PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

MESTINON® 10 mg, tablets

Pyridostigmine bromide, 10 mg

Contains sugar: lactose 30,00 mg

MESTINON® 60 mg, tablets

Pyridostigmine bromide, 60 mg

Contains sugar: sucrose 161,569 mg

Read all of this leaflet carefully before you start taking MESTINON®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse, or other health care provider.
- MESTINON® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MESTINON® is and what it is used for.
2. What you need to know before you take MESTINON®.
3. How to take MESTINON®.
4. Possible side effects.
5. How to store MESTINON®.
6. Contents of the pack and other information.

1. What MESTINON® is and what it is used for What

MESTINON® is:

MESTINON® tablets belong to a group of medicines known as cholinesterase inhibitors.

Myasthenia gravis is caused by excessive activity in the body of a protein called cholinesterase.

MESTINON® tablets as cholinesterase inhibitors stop the excessive activity of cholinesterase and in this way help muscles to work properly.

What it is used for:

MESTINON® tablets are used for the treatment of myasthenia gravis.

In patients who suffer from myasthenia gravis, the muscles quickly become tired and weak and, in severe cases, the muscles may become paralysed.

2. What you need to know before you take MESTINON®:

Do not take MESTINON® tablets if you:

- Are allergic (hypersensitive) to pyridostigmine, bromides or any of the other ingredients of MESTINON® tablets.
- Are constipated or cannot urinate, unless your doctor has told you to use this medicine.

Warnings and precautions

Take special care with MESTINON® tablets:

Before treatment with MESTINON® tablets, tell your doctor if you:

- Suffer from asthma or have other chest problems such as wheeziness, difficulty in breathing or a chronic cough.
- Have recently had a coronary obstruction (heart attack), have a slow heart beat or any other heart condition.
- Have low blood pressure.
- Have a stomach ulcer.
- Have epilepsy.
- Have Parkinson’s disease.
- Have kidney problems.
- Suffer from a condition called vagotonia (this is a condition where overactivity of the vagus nerve causes symptoms such as a slow heart rate, low blood pressure, constipation, sweating and painful muscle spasms).
- Have an overactive thyroid gland.

- Have had an operation to remove your thymus gland.

There is no evidence to suggest that MESTINON® tablets have any special effects on elderly patients.

Other medicines and MESTINON®

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines.

Tell your doctor if you are taking any of the following medicines:

- Corticosteroids (an anti-inflammatory medicine) or other immunosuppressant medicines (medicines that keep your immune system in balance).
- Antimuscarinics e.g. atropine (a medicine used for travel sickness and stomach cramps) and hyoscine (a medicine used for crampy abdominal pain).
- Medicines containing methylcellulose (a medicine used to treat constipation).
- Aminoglycoside antibiotics (medicines used to treat bacterial infections.
- Medicines to treat an irregular heartbeat.
- Other medicines that interfere with transmission between nerves and muscles e.g if you are going to have surgery with some general and local anaesthetics.
- MESTINON® tablets can stop the effect of some medicines used to relax muscles during surgery (e.g. pancuronium, vencuronium). MESTINON® tablets can also lengthen the effect of other muscle relaxants (e.g. suxamethonium).

Pregnancy and breastfeeding and fertility

The safety of MESTINON® during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking MESTINON®.

Driving and using machines

MESTINON® tablets may reduce the sharpness of your eyesight.

It is not always possible to predict to what extent MESTINON® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MESTINON® affects them.

Important information about some of the ingredients of MESTINON® tablets

MESTINON® 10 mg tablets contain lactose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MESTINON® 10 mg tablets.

MESTINON® 60 mg tablets contain sucrose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MESTINON® 60 mg tablets.

3. How to take MESTINON® tablets

Do not share medicines prescribed for you with any other person.

Always take MESTINON® exactly as your doctor or pharmacist has told you.

Swallow the tablets with water or another non-alcoholic drink.

You should check with your doctor or pharmacist if you are not sure how to take MESTINON® tablets.

The dose will depend on your illness, your needs and on your age as follows:

For myasthenia gravis:

- The usual adult dose is: 1-3 60 mg tablets two to four times daily, or higher doses if required.
- For children: 7 mg/kg body-mass daily at four hourly intervals.

It is important to remember that the dosage must be individually titrated.

No response to a specific dosage could be due to underdosage or overdosage.

Usually in the case of too large a dose given too frequently, side effects of the muscarinic and/or nicotinic type will manifest (*see section 4 'Possible side effects'*).

Your doctor will tell you how long your treatment with MESTINON® will last.

If you have the impression that the effect of MESTINON® is too strong or too weak, tell your doctor or pharmacist.

If you take more MESTINON® tablets than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. For symptoms and signs of overdosage see section 4 *'Possible side effects'*.

If you forget to take MESTINON® tablets

Do not take a double dose to make up for a forgotten dose. If you miss more than a single dose, you should contact your doctor for advice.

4. Possible side effects

Like all medicines, MESTINON® tablets can cause side effects.

Not all side effects reported for MESTINON® tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking MESTINON® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MESTINON®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects of less frequent or unknown frequency:

- Visual disturbance, producing more tears than usual; blurred vision.
- An irregular heartbeat, heart block (a condition where the heart beats more slowly or with an abnormal rhythm), hypotension (low blood pressure), flushing.
- Producing more phlegm than usual combined with constriction of the airways (shortness of breath).
- Feeling sick, vomiting, diarrhoea, stomach discomfort, pain and cramps, producing more saliva than usual.
- Excessive sweating.
- Muscle weakness and twitching, shaking, muscle cramps.
- Sudden, compelling urge to urinate.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MESTINON®.

5. How to store MESTINON®

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

Protect from light.

Keep the bottle tightly closed in order to protect from moisture.

Do not use MESTINON® tablets after the expiry date which is stated on the bottle, label and outer carton after the text ″EXP″.

If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your doctor or pharmacist who will tell you what to do.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not store in bathroom.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What MESTINON® 10 mg contains:

MESTINON® 10 mg tablets contain pyridostigmine bromide as the active ingredient.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, pregelatinized starch, talc.

What MESTINON® 60 mg contains:

MESTINON® 60 mg tablets contain pyridostigmine bromide as the active ingredient.

The other ingredients are:

Core: colloidal anhydrous silica, magnesium stearate, maize starch, povidone, pregelatinized starch.

Coating components: acacia spray-dried gum, hard paraffin, iron oxide red (E172), iron oxide yellow (E172), light liquid paraffin, rice starch, sucrose crystalline and talc.

What MESTINON® looks like and contents of the pack:

What MESTINON® looks like:

MESTINON®10 mg tablets:

White to off-white round and biconvex tablets.

MESTINON® 60 mg tablets:

Round, biconvex, orange-white to pale orange, sugar-coated tablets.

In cross-section, the sugar-coated tablets are white to off-white in colour.

Contents of the pack:

MESTINON® 10 mg:

50, 100, 250 tablets are packaged in amber glass bottles closed with high-density (HD) polyethylene screw caps with bellows.

MESTINON® 60 mg:

20, 100, 150 tablets are packed in amber glass bottles, closed with screw caps with or without bellows and a tamper evident ring.

20 tablets in glass bottle with screw cap with bellows.

100 tablets in glass bottle with screw cap without bellows.

150 tablets in glass bottle with screw cap without bellows.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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