast bone, sometimes spreading to the neck and shoulders, and sometimes fever
- Raynaud's disease, where the fingers become white and very painful when cold
- stomach or bowel problems such as abdominal pain, indigestion, nausea, vomiting, constipation and diarrhoea
- irresistible urge to gamble
- increase in sex drive
- hiccups
- warm, red, painful swelling of the extremities.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- breathlessness at rest or exertion
- fatigue, difficulty in breathing, cough, chest pain and palpitations
- sharp chest pain and feeling of tightness in the chest which is worse when breathing in
- fast or irregular heart beat
- sudden increase in body temperature, sweating, fast heart

- beat, muscle stiffness, fluctuating blood pressure and convulsions
- uncontrollable twitching, jerking or writhing movements.

These side effects are rare but may be very serious. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take your tablets out of the blister pack they may not keep as well.

Keep your tablets in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink or stove. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Disposal

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

Product Description

What it looks like

PERMAX tablets are available in three strengths: 50 micrograms (µg), 250 micrograms (µg) and 1 mg.

50 micrograms tablets are ivory coloured, rectangle shaped, scored and debossed with "0.05".

250 micrograms tablets are green coloured, rectangle shaped, scored and debossed with "0.25".

1 mg tablets are pink coloured, rectangle shaped, scored and debossed with "1".

Available in pack sizes of 100 tablets.

Ingredients

Active ingredient:

- 50 micrograms tablets - 50 micrograms pergolide
- 250 micrograms tablets - 250 micrograms pergolide
- 1 mg tablets - 1 mg pergolide.

Inactive ingredients:

- lactose
- croscarmellose sodium
- povidone
- magnesium stearate.

Additional inactive ingredients in each strength:

- 50 micrograms - methionine, iron oxide yellow
- 250 micrograms - methionine, iron oxide yellow, indigo carmine
- 1 mg - iron oxide red.

PERMAX tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Australian Registration Numbers:

50 micrograms: AUST R 49024
250 micrograms: AUST R 93396
1 mg: AUST R 49026

This leaflet was revised in November 2010.

Sponsor

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