**Tadalafil 2.5 m and 5 mg and 10mg and 20mg film-coated tablets**

**What is tadalafil sandoz and what is it used for?**

This medicine contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

The 2.5 mg, 5 mg, 10 mg, and 20 mg tablets of this medicine are used for the treatment of adult men with erectile dysfunction.

This occurs when a man cannot get or keep an erection that is suitable for sexual activity. It has been shown that this medicine significantly improves the ability to achieve an erection suitable for sexual activity.

After sexual stimulation, this medicine helps relax the blood vessels in the penis, allowing blood to flow into your penis. This improves your erection. This medicine does not work if you do not have erectile dysfunction. It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

**5 mg of this medicine is used for the treatment of adult men with urinary symptoms related to a common condition called benign prostatic hyperplasia (a benign enlargement of the prostate).** This occurs when the prostate gland enlarges with age. Symptoms include difficulty starting urination, the feeling of not completely emptying the bladder, and increased urination, even at night. This medicine improves blood flow to the prostate and bladder and relaxes their muscles; this can reduce the symptoms of benign prostatic hyperplasia. It has been found that this medicine improves these urinary symptoms from 1 to 2 weeks after the start of treatment.

**20 mg of this medicine is used for the treatment of pulmonary arterial hypertension in adults.** This medicine works by helping to relax the blood vessels around your lungs, improving blood flow in your lungs. The result is an improved ability to perform physical activities.

**When should you not use this medicine or use it with caution?**

When should you not use this medicine?

* You are allergic to any of the other ingredients in this medicine. You can find these substances in section 6.
* You are using any form of organic nitrate or a medication that releases nitric oxide (such as amyl nitrite). "Nitrates" are a group of medicines used to treat angina pectoris (chest pain). It has been shown that this medicine enhances the effects of these medicines. If you are using any form of nitrate or are unsure if you are using it, please inform your doctor.
* You have a severe heart condition or have had a heart attack in the last 90 days.
* You have had a stroke in the last 6 months.
* You have low blood pressure or high blood pressure that is not under control.
* You have ever experienced loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "eye paralysis."
* You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to increase the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure about it, please contact your doctor.

**When should you use this medicine with caution?**Contact your doctor before using this medicine.

**If you are being treated for erectile dysfunction or benign prostatic hyperplasia:** Be aware that sexual activity can be risky for patients with a heart condition because this activity places an extra strain on your heart. If you have a heart condition, please inform your doctor.

**If you are being treated for benign prostatic hyperplasia:** Because benign prostate enlargement and prostate cancer can have similar symptoms, your doctor will check you for prostate cancer before starting treatment with this medicine for benign prostate enlargement. This medicine does not have an effect on prostate cancer.

**Inform your doctor before taking the tablets if you have any of the following conditions:**

* Sickle cell anemia (a disorder of red blood cells resulting in a shortage of red blood cells).
* Multiple myeloma (bone marrow cancer).
* Leukemia (a specific type of blood cancer).
* A deformity of your penis, or unwanted or prolonged erections lasting more than 4 hours.
* A severe liver problem.
* A severe kidney problem.
* A hereditary eye disorder.
* Heart problems other than your high blood pressure in the pulmonary arteries.
* Blood pressure issues.

**It is not known whether this medicine, when used for the treatment of erectile dysfunction, is effective in patients who have:**

* Undergone pelvic surgery.
* Undergone complete or partial removal of the prostate gland, with the nerve pathways of the prostate being severed (radical non-nerve-sparing prostatectomy).

If you experience a sudden reduction or loss of vision, stop taking this medicine immediately and contact your doctor. Sudden decreased hearing or hearing loss has been observed in some patients after the use of tadalafil. While it is not known whether these cases are directly attributable to tadalafil, you should discontinue this medicine immediately and consult your doctor.

**This medicine should not be used by women for the treatment of erectile dysfunction or benign prostate enlargement because these health conditions only occur in men.**

**Children and adolescents under 18 years of age:** This medicine is not intended for use by children and adolescents under 18 years of age.

**Are you taking any other medicines?**Do you currently use any other medicines, have you used them recently, or is there a possibility that you may use other medicines in the near future? Please inform your doctor. Do not use this medicine if you are already taking nitrates.

Some medicines may be affected by this medicine or may affect how this medicine works. Inform your doctor or pharmacist if you are already taking any of the following medicines:

* An alpha-blocker (used to treat high blood pressure or urinary symptoms related to benign prostatic hyperplasia).
* Other medicines to treat high blood pressure.
* Nitrates (for chest pain).
* Riociguat.
* A 5-alpha-reductase inhibitor (used to treat benign prostatic hyperplasia).
* Protease inhibitors for the treatment of AIDS or HIV infection (ritonavir).
* Phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures).
* Rifampicin, erythromycin, or clarithromycin (for the treatment of bacterial infections).
* Medicines such as ketoconazole or itraconazole (used to treat a fungal infection).
* Bosentan (another treatment for high blood pressure in the pulmonary arteries).
* Other treatments for erectile dysfunction (PDE5 inhibitors).

**What to consider regarding drinking and alcohol?**Refer to section 3 for information about the effects of alcohol. Grapefruit juice may affect how well this medicine works and should be used with caution. Please contact your doctor if you would like more information.

**Pregnancy, breastfeeding, and fertility**Are you pregnant, do you think you might be pregnant, do you plan to become pregnant, or are you breastfeeding? Please contact your doctor or pharmacist before using this medicine.

Do not use this medicine if you are pregnant unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while using these tablets because it is not known if this medicine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

In the treatment of dogs, a reduced amount of sperm in the testes has been observed. In some men, a reduction in sperm has been noted. It is unlikely that these effects lead to infertility.

**Driving and using machines**Check how you react to the tablets before driving a car or operating machinery.
Tadalafil Sandoz contains lactose and sodium.
If your doctor has told you that you have an intolerance to certain sugars, please contact your doctor before taking this medicine.
This medicine contains less than 1 mmol of sodium (23 mg) per film-coated tablet, which means it is essentially "sodium-free."

