Mestinon®

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Mestinon?

Mestinon contains the active ingredient pyridostigmine bromide. Mestinon is used to treat myasthenia gravis. This is a condition whereby you have muscle weakness and tiredness especially on repeated use.

For more information, see Section <u>1. Why am I using</u> Mestinon? in the full CMI.

2. What should I know before I take Mestinon?

Do not take if you have ever had an allergic reaction to Mestinon or any of the ingredients listed at the end of the CMI or have known hypersensitivity to anticholinesterase agents like medicines used in Alzheimer's disease, ambenonium, bromides and neostigmine.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Talk to 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 heartbeats, stomach ulcer kidney and thyroid problems. For more information, see Section 2. What should I know before I use Mestinon? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mestinon and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Mestinon?

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 can be taken once or twice daily.

More instructions can be found in Section <u>4. How do I</u> <u>use Mestinon?</u> in the full CMI.

5. What should I know while taking Mestinon?

Things you should do	 Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are taking Mestinon. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. Contact your doctor immediately if you become pregnant while taking Mestinon.
Things you should not do	 Do not take Mestinon to treat any other complaints unless your doctor tells you to
Looking after your medicine	 Keep your tablets in the bottle until it is time to take them. Keep your tablets in a cool dry place and keep out of reach of children.

For more information, see Section <u>5. What should I know while using Mestinon?</u> in the full CMI.

6. Are there any side effects?

Common side effects include nausea and vomiting, diarrhoea, stomach cramps or pains, increased saliva, chest congestions, low blood pressure, skin rash, muscle cramps and twitching, excessive contraction of the pupil of the eye and excessive sweating.

Serious side effects include slowed heart rate, shortness of breath, severe rash, irritation, swollen face. Seek immediate medical attention if you experience any of these.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Mestinon®

Active ingredient(s): Pyridostigmine Bromide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mestinon. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mestinon.

Where to find information in this leaflet:

- 1. Why am I using Mestinon?
- 2. What should I know before I use Mestinon?
- 3. What if I am taking other medicines?
- 4. How do I use Mestinon?
- 5. What should I know while using Mestinon?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Mestinon?

Mestinon contains the active ingredient pyridostigmine bromide. Mestinon belongs to a group of medicines called cholinergic antimyasthenics and works by preventing the breakdown of a chemical called acetylcholine. Acetylcholine is needed to stimulate muscle movement.

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

2. What should I know before I take Mestinon?

Warnings

Do not take Mestinon if:

- you are allergic to pyridostigmine bromide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take Mestinon.
- you are allergic to other 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.

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
- if you have intestinal blockage or urinary tract blockade or urinary tract infection. Mestinon may make the condition worse.

 it is past the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions including:
 - epilepsy
 - problems with your lungs such as asthma or bronchitis
 - heart problems
 - slow or irregular heart beats
 - stomach ulcer
 - kidney and thyroid problems
- take any medicines for any other condition
 During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Temporary muscle weakness can occur in some newborn babies where those mothers have taken antimyasthenics during pregnancy.

3. What if I am taking other medicines?

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

Some medicines may interfere with Mestinon and affect how it works.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mestinon.

4. How do I take Mestinon?

How much Mestinon to take:

- In adults, the usual 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 may be taken once or twice daily.
- The above doses include only the average doses of these medicines and may be different from what your doctor has instructed. 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 Mestinon and the number of doses you take each day. How long you take Mestinon depends on your medical condition.
- 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.

How to take Mestinon

Swallow the tablets whole with a full glass of water.

When to take Mestinon

Mestinon should be used as needed. Follow your doctor's orders or the directions on the label.

If you forget to take Mestinon

Mestinon should be used as needed. If you miss your dose at the usual time, take it when you remember.

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

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

If you take too much Mestinon

If you think that you have taken too many Mestinon tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Mestinon?

Things you should do:

- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Mestinon. It may affect other medicines used during surgery.
- 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.
- Continue to use Mestinon until your doctor tells you to stop.

Call your doctor straight away if you:

Become pregnant while taking Mestinon tablets.
 Remind any doctor, dentist or pharmacist you visit that you are using Mestinon.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mestinon affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Mestinon 10 and 180 mg: Store below 30°C.

Mestinon 60 mg: Store below 25°C.

Store in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 nausea and vomiting diarrhoea stomach cramps or pains increased saliva chest congestions low blood pressure skin rash muscle cramps and twitching excessive contraction of the pupil of the eye excessive sweating 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 slowed heart rate shortness of breath severe rash irritation swollen face 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Mestinon is only available with a doctor's prescription.

What Mestinon contains

Active ingredient (main ingredient)	Pyridostigmine Bromide
Other ingredients	Mestinon 10 mg:
(inactive ingredients)	colloidal anhydrous silica
	lactose monohydrate
	magnesium stearate
	maize starch
	pregelatinised potato starch
	purified talc
	Mestinon 60 mg:
	Acacia
	colloidal anhydrous silica
	hard paraffin
	iron oxide red
	iron oxide yellow
	liquid paraffin

	magnesium stearate
	maize starch
	povidone
	pregelatinised potato starch
	purified talc
	rice starch
	sucrose
	Mestinon 180 mg:
	calcium phosphate
	carnauba wax
	colloidal anhydrous silica
	magnesium stearate
	zein
Potential allergens	Contains sugars (lactose and sucrose)

Do not take Mestinon if you are allergic to any of these ingredients.

What Mestinon looks like

Mestinon 10 mg: Round, biconvex, white to off-white tablet with no markings. Packed in bottles of 50, 100# or 250# tablets. (AUST R 13747).

Mestinon 60 mg: Round, biconvex, pale orange, sugar coated tablet with no markings. Packed in bottles of 150 tablets. (AUST R 13748).

Mestinon 180 mg: Round, biplanar, grey-yellow tablet with a marking 'M180' on one side and scored on the other side. Packed in bottles of 50 or 100# tablets. (AUST R 13749).

#: Not currently distributed in Australia

Who distributes Mestinon

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

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