Package leaflet: Information for the user

Viagra Connect Melts 50 mg orodispersible films

sildenafil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have taken Viagra Connect Melts as directed and were not able to get or keep an erection firm enough for sex.

What is in this leaflet

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

1. What Viagra Connect Melts is and what it is used for

What Viagra Connect Melts is
Viagra Connect Melts contains the active substance sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by relaxing the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited and causing an erection. Viagra Connect Melts will only help you to get an erection if you are sexually excited (stimulated).

What Viagra Connect Melts is used for
Viagra Connect Melts is a treatment for men aged 18 years and older with erectile dysfunction.

Erectile dysfunction, also known as impotence, is an inability to achieve or maintain an erection that is firm enough to have sex. Erections depend on many different factors, including proper blood flow to the penis. Reduced blood flow to the penis may cause erectile dysfunction. Erectile dysfunction can affect men differently. Some cannot achieve an erection. Others may achieve an erection, but not firm enough for having sex or they may lose the erection before or during sex.

2. What you need to know before you take Viagra Connect Melts

Do not take Viagra Connect Melts
- if you do not have an erection problem
- **if you take any nitrate medicine** for chest pain or heart failure (see "Other medicines and Viagra Connect Melts")
- if you take amyl nitrite, so called "poppers" as recreational drugs
- if you take riociguat (or other guanylate cyclase stimulators) for high blood pressure in the lungs (see "Other medicines and Viagra Connect Melts")
- if you take ritonavir for the treatment of HIV (see "Other medicines and Viagra Connect Melts")
- if you have been advised by your doctor to avoid sexual activity because of a problem with your heart or blood vessels (see "Warnings and precautions")

- if you have a severe heart problem such as a recent heart attack or stroke (within the last 6 months), unstable angina (chest pain) or severe cardiac failure (reduced pumping capacity of the heart)
- if you have a severe liver problem
- if you have low blood pressure (below 90/50 mmHg) which can cause symptoms such as tiredness, dizziness, light-headedness, feeling sick, clammy skin, depression, loss of consciousness, or blurry vision
- if you have ever had severe vision loss because of nerve damage in the eyes, such as non-arteritic anterior ischaemic optic neuropathy (NAION); or have a rare inherited eye disease, such as retinitis pigmentosa (see "Warnings and precautions")
- if you have a deformed penis
- if you are a woman
- if you are under 18 years of age
- if you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
You should schedule a health check-up with your doctor as soon as possible within the first 6 months of starting to use Viagra Connect Melts to ensure that your erection problems are not caused by any serious health condition.
Erectile dysfunction may be an early sign of:
- cardiovascular disease
- diabetes
- high blood pressure
- high cholesterol

Tell your doctor about your problems if you have not already done so.

Cardiovascular risk factors
Sexual activity can put a strain on your heart (see "Do not take Viagra Connect Melts if you" above).
Talk to your doctor before taking Viagra Connect Melts if you:
- get very breathless or feel any pain in the chest with light or moderate activity (e.g. walking briskly for 20 minutes or climbing two flights of stairs). Your doctor may need to check whether your heart can take the additional strain of having sex.
- have a problem with a valve in your heart (valvular heart disease).
- have a disease in which the heart muscle becomes inflamed and does not work as well as it should (cardiomyopathy).
- have an irregular heart beat (arrhythmia).
- you have had surgery to improve blood flow to your heart, or you have high blood pressure which is now adequately treated.
- have high blood pressure that is not controlled.

Other risk factors
Talk to your doctor before taking Viagra Connect Melts if you:
- have ever had an erection that lasted more than 4 hours (priapism). Some conditions can increase the probability of having a persistent erection, such as sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), or multiple myeloma (cancer of bone marrow). Use of impotence medicines may increase the risk of priapism. Long lasting erection may cause damage to the tissue in the penis and permanent loss of ability to have an erection.
- have a stomach ulcer or a bleeding disorder (such as haemophilia).
- have previously been diagnosed with mild to moderate liver disease, or severe kidney problems. Viagra Connect Melts may not be suitable for you, you should consult your doctor before taking Viagra Connect Melts.

You should not use Viagra Connect Melts with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.
If you experience any sudden visual defect, you should stop taking Viagra Connect Melts and contact your doctor immediately. Cases of visual effects have been reported when using sildenafil.

Children and adolescents
This medicine should not be given to children or adolescents under the age of 18 years.

Other medicines and Viagra Connect Melts
Tell your pharmacist or doctor if you are taking, have recently taken or might take any other medicines. Some medicines may be affected by Viagra Connect Melts or they may affect how Viagra Connect Melts works and this may result in side effects.

Do not use Viagra Connect Melts if you take:

- Nitrate medicines: Do not take Viagra Connect Melts if you are taking nitrate medicines (such as glyceryl trinitrate, isosorbide mononitrate, isosorbide dinitrate) against chest pain (*angina pectoris*) or heart failure or "poppers" as recreational drugs (nitric oxide donors (such as amyl nitrite), nicorandil or sodium nitroprusside). This is because these substances could lead to a dangerous fall in blood pressure if taken together with Viagra Connect Melts.
- Riociguat: Do not take Viagra Connect Melts if you are taking a medicine called riociguat (or other medicines of a group called guanylate cyclase stimulators). Riociguat is used to treat high blood pressure in the lungs and can lead to a dangerous fall in blood pressure if taken together with Viagra Connect Melts.
- Medicines to treat HIV-infections: Ritonavir is a medicine used to treat HIV-infections. Do not take Viagra Connect Melts if you are taking ritonavir since this combination can lead to a dangerous fall in blood pressure.