**How to use this medicine?**Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, please contact your doctor or pharmacist.
Swallow the tablet whole with some water. Tadalafil Sandoz 20 mg tablets can be divided into equal doses.
You can take the tablets with or without food.

**For the treatment of erectile dysfunction:** Flexible dose, if needed:

The recommended initial dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak, your doctor may increase the dose to 20 mg. This medicine is for oral use.

You can take a tablet of this medicine at least 30 minutes before sexual activity. This medicine can remain effective for up to 36 hours after the tablet is taken.

10 mg and 20 mg of this medicine are intended for use in planned sexual activity and are not recommended for daily use.

**Once-daily administration:**The recommended dose is 5 mg once daily, taken at approximately the same time each day. Depending on your response to this medicine, your doctor may adjust the dose to 2.5 mg. This will be given as a 2.5 mg tablet.
When taking this medicine once daily, you will be able to achieve an erection at any time of day when sexually stimulated.
Once-daily administration of this medicine may be beneficial for men who expect to be sexually active two or more times a week.

Do not take this medicine more than once a day.

It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would if you were not using a medicine for erectile dysfunction. Drinking alcohol can affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or plan to take this medicine, avoid excessive alcohol consumption (blood alcohol level of 0.08% or higher), as this can increase the risk of dizziness when standing up.

**For the treatment of benign prostatic hyperplasia:** The dose is one 5 mg tablet once daily, taken at approximately the same time each day. If you have both benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet once daily. Do not take this medicine more than once a day.

**For the treatment of pulmonary arterial hypertension:** The usual dose is two 20 mg tablets once daily. Take both tablets one after the other at the same time. If you have mild to moderate liver or kidney disease, your doctor may advise you to take only 20 mg per day.

**Have you taken too much of this medicine?**If you or someone else has taken more tablets than you should, tell your doctor or go to a hospital immediately, and take the medicine or packaging with you. You may experience the side effects listed in section 4.

**Have you forgotten to use this medicine?**Take your dose as soon as you remember, if it was less than 8 hours ago when you should have taken the dose. Do not take a double dose to make up for a forgotten tablet. You should not take this medicine more than once a day.

**If you stop using this medicine**For the treatment of benign prostatic hyperplasia and pulmonary arterial hypertension, do not stop taking your tablets unless your doctor advises you to do so.

Do you have any other questions about the use of this medicine? Then please contact your doctor or pharmacist.

**Possible Side Effects**

Like all medicines, this medicine can have side effects, although not everyone gets them. These side effects are usually mild to moderate. If you experience any of the following side effects, stop taking this medicine and seek medical assistance immediately:

* Allergic reactions including skin rash (occurring in less than 1 in 10 users).
* Chest pain - do not use nitrates but seek medical help immediately (occurring in less than 1 in 10 users).
* Priapism, a prolonged and possibly painful erection after taking this medicine (occurring in less than 1 in 100 users).
* If you experience an erection that lasts longer than 4 hours, contact your doctor immediately.
* Sudden loss of vision (occurring in less than 1 in 1,000 users).

**Other reported side effects, categorized by indication:**

**Side effects when used for erectile dysfunction or benign prostatic hyperplasia:**

**Common (occurring in less than 1 in 10 users)**

• Headache, back pain, muscle pain, pain in the arms and legs, flushing, stuffy nose, and indigestion.

**Uncommon (occurring in less than 1 in 100 users)**

• Dizziness, abdominal pain, nausea, vomiting, acid reflux, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, palpitations, rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, swelling of the hands, feet, or ankles, and feeling tired.

**Rare (occurring in less than 1 in 1,000 users)**

* Fainting, seizures, transient memory loss, swelling of the eyelids, red eyes, sudden reduction or loss of hearing, hives (an itchy skin rash with bumps), bleeding from the penis, presence of blood in semen, and excessive sweating.
* Heart attack and stroke have also been rarely reported in men using this medicine. Most of these men already had heart problems before taking this medication.
* Partial, temporary, or permanent reduction or loss of vision in one or both eyes.

**Additionally, there have been rare side effects reported in men taking this medicine that were not observed during clinical trials. These include:**

• Migraine, facial swelling, severe allergic reaction causing swelling of the face and throat, severe skin rash, certain disorders of blood flow to the eyes, irregular heartbeat, chest pain, and sudden death with the heart as the cause.

The side effect of dizziness has been reported more frequently in men over 75 years of age using this medicine. Diarrhea has been reported more frequently in men over 65 years of age using this medicine for the treatment of erectile dysfunction.

**Side effects when used for pulmonary arterial hypertension:**

**Very common (occurring in more than 1 in 10 users)**

**Common (occurring in less than 1 in 10 users)**

• Headache, flushing, stuffy nose, blocked sinuses, nausea, upset stomach (with abdominal pain or discomfort), muscle pain, back pain, and pain in the arms and legs (including discomfort in the limbs).

**Frequent (occurring in less than 1 in 10 users)**

• Blurred vision, low blood pressure, nosebleeds, vomiting, increased or abnormal uterine bleeding, facial swelling, heartburn, migraine, irregular heartbeat, and fainting.

**Occasional (occurring in less than 1 in 100 users)**

• Seizures, transient memory loss, hives, excessive sweating, bleeding from the penis, presence of blood in semen and/or urine, high blood pressure, rapid heart rate, sudden death with the heart as the cause, and tinnitus.

Most, but not all, men who reported rapid heart rate, irregular heartbeat, heart attack, stroke, and sudden death with the heart as the cause had pre-existing heart problems before taking this medicine. It is not possible to determine whether these events were directly related to this medicine (see "Side effects when used for erectile dysfunction or benign prostatic hyperplasia" above).

**How to store this medicine?**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister pack after "EXP:". The expiry date refers to the last day of that month.

There are no specific storage conditions for this medicine.

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

**Tadalafil 2.5 m and 5 mg and 10mg and 20mg film-coated tablets**

**What is tadalafil sandoz and what is it used for?**

This medicine contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

The 2.5 mg, 5 mg, 10 mg, and 20 mg tablets of this medicine are used for the treatment of adult men with erectile dysfunction.

