# **MESTINON DRAGEES TABLET**

Pyridostigmine Bromide (60mg)

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#### What Mestinon is used for

Mestinon is used for the treatment of myasthenia gravis. This is a condition whereby you have muscle weakness and tiredness especially on repeated use.

#### How Mestinon works

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

#### Before you use Mestinon

- When you must not use it

## Do not take Mestinon if you are:

- allergic (hypersensitive) to pyridostigmine, bromides or any of the other ingredients of Mestinon.
- suffering from mechanical obstruction (blockage) of the intestinal or urinary tract.

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

#### - Before you start to use it

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

#### - Taking other medicines

Tell your doctor if you have or have had any of the following medical medical conditions (ie: kidney problem) or taking any other medicines, including medicines obtained without a prescription.

Some medicines and Mestinon may interfere with each other. These include:

muscle relaxants
atropine contained in medicines for travel sickness and stomach cramps, or use in surgery (injection) or used as an antidote to insecticide poisoning (tablets)

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

- Pregnancy and Lactation The safety of Mestinon for use during pregnancy has not been established. Hence, it should only be used strictly as directed by your doctor. Since it is not known whether the active ingredient in MESTINON passes into breast milk, nursing mothers are advised to refrain from breast feeding their babies during treatment. Your doctor can advise you of the risks and benefits of taking MESTINON while you are pregnant or breast feeding. Ask your doctor or pharmacisr for advice before taking any medicine.

#### How to use Mestinon

#### - How much to use

When using Mestinon, it is important to remember that the full effect appears gradually, usually within 15-30 minutes. You should try to take your medicine so that it can work when your muscles are needed most, for example when getting up and at meal times. Swallow the tablets whole with water. If you have difficulty swallowing, you can break the tablets into pieces.

The number of tablets you take depends on your illness and age. Also the number of doses you take each day, the interval between doses should be at least 6 hours.

*Adult:* The usual adult dose is 1 to 3 tablets, 2 to 4 times daily or higher doses if required.

*Children:* For children under 6 years the usual dose is half a tablet (30mg). For children aged 6 to 12 years, the usual starting dose is 1 tablet (60mg). The doctor will then gradually increase the dose until maximum improvement is seen. In children the total dose per day is usually 30 to 360mg.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

#### - <u>When to take it</u>

Mestinon should be taken 30 to 60 minutes before meals.

#### -<u>How long to take it</u>

It is important that you keep taking these tablets until your doctor tells you to stop.

#### - <u>If you forget to take it</u>

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose, just carry on as before.

### - <u>If you take too much (overdose)</u>

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

Taking too many tablets may cause pronounced muscle weakness or exacerbated muscle weakness, bradycardia (slow heart rate), tachycardia (fast heart rate)

#### While you are taking 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 test, 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.

- <u>Things to be careful of</u>

Do not take the medicine if the packaging appears to have been tampered with or if the medicine shows any signs of damage.

You must not take the medicine after the expiry date shown on the packaging.

## -Driving and using machines

The effects of Mestinon on the ability to drive and operate machinery have not been established. Mestinon contains lactose. Therefore, if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

#### Side effects

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

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

- nausea and vomiting
- diarrhea
- stomach cramps or pains
- increased saliva
- skin rash

The above list includes serious side effects which may require urgent medical attention. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <u>npra.moh.gov.my</u> (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines).

#### **Storage and Disposal of Mestinon**

#### - <u>Storage</u>

Do not store Mestinon in bathrooms or kitchens where there is a higher incidence of moisture in the air. Store below  $30^{\circ}$ C.

#### - <u>Disposal</u>

You must not take the medicine after the expiry date shown on the packaging. If you have any unused medicine, return it to your pharmacist who will dispose of it safely.

#### **Product Description**

#### - <u>What it looks like</u>

Round biconvex sugar-coated tablets, orange-white or pale orange coloured.

## -Ingredients

#### Active ingredients

• Pyridostigmine Bromide

## Inactive ingredients

 Rice starch, Maize starch, Povidone K30, Pregelatinised starch, CI 77491, CI 77492, Light Liquid Paraffin Bp, Paraffin Hard, Talc, Magnesium Stearate, Absolute Alcohol, Ethyl Alcohol, Acacia/Gum Arabic, Colloidal anhydrous silica, Ethanol/Alcohol 95%, Purified water, Sucrose

MAL number: MAL04112698ACRZ

#### Manufacturer

Labiana Pharmaceuticals, SL, Spain

## Product Registration Holder:

A.Menarini Singapore Pte.Ltd. (994247-T) B-18-2, Level 18, The Ascent Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor Darull Ehsan, Malaysia.

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