Talk to your pharmacist or doctor before using **Viagra Connect Melts** if you are taking:

- Medicines to treat fungal infections and antibiotics: Medicines to treat fungal infections called itraconazole or ketoconazole and an antibiotic called erythromycin increase the concentration of Viagra Connect Melts in the body and may result in side effects. You should contact your doctor before taking Viagra Connect Melts if you are using these medicines.
- Heartburn treatment: The medicine to treat heartburn, cimetidine, increases the concentration of Viagra Connect Melts in the body and may result in side effects. You should contact your doctor before taking Viagra Connect Melts.
- Other treatments for erectile dysfunction: The safety and efficacy of combinations of Viagra Connect Melts with other treatments for erectile dysfunction have not been studied and this combination is therefore not recommended.
- Alpha-blockers used to treat urinary problems or high blood pressure: Alpha-blockers used to treat urinary problems due to enlarged prostate (such as alfuzosin, doxazocin or tamsulosin) may lead to dizziness, light-headedness, nausea, fainting, lack of concentration, or blurred vision due to low blood pressure (symptomatic hypotension).
- Medicines containing sacubitril/valsartan, used to treat heart failure: You should contact your doctor or pharmacist before taking Viagra Connect Melts.

Viagra Connect Melts with food and drink
Viagra Connect Melts can be taken with or without food. When this medicine is taken after a high-fat meal, it may take a little longer to start working.
Do not take Viagra Connect Melts with grapefruit or grapefruit juice, because this can affect how the medicine works.
Drinking excessive alcohol can temporarily reduce your ability to achieve an erection. To get a benefit from the medicine, you are advised not to drink large amounts of alcohol before sexual activity.

Pregnancy, breast-feeding and fertility
This medicine should not be used by women.

Driving and using machines
Viagra Connect Melts can cause dizziness and can affect your vision. Do not drive or use machines if you suffer from these side effects after taking this medicine.

3. How to take Viagra Connect Melts

Always take this medicine exactly as described in this leaflet or as your pharmacist or doctor have told you. Check with your pharmacist or doctor if you are not sure.

- Take 1 orodispersible film, as needed, approximately 1 hour before sexual activity.
- Carefully peel open the aluminium pouch with dry hands. Do not cut it open.
- Take out the orodispersible film with a dry finger and immediately place the orodispersible film on the tongue, where it will disintegrate in seconds with or without water. During disintegration saliva may be swallowed, but without swallowing the film.
- Do not take more than 1 orodispersible film a day.

Viagra Connect Melts will only help you achieve an erection if you are sexually aroused. You and your partner should engage in foreplay just as you would if you were not taking a medicine for erectile dysfunction.

The amount of time this medicine takes to work varies from person to person, but it normally takes between 30 to 60 minutes. You may take it up to 4 hours before sexual activity.

The orodispersible film should be taken on an empty stomach as you may find that it takes longer to start working if you take it with a heavy meal.
Relax and be patient if Viagra Connect Melts does not help you the first time. You can try again later but remember you can only take one orodispersible film a day. For most men, Viagra Connect Melts will work the first or second time they try it. If it has been some time since you were able to get or keep an erection, it may take a couple of attempts before you achieve the desired effect. Talk to your doctor if you have tried Viagra Connect Melts and are still not able to get and keep an erection.
If you feel the effect of Viagra Connect Melts is too strong, talk to your pharmacist or doctor.

If you take more Viagra Connect Melts than you should
If you take more orodispersible films than recommended, contact your pharmacist or doctor immediately. Taking more than the recommended dose may result in side effects and/or more severe side effects.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These side effects are usually mild to moderate and of a short duration.

Seek medical attention immediately if you experience any of the following serious side effects:
- 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
  - Get in a semi-sitting position and try to relax.
  - **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**
- Serious skin reactions - this occurs **rarely**
  Symptoms may include severe peeling and swelling of the skin, blistering of the mouth, genitals 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, indigestion, stuffy nose, dizziness
- facial flushing, hot flush (a sudden feeling of heat in your upper body)
- colour tinge to vision, blurred vision, visual disturbance

Uncommon (may affect up to 1 in 100 people):
- vomiting, upper abdominal pain, acid reflux (including heartburn)
- skin rash, pain in the arms or legs, nosebleed, feeling hot, feeling tired (fatigue)
- 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 (typical signs are dizziness, fainting, blurred vision, nausea and tiredness)
- 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 (can be experienced as runny nose, sneezing and stuffy nose)
- presence of blood in urine

Rare (may affect up to 1 in 1,000 people):
- fainting, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing
- sudden unexpected death caused by loss of heart function (sudden cardiac arrest), stroke, heart attack, chest pains (angina), 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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal . By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Viagra Connect Melts

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pouch after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Viagra Connect Melts contains
- The active substance is sildenafil. Each orodispersible film contains 50 mg of sildenafil (as citrate).
- The other ingredients are hydroxypropylcellulose (E 463), macrogol, crospovidone (E 1202), povidone (E 1201), sucralose (E 955), macrogol poly(vinyl alcohol) grafted copolymer, levomenthol, hypromellose (E 464), titanium dioxide (E 171), iron oxide red (E 172).

What Viagra Connect Melts looks like and contents of the pack
Each orodispersible film is packed in an individual foil pouch.
They are supplied in cartons containing 2, 4, or 8 pouches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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