This occurs when a man cannot get or keep an erection that is suitable for sexual activity. It has been shown that this medicine significantly improves the ability to achieve an erection suitable for sexual activity.

After sexual stimulation, this medicine helps relax the blood vessels in the penis, allowing blood to flow into your penis. This improves your erection. This medicine does not work if you do not have erectile dysfunction. It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

**5 mg of this medicine is used for the treatment of adult men with urinary symptoms related to a common condition called benign prostatic hyperplasia (a benign enlargement of the prostate).** This occurs when the prostate gland enlarges with age. Symptoms include difficulty starting urination, the feeling of not completely emptying the bladder, and increased urination, even at night. This medicine improves blood flow to the prostate and bladder and relaxes their muscles; this can reduce the symptoms of benign prostatic hyperplasia. It has been found that this medicine improves these urinary symptoms from 1 to 2 weeks after the start of treatment.

**20 mg of this medicine is used for the treatment of pulmonary arterial hypertension in adults.** This medicine works by helping to relax the blood vessels around your lungs, improving blood flow in your lungs. The result is an improved ability to perform physical activities.

**When should you not use this medicine or use it with caution?**

When should you not use this medicine?

* You are allergic to any of the other ingredients in this medicine. You can find these substances in section 6.
* You are using any form of organic nitrate or a medication that releases nitric oxide (such as amyl nitrite). "Nitrates" are a group of medicines used to treat angina pectoris (chest pain). It has been shown that this medicine enhances the effects of these medicines. If you are using any form of nitrate or are unsure if you are using it, please inform your doctor.
* You have a severe heart condition or have had a heart attack in the last 90 days.
* You have had a stroke in the last 6 months.
* You have low blood pressure or high blood pressure that is not under control.
* You have ever experienced loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "eye paralysis."
* You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to increase the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure about it, please contact your doctor.

**When should you use this medicine with caution?**Contact your doctor before using this medicine.

**If you are being treated for erectile dysfunction or benign prostatic hyperplasia:** Be aware that sexual activity can be risky for patients with a heart condition because this activity places an extra strain on your heart. If you have a heart condition, please inform your doctor.

**If you are being treated for benign prostatic hyperplasia:** Because benign prostate enlargement and prostate cancer can have similar symptoms, your doctor will check you for prostate cancer before starting treatment with this medicine for benign prostate enlargement. This medicine does not have an effect on prostate cancer.

**Inform your doctor before taking the tablets if you have any of the following conditions:**

* Sickle cell anemia (a disorder of red blood cells resulting in a shortage of red blood cells).
* Multiple myeloma (bone marrow cancer).
* Leukemia (a specific type of blood cancer).
* A deformity of your penis, or unwanted or prolonged erections lasting more than 4 hours.
* A severe liver problem.
* A severe kidney problem.
* A hereditary eye disorder.
* Heart problems other than your high blood pressure in the pulmonary arteries.
* Blood pressure issues.

**It is not known whether this medicine, when used for the treatment of erectile dysfunction, is effective in patients who have:**

* Undergone pelvic surgery.
* Undergone complete or partial removal of the prostate gland, with the nerve pathways of the prostate being severed (radical non-nerve-sparing prostatectomy).

If you experience a sudden reduction or loss of vision, stop taking this medicine immediately and contact your doctor. Sudden decreased hearing or hearing loss has been observed in some patients after the use of tadalafil. While it is not known whether these cases are directly attributable to tadalafil, you should discontinue this medicine immediately and consult your doctor.

**This medicine should not be used by women for the treatment of erectile dysfunction or benign prostate enlargement because these health conditions only occur in men.**

**Children and adolescents under 18 years of age:** This medicine is not intended for use by children and adolescents under 18 years of age.

**Are you taking any other medicines?**Do you currently use any other medicines, have you used them recently, or is there a possibility that you may use other medicines in the near future? Please inform your doctor. Do not use this medicine if you are already taking nitrates.

Some medicines may be affected by this medicine or may affect how this medicine works. Inform your doctor or pharmacist if you are already taking any of the following medicines:

* An alpha-blocker (used to treat high blood pressure or urinary symptoms related to benign prostatic hyperplasia).
* Other medicines to treat high blood pressure.
* Nitrates (for chest pain).
* Riociguat.
* A 5-alpha-reductase inhibitor (used to treat benign prostatic hyperplasia).
* Protease inhibitors for the treatment of AIDS or HIV infection (ritonavir).
* Phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures).
* Rifampicin, erythromycin, or clarithromycin (for the treatment of bacterial infections).
* Medicines such as ketoconazole or itraconazole (used to treat a fungal infection).
* Bosentan (another treatment for high blood pressure in the pulmonary arteries).
* Other treatments for erectile dysfunction (PDE5 inhibitors).

**What to consider regarding drinking and alcohol?**Refer to section 3 for information about the effects of alcohol. Grapefruit juice may affect how well this medicine works and should be used with caution. Please contact your doctor if you would like more information.

**Pregnancy, breastfeeding, and fertility**Are you pregnant, do you think you might be pregnant, do you plan to become pregnant, or are you breastfeeding? Please contact your doctor or pharmacist before using this medicine.

Do not use this medicine if you are pregnant unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while using these tablets because it is not known if this medicine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

In the treatment of dogs, a reduced amount of sperm in the testes has been observed. In some men, a reduction in sperm has been noted. It is unlikely that these effects lead to infertility.

**Driving and using machines**Check how you react to the tablets before driving a car or operating machinery.
Tadalafil Sandoz contains lactose and sodium.
If your doctor has told you that you have an intolerance to certain sugars, please contact your doctor before taking this medicine.
This medicine contains less than 1 mmol of sodium (23 mg) per film-coated tablet, which means it is essentially "sodium-free."

**How to use this medicine?**Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, please contact your doctor or pharmacist.
Swallow the tablet whole with some water. Tadalafil Sandoz 20 mg tablets can be divided into equal doses.
You can take the tablets with or without food.

