



**Read all of this leaflet carefully before you start taking this medicine:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What MOMINT® is and what it is used for.
2. Before you take MOMINT®
3. How to take MOMINT®
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**1. What MOMINT® is and what it is used for:**

MOMINT® contains the active substance sildenafil which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. MOMINT® will only help you to get an erection if you are sexually stimulated.

MOMINT® is a treatment for adult men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

**2. Before you take MOMINT®**

**a. Do not Take MOMINT®**

- If you are allergic to sildenafil or any of the other ingredients of this medicine.
- If you are taking medicines called nitrates, as the combination may lead to a dangerous fall in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or "chest pain"). If you are not certain, ask your doctor or pharmacist.

- If you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers"), as the combination may also lead to a dangerous fall in your blood pressure.

- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as MOMINT® have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

- If you have a severe heart or liver problem.

- If you have recently had a stroke or a heart attack, or if you have low blood pressure.

- If you have certain rare inherited eye diseases (such as retinitis pigmentosa).

- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

**b. Take special care with MOMINT®**

Talk to your doctor, pharmacist or nurse before taking MOMINT®

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).

- If you have a deformity of your penis or Peyronie's Disease.

- If you have problems with your heart. Your doctor should carefully check whether your heart can take the additional strain of having sex.

- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).

- If you experience sudden decrease or loss of vision, stop taking MOMINT® and

contact your doctor immediately. You should not use MOMINT® with any other oral or local treatments for erectile dysfunction.

You should not use MOMINT® with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors. You should not take MOMINT® if you do not have erectile dysfunction.

You should not take MOMINT® if you are a woman.

**Special considerations for patients with kidney or liver problems** You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

**Children and adolescents** MOMINT® should not be given to children under the age of 18.

**c. Taking other medicines, herbal or dietary supplements:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

MOMINT® tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell your doctor, pharmacist or nurse that you have taken MOMINT® and when you did. Do not take MOMINT® with other medicines unless your doctor tells you that you can.

You should not take MOMINT® if you are taking medicines called nitrates, as the combination of these medicines may lead to a dangerous fall in your blood pressure. Always tell your doctor, pharmacist or nurse if you are taking any of these medicines that are often used for the relief of angina pectoris (or "chest pain").

You should not take MOMINT® if you are using any of the medicines known as nitric oxide donors such as amyl nitrite ("poppers") as the combination may also lead to a dangerous fall in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat. If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of MOMINT®.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking MOMINT® with alpha-blockers. This is most likely to happen within 4 hours after taking MOMINT®. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start MOMINT®.

Your doctor may start you on a lower dose (25 mg) of MOMINT®.

**MOMINT® with food and drink and alcohol** MOMINT® can be taken with or without food. However, you may find that MOMINT® takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking MOMINT®.

**e. Pregnancy and breast-feeding:**

MOMINT® is not indicated for use by women.

**f. Driving and using machines:**

MOMINT® can cause dizziness and can affect vision. You should be aware of how you react to MOMINT® before you drive or use machinery.

**g. Important information about some of the ingredients of MOMINT®:**

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking MOMINT®.

**3. How to take MOMINT®**

Always take this medicine exactly as your

doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dose is 50 mg. You should not take MOMINT® more than once a day.

If you feel that the effect of MOMINT® is too strong or too weak, talk to your doctor or pharmacist.

MOMINT® will only help you to get an erection if you are sexually stimulated. The amount of time.

MOMINT® takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that MOMINT® takes longer to work if you take it with a heavy meal.

If MOMINT® does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

**If you take more MOMINT® than you should**

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy. You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects although not everybody gets them. The side effects reported in association with the use of MOMINT® are usually mild to moderate and of a short duration.

If you experience any of the following serious side effects stop taking MOMINT® and seek medical help immediately:

- An allergic reaction - this occurs uncommonly (may affect up to 1 in 100 people)

Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

- Chest pains - this occurs uncommonly if this occurs during or after intercourse

- Do not use nitrates to treat your chest pain.

- Prolonged and sometimes painful erections - this occurs rarely (may affect up to 1 in 1,000 people)

If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

- A sudden decrease or loss of vision - this occurs rarely.

Symptoms may include severe peeling and swelling of the skin, blistering of the skin, genitalis and around the eyes, fever.

- Seizures or fits - this occurs rarely

**Other side effects:**

**Very common (may affect more than 1 in 10 people):** headache.

**Common (may affect up to 1 in 10 people):** nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

**Uncommon (may affect up to 1 in 100 people):** vomiting, skin rash, eye irritation, bloodshot eyes / red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot and feeling tired.

**Rare (may affect up to 1 in 1,000 people):** fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing

halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

From post-marketing experience cases of unstable angina (a heart condition) and sudden death have been reported rarely. Of note, most, but not all, of the men who experienced these side effects had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to MOMINT®

**Reporting of suspected adverse reactions**

Website: [jpc@fd.ja](mailto:jpc@fd.ja)

**The link to the electronic reporting on JFDA website (WWW.fda.com):** <https://primaryreporting.who-umc.org/JO>

Tel: +962-6-5632000

rapid response number QR Code:



**5. How to store MOMINT®**

- Keep out of the reach and sight of children.

- Do not store above 30°C.

- Do not use MOMINT® after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

- MOMINT® does not require any special storage conditions.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Further information**

**a. What MOMINT® contains**

The active substance is sildenafil citrate. MOMINT® 25: Each Chewable tablet contains 25mg sildenafil as sildenafil citrate in packs of 4, 10 & 30 tablets.

MOMINT® 50: Each Chewable tablet contains 50mg sildenafil as sildenafil citrate in packs of 4 & 8 tablets.

MOMINT® 100: Each Chewable tablet contains 100mg sildenafil as sildenafil citrate in packs of 4 & 8 tablets.

The other ingredients are: Silica, colloidal Anhydrous, ludipress LCE powder, Aspartame powder, croscarmellose sodium, peppermint flavor powder, magnesium stearate, polacrillin potassium.

**b. What MOMINT® looks like and contents of the pack**

- **Pharmaceutical form:** Chewable Tablets for oral use.

**- Physical Description:**

• MOMINT® 25mg: white triangular biconvex tablet engraved with (TQ) on one side and plain on the other side.

• MOMINT® 50mg: white triangular biconvex tablet engraved with (TQ) on one side and plain on the other side.

• MOMINT® 100mg: white triangular biconvex tablet engraved with (TQ) on one side and plain on the other side.

MOMINT® is supplied in PVC /PCTFE - Aluminum Blister, in carton box with a folded leaflet.

**c. Marketing Authorisation Holder and Manufacturer**

**Al-Taqaddom Pharmaceutical Industries**

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This is a medicament

• A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

• Follow exactly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

• The doctor and the pharmacist are experts in medicine, its benefits and risks.

• Do not by yourself interrupt the period of treatment prescribed for you.

• Do not repeat the same prescription without consulting your doctor

• Keep medicament out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS  
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