

MODURIDE TABLET®

Amiloride Hydrochloride/Hydrochlorothiazide (5/50mg)

What is in the leaflet?

1. What MODURIDE is used for
2. How MODURIDE works
3. Before you use MODURIDE
4. How to use MODURIDE
5. While you are using it
6. Side effects
7. Storage and Disposal of MODURIDE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What MODURIDE is used for

MODURIDE is used to help reduce the amount of excess fluid in the body for people who have:

- oedema, swelling of the ankles, feet and legs
- ascites due to liver disease, resulting in fluid accumulation in the stomach area.

MODURIDE is also used to help people with hypertension or high blood pressure.

How MODURIDE works

The combination of active ingredients in MODURIDE work by making your kidneys pass more water and salt whilst minimizing potassium loss. This helps reduce high blood pressure and some forms of swelling, while at the same time helping to maintain normal levels of potassium in your blood.

Before you use MODURIDE

- When you must not use it

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

- amiloride hydrochloride

- hydrochlorothiazide, sulphonamide or sulfur medicines

Hydrochlorothiazide is a sulfur containing medicine (a sulfonamide). Therefore, if you are allergic to sulfur medicines, such as some antibiotics, you are likely to be allergic to MODURIDE.

Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur medicines.

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

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

Do not take MODURIDE if you are pregnant or intend to become pregnant unless you and your doctor have discussed the risks and benefits involved.

It may affect your developing baby if you take it during pregnancy.

Do not take MODURIDE if you are breast-feeding or intend to breast-feed.

This medicine can pass into breast milk and therefore may harm the baby.

Do not take MODURIDE if:

- you have kidney disease
- your doctor advises you that you have too much potassium in your blood
- you are taking medicines which can increase the amount of potassium in the blood or you are eating a potassium-rich diet.

MODURIDE helps to maintain normal levels of potassium in your blood. If you are taking potassium tablets or supplements, other potassium-conserving medicines or a potassium-rich diet, your potassium levels may increase too much.

Ask your doctor or pharmacist if you are not sure whether you are taking any of these.

Do not give MODURIDE to a child.

The safety of MODURIDE in children has not been established.

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

Do not take this medicine after the expiry date printed on the pack.

- Before you start to use it

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 of the following medical conditions:

- high potassium level in the blood
- diabetes
- liver disease
- kidney disease
- heart and lung disease
- high cholesterol
- gout
- asthma
- *lupus erythematosus*

Before taking MODURIDE, tell your doctor if you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking

MODURIDE, seek medical attention immediately.

- Taking other medicines

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

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

- potassium tablets or other potassium-conserving medicines
- ACE inhibitors, medicines used to treat high blood pressure
- other medicines used to treat high blood pressure
- other fluid tablets (diuretics)
- lithium, used to treat severe mood swings and some types of depression
- non-steroidal anti-inflammatory medicines (NSAIDs), used to treat inflammation, pain and arthritis
- steroid medicines such as cortisone, prednisone
- insulin and tablets used to treat diabetes
- cyclosporine and tacrolimus, medicines used to suppress the immune system
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery
- medicines used in emergency situations such as adrenaline
- alcohol

These medicines may be affected by MODURIDE 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 or pharmacist has more information on medicines to be careful with or to avoid while taking MODURIDE.

Inform your healthcare providers before taking MODURIDE if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking MODURIDE.

How to use MODURIDE

- How much to use

Your doctor will decide on the amount of MODURIDE tablet you should start taking. This may be increased depending on your condition and other medicines you are taking. Always take MODURIDE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not change the amount of medicines you take unless your doctor tells you.

Your initial dose will be maintained or adjusted until your condition is under control, but not more than 4 tablets a day.

- When to use it

If you are taking a single dose a day, take it in the morning. If you are taking more than one dose a day, take the last dose in the early evening, unless your doctor tells you otherwise.

MODURIDE may increase the amount of urine you pass and the number of times you go to the toilet.

By taking the last dose in the

early evening there may be less chance of your sleep being disturbed.

Take MODURIDE at about the same time each day, unless your doctor tells you otherwise. This will help you remember when to take the tablets.

- How long to use it

Continue taking MODURIDE for as long as your doctor recommends.

If you have medicine high blood pressure, this medicine helps to control this condition but does not cure it.

Therefore, MODURIDE must be taken every day.

If you have oedema or ascites, your doctor will tell you how long to take it.

- If you forget to use 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 it as soon as you remember and 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 use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much MODURIDE. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are using it

- Things you must do

Visit your doctor regularly for a blood pressure test so they can make sure that MODURIDE is working properly and to check for any unwanted side effects.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take MODURIDE. This is because your blood pressure is falling suddenly.

If this problem gets worse or continues, talk to your doctor.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking MODURIDE.

Tell any other doctor, dentist or pharmacist who is treating you that you are taking MODURIDE, especially if you are about to be stated on any new medicines.

Tell your doctor if you become pregnant while taking MODURIDE.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take MODURIDE 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.

- Things to be careful of

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

MODURIDE may cause dizziness or light-headedness in some people, especially after the first few doses or if the dose is increased. Make sure you know how you react to it before you

drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

If you drink alcohol, or take strong pain killers or barbiturates, dizziness and light-headedness may be worse.

Talk to your doctor about foods or drinks that have high potassium content.

MODURIDE helps to maintain normal potassium levels in your body. However, if you eat foods or have drinks that are high in potassium this may lead to an increase of potassium in your body.

Too much potassium can be harmful, therefore it is important to discuss your diet with your doctor.

Tell your doctor if you are being treated for diabetes.

MODURIDE may change how well your diabetes is controlled. Your doses of diabetic medicines, including insulin, may need to change.

Side effects

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

MODURIDE helps most people with high blood pressure or some forms of swelling, 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 treatment if you get some of the side effects.

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

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

you:

- nausea, vomiting, loss of appetite
- diarrhoea, constipation, stomach pain, wind
- thirst
- dizziness or light-headedness
- weakness, drowsiness
- passing less urine than normal

Frequency 'not known':

- Skin and lip cancer (Non-melanoma skin cancer).
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

Very Rare:

- Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion)

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 npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MODURIDE

- Storage

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

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other

medicine in the bathroom or near a sink. Do not leave it in a car or on window sills.

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 MODURIDE or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

- What it looks like

MODURIDE 5 mg tablet is a 7mm round, scored tablet, light purple in colour with markings 'DUO 861' and 'd'.

- Ingredients

Active ingredient:

- Amiloride hydrochloride
5mg
- Hydrochlorothiazide
50mg

Inactive ingredients:

- Starch
- Sodium starch glycolate
- Deionised water
- Carmoisine
- Cornstarch
- Lactose monohydrate
- Magnesium stearate
- Dibasic Calcium Phosphate
Anhydrous

- MAL number

MAL1990184AZ

Product Registration Holder & Manufacturer

DUOPHARMA (M) SDN. BHD.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,

41200 Klang, Selangor Darul
Ehsan, Malaysia.

Serial Number:

NPRA(R2/1)190925/255

Date of Revision

07/05/2024