**For the treatment of erectile dysfunction:** Flexible dose, if needed:

The recommended initial dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak, your doctor may increase the dose to 20 mg. This medicine is for oral use.

You can take a tablet of this medicine at least 30 minutes before sexual activity. This medicine can remain effective for up to 36 hours after the tablet is taken.

10 mg and 20 mg of this medicine are intended for use in planned sexual activity and are not recommended for daily use.

**Once-daily administration:**The recommended dose is 5 mg once daily, taken at approximately the same time each day. Depending on your response to this medicine, your doctor may adjust the dose to 2.5 mg. This will be given as a 2.5 mg tablet.
When taking this medicine once daily, you will be able to achieve an erection at any time of day when sexually stimulated.
Once-daily administration of this medicine may be beneficial for men who expect to be sexually active two or more times a week.

Do not take this medicine more than once a day.

It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would if you were not using a medicine for erectile dysfunction. Drinking alcohol can affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or plan to take this medicine, avoid excessive alcohol consumption (blood alcohol level of 0.08% or higher), as this can increase the risk of dizziness when standing up.

**For the treatment of benign prostatic hyperplasia:** The dose is one 5 mg tablet once daily, taken at approximately the same time each day. If you have both benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet once daily. Do not take this medicine more than once a day.

**For the treatment of pulmonary arterial hypertension:** The usual dose is two 20 mg tablets once daily. Take both tablets one after the other at the same time. If you have mild to moderate liver or kidney disease, your doctor may advise you to take only 20 mg per day.

**Have you taken too much of this medicine?**If you or someone else has taken more tablets than you should, tell your doctor or go to a hospital immediately, and take the medicine or packaging with you. You may experience the side effects listed in section 4.

**Have you forgotten to use this medicine?**Take your dose as soon as you remember, if it was less than 8 hours ago when you should have taken the dose. Do not take a double dose to make up for a forgotten tablet. You should not take this medicine more than once a day.

**If you stop using this medicine**For the treatment of benign prostatic hyperplasia and pulmonary arterial hypertension, do not stop taking your tablets unless your doctor advises you to do so.

Do you have any other questions about the use of this medicine? Then please contact your doctor or pharmacist.

**Possible Side Effects**

Like all medicines, this medicine can have side effects, although not everyone gets them. These side effects are usually mild to moderate. If you experience any of the following side effects, stop taking this medicine and seek medical assistance immediately:

* Allergic reactions including skin rash (occurring in less than 1 in 10 users).
* Chest pain - do not use nitrates but seek medical help immediately (occurring in less than 1 in 10 users).
* Priapism, a prolonged and possibly painful erection after taking this medicine (occurring in less than 1 in 100 users).
* If you experience an erection that lasts longer than 4 hours, contact your doctor immediately.
* Sudden loss of vision (occurring in less than 1 in 1,000 users).

**Other reported side effects, categorized by indication:**

**Side effects when used for erectile dysfunction or benign prostatic hyperplasia:**

**Common (occurring in less than 1 in 10 users)**

• Headache, back pain, muscle pain, pain in the arms and legs, flushing, stuffy nose, and indigestion.

**Uncommon (occurring in less than 1 in 100 users)**

• Dizziness, abdominal pain, nausea, vomiting, acid reflux, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, palpitations, rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, swelling of the hands, feet, or ankles, and feeling tired.

**Rare (occurring in less than 1 in 1,000 users)**

* Fainting, seizures, transient memory loss, swelling of the eyelids, red eyes, sudden reduction or loss of hearing, hives (an itchy skin rash with bumps), bleeding from the penis, presence of blood in semen, and excessive sweating.
* Heart attack and stroke have also been rarely reported in men using this medicine. Most of these men already had heart problems before taking this medication.
* Partial, temporary, or permanent reduction or loss of vision in one or both eyes.

**Additionally, there have been rare side effects reported in men taking this medicine that were not observed during clinical trials. These include:**

• Migraine, facial swelling, severe allergic reaction causing swelling of the face and throat, severe skin rash, certain disorders of blood flow to the eyes, irregular heartbeat, chest pain, and sudden death with the heart as the cause.

The side effect of dizziness has been reported more frequently in men over 75 years of age using this medicine. Diarrhea has been reported more frequently in men over 65 years of age using this medicine for the treatment of erectile dysfunction.

**Side effects when used for pulmonary arterial hypertension:**

**Very common (occurring in more than 1 in 10 users)**

**Common (occurring in less than 1 in 10 users)**

• Headache, flushing, stuffy nose, blocked sinuses, nausea, upset stomach (with abdominal pain or discomfort), muscle pain, back pain, and pain in the arms and legs (including discomfort in the limbs).

**Frequent (occurring in less than 1 in 10 users)**

• Blurred vision, low blood pressure, nosebleeds, vomiting, increased or abnormal uterine bleeding, facial swelling, heartburn, migraine, irregular heartbeat, and fainting.

**Occasional (occurring in less than 1 in 100 users)**

• Seizures, transient memory loss, hives, excessive sweating, bleeding from the penis, presence of blood in semen and/or urine, high blood pressure, rapid heart rate, sudden death with the heart as the cause, and tinnitus.

Most, but not all, men who reported rapid heart rate, irregular heartbeat, heart attack, stroke, and sudden death with the heart as the cause had pre-existing heart problems before taking this medicine. It is not possible to determine whether these events were directly related to this medicine (see "Side effects when used for erectile dysfunction or benign prostatic hyperplasia" above).

**How to store this medicine?**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister pack after "EXP:". The expiry date refers to the last day of that month.

There are no specific storage conditions for this medicine.

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

**Tadalafil 2.5 m and 5 mg and 10mg and 20mg film-coated tablets**

**What is tadalafil sandoz and what is it used for?**

This medicine contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

The 2.5 mg, 5 mg, 10 mg, and 20 mg tablets of this medicine are used for the treatment of adult men with erectile dysfunction.

This occurs when a man cannot get or keep an erection that is suitable for sexual activity. It has been shown that this medicine significantly improves the ability to achieve an erection suitable for sexual activity.

