

MESTINON®

Pyridostigmine Bromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MESTINON. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

MESTINON is a prescription medicine, it should be used only under strict medical supervision.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MESTINON 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.

You may need to read it again.

What MESTINON is used for

MESTINON is used to treat myasthenia gravis. This is a condition whereby you have muscle weakness and tiredness especially on repeated use.

MESTINON belongs to a group of medicines called cholinergic antimuscarinics. It works by preventing the breakdown of a chemical called acetylcholine. This chemical is needed to stimulate muscle movement.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children.

Before you take MESTINON

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make.

When you must not take it

Do not take MESTINON if you have an allergy to:

- any medicine containing pyridostigmine bromide

- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take MESTINON if you have intestinal blockage or urinary tract blockage or urinary tract infection.

This medicine may make the condition worse.

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 it has expired or is damaged, return it to your pharmacist for disposal.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

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

Before you start to take it

Tell your doctor if you have had any unusual or allergic reactions to

- anticholinesterase agents like medicines used in Alzheimer's disease, ambenonium, bromides and neostigmine. Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines
- other substances such as foods, preservatives or dyes

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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

- epilepsy
- problems with your lungs such as asthma or bronchitis
- heart problems
- slow or irregular heart beats
- stomach ulcer
- kidney and thyroid problems

Tell your doctor if you are pregnant or planning to fall pregnant.

Muscle weakness has occurred temporarily in some newborn babies whose mothers took antimyasthenics during pregnancy.

Tell your doctor if you are breast-feeding.

It is not known whether the active ingredient in MESTINON passes into breast milk and could affect your baby.

Your doctor can advise you of the risks and benefits of taking MESTINON while you are pregnant or breast feeding.

If you have not told your doctor about any of the above, tell him/her before you start taking MESTINON.

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 MESTINON may interfere with each other. These include:

- muscle relaxants such as suxamethonium
- atropine contained in medicines for travel sickness and stomach cramps, or use in surgery (injection) or used as an antidote to insecticide poisoning (tablets)
- aminoglycoside antibiotics such as gentamicin which are used to treat bacterial infections.
- some general and local anaesthetics
- medicines to treat abnormal heart rhythms

- methocarbamol, a medicine to treat muscle pain and spasms
- dexpanthenol (not available in Australia)

These medicines may be affected by MESTINON or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines. Your doctor or pharmacist will advise you.

How to take MESTINON

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

They may differ from the information contained in this leaflet.

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

How much to take

The dose of MESTINON will be different for different patients. Follow your doctor's orders or the directions on the label. The following doses include only the average doses of these medicines. If your dose is different, do not change it unless your doctor tells you to do so.

The number of tablets you take depends on the strength of the medicine. Also, the number of doses you take each day, the

interval between doses should be at least six hours, and the length of time you take the medicine depend on the medical problem for which you are taking these medicines.

The usual adult dose is one to three MESTINON 60 mg tablets two to four times daily. In severe cases, one to three MESTINON Timespan 180 mg tablets once or twice daily.

If you have difficulty in eating, your doctor will adjust your dosage so that you may need to take larger doses at times of greatest fatigue e.g. 30-45 minutes before meals.

Mestinon may not restore your muscle strength to normal and you should not increase your dose above the maximum response level in an attempt to relieve all symptoms

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

They may differ from the information contained in this leaflet.

How to take it

Swallow the tablets whole with a full glass of water.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia 13 11 26; in New Zealand 03 474 7000) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MESTINON.

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

You may need urgent medical attention.

If you take too much, you are more likely to experience side effects listed in the side effects section below.

While you are using MESTINON

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MESTINON.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

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

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.

Things you must not do

Do not take MESTINON to treat any other complaints unless your doctor tells you to.

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

Side effects

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

This medicine helps most people with myasthenia gravis, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea and vomiting
- diarrhoea
- stomach cramps or pains

- increased saliva
- chest congestions
- low blood pressure
- skin rash
- muscle cramps and twitching

The above list includes the more common side effects of your medicine. These are all mild side effects of MESTINON.

Tell your doctor or health professional as soon as possible if you notice any of the following:

- slowed heart rate
- shortness of breath
- severe rash
- irritation
- swollen face

The above list includes serious side effects which may require urgent medical attention.

After using MESTINON

Storage

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

If you take the tablets out of the bottle they may not keep well.

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

Do not store MESTINON or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MESTINON 10 mg is round, biconvex, white to off-white tablet with no markings and comes in packs of 50, 100# and 250# tablets.

MESTINON 60 mg is round, biconvex, pale orange, sugar coated tablet with no markings and comes in a pack of 150s.

MESTINON Timespan 180 mg is round, biplanar, grey-yellow tablet with a marking 'VM180' on one side and scored on the other side and comes in packs of 50 and 100# tablets.

Ingredients

MESTINON 10mg contains 10 mg of pyridostigmine bromide as the active ingredient. It also contains:

- maize starch
- colloidal anhydrous silica
- lactose monohydrate
- purified talc
- magnesium stearate
- pregelatinised potato starch

MESTINON 60mg contains 60 mg of pyridostigmine bromide as the active ingredient. It also contains:

- maize starch
- colloidal anhydrous silica
- purified talc
- povidone
- acacia

- iron oxide red CI77491
- iron oxide yellow CI77492
- magnesium stearate
- pregelatinised potato starch
- liquid paraffin
- hard paraffin
- sucrose
- rice starch

MESTINON Timespan 180mg contains 180 mg of pyridostigmine bromide as the active ingredient. It also contains:

- carnauba wax
- colloidal anhydrous silica
- calcium phosphate
- zein
- magnesium stearate

Sponsor

MESTINON is distributed in Australia by:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

Tel: 1800 630 056

Australian Registration Numbers

MESTINON 10mg - AUST R 13747

MESTINON 60mg - AUST R 13748

MESTINON Timespan 180mg - AUST R 13749

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- not currently distributed in Australia

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