After sexual stimulation, this medicine helps relax the blood vessels in the penis, allowing blood to flow into your penis. This improves your erection. This medicine does not work if you do not have erectile dysfunction. It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

**5 mg of this medicine is used for the treatment of adult men with urinary symptoms related to a common condition called benign prostatic hyperplasia (a benign enlargement of the prostate).** This occurs when the prostate gland enlarges with age. Symptoms include difficulty starting urination, the feeling of not completely emptying the bladder, and increased urination, even at night. This medicine improves blood flow to the prostate and bladder and relaxes their muscles; this can reduce the symptoms of benign prostatic hyperplasia. It has been found that this medicine improves these urinary symptoms from 1 to 2 weeks after the start of treatment.

**20 mg of this medicine is used for the treatment of pulmonary arterial hypertension in adults.** This medicine works by helping to relax the blood vessels around your lungs, improving blood flow in your lungs. The result is an improved ability to perform physical activities.

**When should you not use this medicine or use it with caution?**

When should you not use this medicine?

* You are allergic to any of the other ingredients in this medicine. You can find these substances in section 6.
* You are using any form of organic nitrate or a medication that releases nitric oxide (such as amyl nitrite). "Nitrates" are a group of medicines used to treat angina pectoris (chest pain). It has been shown that this medicine enhances the effects of these medicines. If you are using any form of nitrate or are unsure if you are using it, please inform your doctor.
* You have a severe heart condition or have had a heart attack in the last 90 days.
* You have had a stroke in the last 6 months.
* You have low blood pressure or high blood pressure that is not under control.
* You have ever experienced loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "eye paralysis."
* You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to increase the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure about it, please contact your doctor.

**When should you use this medicine with caution?**Contact your doctor before using this medicine.

**If you are being treated for erectile dysfunction or benign prostatic hyperplasia:** Be aware that sexual activity can be risky for patients with a heart condition because this activity places an extra strain on your heart. If you have a heart condition, please inform your doctor.

**If you are being treated for benign prostatic hyperplasia:** Because benign prostate enlargement and prostate cancer can have similar symptoms, your doctor will check you for prostate cancer before starting treatment with this medicine for benign prostate enlargement. This medicine does not have an effect on prostate cancer.

**Inform your doctor before taking the tablets if you have any of the following conditions:**

* Sickle cell anemia (a disorder of red blood cells resulting in a shortage of red blood cells).
* Multiple myeloma (bone marrow cancer).
* Leukemia (a specific type of blood cancer).
* A deformity of your penis, or unwanted or prolonged erections lasting more than 4 hours.
* A severe liver problem.
* A severe kidney problem.
* A hereditary eye disorder.
* Heart problems other than your high blood pressure in the pulmonary arteries.
* Blood pressure issues.

**It is not known whether this medicine, when used for the treatment of erectile dysfunction, is effective in patients who have:**

* Undergone pelvic surgery.
* Undergone complete or partial removal of the prostate gland, with the nerve pathways of the prostate being severed (radical non-nerve-sparing prostatectomy).

If you experience a sudden reduction or loss of vision, stop taking this medicine immediately and contact your doctor. Sudden decreased hearing or hearing loss has been observed in some patients after the use of tadalafil. While it is not known whether these cases are directly attributable to tadalafil, you should discontinue this medicine immediately and consult your doctor.

**This medicine should not be used by women for the treatment of erectile dysfunction or benign prostate enlargement because these health conditions only occur in men.**

**Children and adolescents under 18 years of age:** This medicine is not intended for use by children and adolescents under 18 years of age.

**Are you taking any other medicines?**Do you currently use any other medicines, have you used them recently, or is there a possibility that you may use other medicines in the near future? Please inform your doctor. Do not use this medicine if you are already taking nitrates.

Some medicines may be affected by this medicine or may affect how this medicine works. Inform your doctor or pharmacist if you are already taking any of the following medicines:

* An alpha-blocker (used to treat high blood pressure or urinary symptoms related to benign prostatic hyperplasia).
* Other medicines to treat high blood pressure.
* Nitrates (for chest pain).
* Riociguat.
* A 5-alpha-reductase inhibitor (used to treat benign prostatic hyperplasia).
* Protease inhibitors for the treatment of AIDS or HIV infection (ritonavir).
* Phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures).
* Rifampicin, erythromycin, or clarithromycin (for the treatment of bacterial infections).
* Medicines such as ketoconazole or itraconazole (used to treat a fungal infection).
* Bosentan (another treatment for high blood pressure in the pulmonary arteries).
* Other treatments for erectile dysfunction (PDE5 inhibitors).

**What to consider regarding drinking and alcohol?**Refer to section 3 for information about the effects of alcohol. Grapefruit juice may affect how well this medicine works and should be used with caution. Please contact your doctor if you would like more information.

**Pregnancy, breastfeeding, and fertility**Are you pregnant, do you think you might be pregnant, do you plan to become pregnant, or are you breastfeeding? Please contact your doctor or pharmacist before using this medicine.

Do not use this medicine if you are pregnant unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while using these tablets because it is not known if this medicine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

In the treatment of dogs, a reduced amount of sperm in the testes has been observed. In some men, a reduction in sperm has been noted. It is unlikely that these effects lead to infertility.

**Driving and using machines**Check how you react to the tablets before driving a car or operating machinery.
Tadalafil Sandoz contains lactose and sodium.
If your doctor has told you that you have an intolerance to certain sugars, please contact your doctor before taking this medicine.
This medicine contains less than 1 mmol of sodium (23 mg) per film-coated tablet, which means it is essentially "sodium-free."

**How to use this medicine?**Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, please contact your doctor or pharmacist.
Swallow the tablet whole with some water. Tadalafil Sandoz 20 mg tablets can be divided into equal doses.
You can take the tablets with or without food.

**For the treatment of erectile dysfunction:** Flexible dose, if needed:

The recommended initial dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak, your doctor may increase the dose to 20 mg. This medicine is for oral use.

You can take a tablet of this medicine at least 30 minutes before sexual activity. This medicine can remain effective for up to 36 hours after the tablet is taken.

10 mg and 20 mg of this medicine are intended for use in planned sexual activity and are not recommended for daily use.

**Once-daily administration:**The recommended dose is 5 mg once daily, taken at approximately the same time each day. Depending on your response to this medicine, your doctor may adjust the dose to 2.5 mg. This will be given as a 2.5 mg tablet.
When taking this medicine once daily, you will be able to achieve an erection at any time of day when sexually stimulated.
Once-daily administration of this medicine may be beneficial for men who expect to be sexually active two or more times a week.

Do not take this medicine more than once a day.

It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would if you were not using a medicine for erectile dysfunction. Drinking alcohol can affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or plan to take this medicine, avoid excessive alcohol consumption (blood alcohol level of 0.08% or higher), as this can increase the risk of dizziness when standing up.

**For the treatment of benign prostatic hyperplasia:** The dose is one 5 mg tablet once daily, taken at approximately the same time each day. If you have both benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet once daily. Do not take this medicine more than once a day.

**For the treatment of pulmonary arterial hypertension:** The usual dose is two 20 mg tablets once daily. Take both tablets one after the other at the same time. If you have mild to moderate liver or kidney disease, your doctor may advise you to take only 20 mg per day.

**Have you taken too much of this medicine?**If you or someone else has taken more tablets than you should, tell your doctor or go to a hospital immediately, and take the medicine or packaging with you. You may experience the side effects listed in section 4.

**Have you forgotten to use this medicine?**Take your dose as soon as you remember, if it was less than 8 hours ago when you should have taken the dose. Do not take a double dose to make up for a forgotten tablet. You should not take this medicine more than once a day.

**If you stop using this medicine**For the treatment of benign prostatic hyperplasia and pulmonary arterial hypertension, do not stop taking your tablets unless your doctor advises you to do so.

Do you have any other questions about the use of this medicine? Then please contact your doctor or pharmacist.

**Possible Side Effects**

Like all medicines, this medicine can have side effects, although not everyone gets them. These side effects are usually mild to moderate. If you experience any of the following side effects, stop taking this medicine and seek medical assistance immediately:

* Allergic reactions including skin rash (occurring in less than 1 in 10 users).
* Chest pain - do not use nitrates but seek medical help immediately (occurring in less than 1 in 10 users).
* Priapism, a prolonged and possibly painful erection after taking this medicine (occurring in less than 1 in 100 users).
* If you experience an erection that lasts longer than 4 hours, contact your doctor immediately.
* Sudden loss of vision (occurring in less than 1 in 1,000 users).

**Other reported side effects, categorized by indication:**

**Side effects when used for erectile dysfunction or benign prostatic hyperplasia:**

**Common (occurring in less than 1 in 10 users)**

• Headache, back pain, muscle pain, pain in the arms and legs, flushing, stuffy nose, and indigestion.

**Uncommon (occurring in less than 1 in 100 users)**

• Dizziness, abdominal pain, nausea, vomiting, acid reflux, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, palpitations, rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, swelling of the hands, feet, or ankles, and feeling tired.

**Rare (occurring in less than 1 in 1,000 users)**

* Fainting, seizures, transient memory loss, swelling of the eyelids, red eyes, sudden reduction or loss of hearing, hives (an itchy skin rash with bumps), bleeding from the penis, presence of blood in semen, and excessive sweating.
* Heart attack and stroke have also been rarely reported in men using this medicine. Most of these men already had heart problems before taking this medication.
* Partial, temporary, or permanent reduction or loss of vision in one or both eyes.

**Additionally, there have been rare side effects reported in men taking this medicine that were not observed during clinical trials. These include:**

• Migraine, facial swelling, severe allergic reaction causing swelling of the face and throat, severe skin rash, certain disorders of blood flow to the eyes, irregular heartbeat, chest pain, and sudden death with the heart as the cause.

The side effect of dizziness has been reported more frequently in men over 75 years of age using this medicine. Diarrhea has been reported more frequently in men over 65 years of age using this medicine for the treatment of erectile dysfunction.

**Side effects when used for pulmonary arterial hypertension:**

**Very common (occurring in more than 1 in 10 users)**

**Common (occurring in less than 1 in 10 users)**

• Headache, flushing, stuffy nose, blocked sinuses, nausea, upset stomach (with abdominal pain or discomfort), muscle pain, back pain, and pain in the arms and legs (including discomfort in the limbs).

**Frequent (occurring in less than 1 in 10 users)**

• Blurred vision, low blood pressure, nosebleeds, vomiting, increased or abnormal uterine bleeding, facial swelling, heartburn, migraine, irregular heartbeat, and fainting.

**Occasional (occurring in less than 1 in 100 users)**

• Seizures, transient memory loss, hives, excessive sweating, bleeding from the penis, presence of blood in semen and/or urine, high blood pressure, rapid heart rate, sudden death with the heart as the cause, and tinnitus.

Most, but not all, men who reported rapid heart rate, irregular heartbeat, heart attack, stroke, and sudden death with the heart as the cause had pre-existing heart problems before taking this medicine. It is not possible to determine whether these events were directly related to this medicine (see "Side effects when used for erectile dysfunction or benign prostatic hyperplasia" above).

**How to store this medicine?**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister pack after "EXP:". The expiry date refers to the last day of that month.

There are no specific storage conditions for this medicine.

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

**Tadalafil 2.5 m and 5 mg and 10mg and 20mg film-coated tablets**

**What is tadalafil sandoz and what is it used for?**

This medicine contains the active substance tadalafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors.

The 2.5 mg, 5 mg, 10 mg, and 20 mg tablets of this medicine are used for the treatment of adult men with erectile dysfunction.

This occurs when a man cannot get or keep an erection that is suitable for sexual activity. It has been shown that this medicine significantly improves the ability to achieve an erection suitable for sexual activity.

After sexual stimulation, this medicine helps relax the blood vessels in the penis, allowing blood to flow into your penis. This improves your erection. This medicine does not work if you do not have erectile dysfunction. It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would do if you were not using a medicine for erectile dysfunction.

**5 mg of this medicine is used for the treatment of adult men with urinary symptoms related to a common condition called benign prostatic hyperplasia (a benign enlargement of the prostate).** This occurs when the prostate gland enlarges with age. Symptoms include difficulty starting urination, the feeling of not completely emptying the bladder, and increased urination, even at night. This medicine improves blood flow to the prostate and bladder and relaxes their muscles; this can reduce the symptoms of benign prostatic hyperplasia. It has been found that this medicine improves these urinary symptoms from 1 to 2 weeks after the start of treatment.

**20 mg of this medicine is used for the treatment of pulmonary arterial hypertension in adults.** This medicine works by helping to relax the blood vessels around your lungs, improving blood flow in your lungs. The result is an improved ability to perform physical activities.

**When should you not use this medicine or use it with caution?**

When should you not use this medicine?

* You are allergic to any of the other ingredients in this medicine. You can find these substances in section 6.
* You are using any form of organic nitrate or a medication that releases nitric oxide (such as amyl nitrite). "Nitrates" are a group of medicines used to treat angina pectoris (chest pain). It has been shown that this medicine enhances the effects of these medicines. If you are using any form of nitrate or are unsure if you are using it, please inform your doctor.
* You have a severe heart condition or have had a heart attack in the last 90 days.
* You have had a stroke in the last 6 months.
* You have low blood pressure or high blood pressure that is not under control.
* You have ever experienced loss of vision due to non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "eye paralysis."
* You are using riociguat. This medicine is used to treat pulmonary arterial hypertension (high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs due to blood clots). PDE5 inhibitors, such as this medicine, have been shown to increase the blood pressure-lowering effect of this medicine. If you are using riociguat or are unsure about it, please contact your doctor.

**When should you use this medicine with caution?**Contact your doctor before using this medicine.

**If you are being treated for erectile dysfunction or benign prostatic hyperplasia:** Be aware that sexual activity can be risky for patients with a heart condition because this activity places an extra strain on your heart. If you have a heart condition, please inform your doctor.

**If you are being treated for benign prostatic hyperplasia:** Because benign prostate enlargement and prostate cancer can have similar symptoms, your doctor will check you for prostate cancer before starting treatment with this medicine for benign prostate enlargement. This medicine does not have an effect on prostate cancer.

**Inform your doctor before taking the tablets if you have any of the following conditions:**

* Sickle cell anemia (a disorder of red blood cells resulting in a shortage of red blood cells).
* Multiple myeloma (bone marrow cancer).
* Leukemia (a specific type of blood cancer).
* A deformity of your penis, or unwanted or prolonged erections lasting more than 4 hours.
* A severe liver problem.
* A severe kidney problem.
* A hereditary eye disorder.
* Heart problems other than your high blood pressure in the pulmonary arteries.
* Blood pressure issues.

**It is not known whether this medicine, when used for the treatment of erectile dysfunction, is effective in patients who have:**

* Undergone pelvic surgery.
* Undergone complete or partial removal of the prostate gland, with the nerve pathways of the prostate being severed (radical non-nerve-sparing prostatectomy).

If you experience a sudden reduction or loss of vision, stop taking this medicine immediately and contact your doctor. Sudden decreased hearing or hearing loss has been observed in some patients after the use of tadalafil. While it is not known whether these cases are directly attributable to tadalafil, you should discontinue this medicine immediately and consult your doctor.

**This medicine should not be used by women for the treatment of erectile dysfunction or benign prostate enlargement because these health conditions only occur in men.**

**Children and adolescents under 18 years of age:** This medicine is not intended for use by children and adolescents under 18 years of age.

**Are you taking any other medicines?**Do you currently use any other medicines, have you used them recently, or is there a possibility that you may use other medicines in the near future? Please inform your doctor. Do not use this medicine if you are already taking nitrates.

Some medicines may be affected by this medicine or may affect how this medicine works. Inform your doctor or pharmacist if you are already taking any of the following medicines:

* An alpha-blocker (used to treat high blood pressure or urinary symptoms related to benign prostatic hyperplasia).
* Other medicines to treat high blood pressure.
* Nitrates (for chest pain).
* Riociguat.
* A 5-alpha-reductase inhibitor (used to treat benign prostatic hyperplasia).
* Protease inhibitors for the treatment of AIDS or HIV infection (ritonavir).
* Phenobarbital, phenytoin, and carbamazepine (medicines to treat seizures).
* Rifampicin, erythromycin, or clarithromycin (for the treatment of bacterial infections).
* Medicines such as ketoconazole or itraconazole (used to treat a fungal infection).
* Bosentan (another treatment for high blood pressure in the pulmonary arteries).
* Other treatments for erectile dysfunction (PDE5 inhibitors).

**What to consider regarding drinking and alcohol?**Refer to section 3 for information about the effects of alcohol. Grapefruit juice may affect how well this medicine works and should be used with caution. Please contact your doctor if you would like more information.

**Pregnancy, breastfeeding, and fertility**Are you pregnant, do you think you might be pregnant, do you plan to become pregnant, or are you breastfeeding? Please contact your doctor or pharmacist before using this medicine.

Do not use this medicine if you are pregnant unless it is strictly necessary and you have discussed this with your doctor.

Do not breastfeed while using these tablets because it is not known if this medicine passes into breast milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

In the treatment of dogs, a reduced amount of sperm in the testes has been observed. In some men, a reduction in sperm has been noted. It is unlikely that these effects lead to infertility.

**Driving and using machines**Check how you react to the tablets before driving a car or operating machinery.
Tadalafil Sandoz contains lactose and sodium.
If your doctor has told you that you have an intolerance to certain sugars, please contact your doctor before taking this medicine.
This medicine contains less than 1 mmol of sodium (23 mg) per film-coated tablet, which means it is essentially "sodium-free."

**How to use this medicine?**Always use this medicine exactly as your doctor has told you. If you are unsure about the correct usage, please contact your doctor or pharmacist.
Swallow the tablet whole with some water. Tadalafil Sandoz 20 mg tablets can be divided into equal doses.
You can take the tablets with or without food.

**For the treatment of erectile dysfunction:** Flexible dose, if needed:

The recommended initial dose is one 10 mg tablet before sexual activity. If the effect of this dose is too weak, your doctor may increase the dose to 20 mg. This medicine is for oral use.

You can take a tablet of this medicine at least 30 minutes before sexual activity. This medicine can remain effective for up to 36 hours after the tablet is taken.

10 mg and 20 mg of this medicine are intended for use in planned sexual activity and are not recommended for daily use.

**Once-daily administration:**The recommended dose is 5 mg once daily, taken at approximately the same time each day. Depending on your response to this medicine, your doctor may adjust the dose to 2.5 mg. This will be given as a 2.5 mg tablet.
When taking this medicine once daily, you will be able to achieve an erection at any time of day when sexually stimulated.
Once-daily administration of this medicine may be beneficial for men who expect to be sexually active two or more times a week.

Do not take this medicine more than once a day.

It is important to know that this medicine does not work without sexual stimulation. You and your partner should be aware that foreplay is necessary, just as you would if you were not using a medicine for erectile dysfunction. Drinking alcohol can affect your ability to get an erection and may temporarily lower your blood pressure. If you have taken or plan to take this medicine, avoid excessive alcohol consumption (blood alcohol level of 0.08% or higher), as this can increase the risk of dizziness when standing up.

**For the treatment of benign prostatic hyperplasia:** The dose is one 5 mg tablet once daily, taken at approximately the same time each day. If you have both benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet once daily. Do not take this medicine more than once a day.

**For the treatment of pulmonary arterial hypertension:** The usual dose is two 20 mg tablets once daily. Take both tablets one after the other at the same time. If you have mild to moderate liver or kidney disease, your doctor may advise you to take only 20 mg per day.

**Have you taken too much of this medicine?**If you or someone else has taken more tablets than you should, tell your doctor or go to a hospital immediately, and take the medicine or packaging with you. You may experience the side effects listed in section 4.

**Have you forgotten to use this medicine?**Take your dose as soon as you remember, if it was less than 8 hours ago when you should have taken the dose. Do not take a double dose to make up for a forgotten tablet. You should not take this medicine more than once a day.

**If you stop using this medicine**For the treatment of benign prostatic hyperplasia and pulmonary arterial hypertension, do not stop taking your tablets unless your doctor advises you to do so.

Do you have any other questions about the use of this medicine? Then please contact your doctor or pharmacist.

**Possible Side Effects**

Like all medicines, this medicine can have side effects, although not everyone gets them. These side effects are usually mild to moderate. If you experience any of the following side effects, stop taking this medicine and seek medical assistance immediately:

* Allergic reactions including skin rash (occurring in less than 1 in 10 users).
* Chest pain - do not use nitrates but seek medical help immediately (occurring in less than 1 in 10 users).
* Priapism, a prolonged and possibly painful erection after taking this medicine (occurring in less than 1 in 100 users).
* If you experience an erection that lasts longer than 4 hours, contact your doctor immediately.
* Sudden loss of vision (occurring in less than 1 in 1,000 users).

**Other reported side effects, categorized by indication:**

**Side effects when used for erectile dysfunction or benign prostatic hyperplasia:**

**Common (occurring in less than 1 in 10 users)**

• Headache, back pain, muscle pain, pain in the arms and legs, flushing, stuffy nose, and indigestion.

**Uncommon (occurring in less than 1 in 100 users)**

• Dizziness, abdominal pain, nausea, vomiting, acid reflux, blurred vision, eye pain, difficulty breathing, presence of blood in the urine, prolonged erection, palpitations, rapid heart rate, high blood pressure, low blood pressure, nosebleeds, ringing in the ears, swelling of the hands, feet, or ankles, and feeling tired.

**Rare (occurring in less than 1 in 1,000 users)**

* Fainting, seizures, transient memory loss, swelling of the eyelids, red eyes, sudden reduction or loss of hearing, hives (an itchy skin rash with bumps), bleeding from the penis, presence of blood in semen, and excessive sweating.
* Heart attack and stroke have also been rarely reported in men using this medicine. Most of these men already had heart problems before taking this medication.
* Partial, temporary, or permanent reduction or loss of vision in one or both eyes.

**Additionally, there have been rare side effects reported in men taking this medicine that were not observed during clinical trials. These include:**

• Migraine, facial swelling, severe allergic reaction causing swelling of the face and throat, severe skin rash, certain disorders of blood flow to the eyes, irregular heartbeat, chest pain, and sudden death with the heart as the cause.

The side effect of dizziness has been reported more frequently in men over 75 years of age using this medicine. Diarrhea has been reported more frequently in men over 65 years of age using this medicine for the treatment of erectile dysfunction.

**Side effects when used for pulmonary arterial hypertension:**

**Very common (occurring in more than 1 in 10 users)**

**Common (occurring in less than 1 in 10 users)**

• Headache, flushing, stuffy nose, blocked sinuses, nausea, upset stomach (with abdominal pain or discomfort), muscle pain, back pain, and pain in the arms and legs (including discomfort in the limbs).

**Frequent (occurring in less than 1 in 10 users)**

• Blurred vision, low blood pressure, nosebleeds, vomiting, increased or abnormal uterine bleeding, facial swelling, heartburn, migraine, irregular heartbeat, and fainting.

**Occasional (occurring in less than 1 in 100 users)**

• Seizures, transient memory loss, hives, excessive sweating, bleeding from the penis, presence of blood in semen and/or urine, high blood pressure, rapid heart rate, sudden death with the heart as the cause, and tinnitus.

Most, but not all, men who reported rapid heart rate, irregular heartbeat, heart attack, stroke, and sudden death with the heart as the cause had pre-existing heart problems before taking this medicine. It is not possible to determine whether these events were directly related to this medicine (see "Side effects when used for erectile dysfunction or benign prostatic hyperplasia" above).

**How to store this medicine?**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister pack after "EXP:". The expiry date refers to the last day of that month.

There are no specific storage conditions for this medicine.

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.