

BLUVISA®

Sildenafil Citrate

Description:

BLUVISA® (Sildenafil Citrate) is an oral therapy for erectile dysfunction. It is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). **BLUVISA®** restores impaired erectile function by increasing the blood flow to the penis, but sexual stimulation is needed.

Properties:

Sildenafil is rapidly absorbed after oral administration, reaches the maximum plasma concentration after 30 - 120 minutes with absolute bioavailability of about 40%. Sildenafil absorption is reduced when taken with food and it is highly protein bound of about 96%. It is eliminated predominantly by hepatic metabolism (mainly Cytochrome P450 isoforms 3A4 as major route and 2C9 as a minor route) and converted to an active metabolite with similar properties to Sildenafil. About 80% of administered oral Sildenafil dose is excreted as metabolites predominantly in the faeces and about 13% in the urine.

Indications:

BLUVISA® is indicated for the treatment of erectile dysfunction.

Dosage and administration:

For the most of patients, the recommended daily dose is 50 mg to be taken as needed, approximately 1 hour before the sexual activity. Based on efficacy and toleration, the dosage may be increased to the maximum recommended daily dose of 100 mg or decreased to 25 mg. The maximum recommended dosing frequency is once per day.

Patient notes:

- Sildenafil may be taken from 0.5 hour to 4 hours before the sexual activity.
- Patients who experience symptoms (e.g. angina pectoris, dizziness, nausea) upon initiation of sexual activity should be advised to refrain from further activity and should discuss this episode with their physician.
- Since Sildenafil clearance is reduced in patients with severe renal and hepatic impairments, a 25 mg dose of Sildenafil should be considered, and to be increased to 50 or 100 mg based on efficacy and toleration.
- The use of Sildenafil offers no protection against sexually transmitted diseases. Counseling of patients about the protective measures necessary to guard against sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV), may be considered.

Contraindications:

- Known hypersensitivity to Sildenafil or to any other component of the product.
- Concomitant administration of Sildenafil with nitrate derivatives, due to Sildenafil potentiation of hypotensive effect of nitrates.
- Sildenafil is not indicated for individuals below 18 years of age, and not indicated for women also.
- Agents for the treatment of erectile dysfunction, including Sildenafil, should not be used in men for whom sexual activity is inadvisable (e.g. patients with severe cardiovascular diseases).

Precautions:

- Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status, medical history, physical examination and determine potential underlying cause to the patients.
- Sildenafil should be used with caution in patients with anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie's disease) or in patients who have conditions which may predispose them to priapism (such as sickle cell anemia, multiple myeloma, or leukemia).
- The safety and efficacy of combinations of Sildenafil with other treatments for erectile dysfunction have not been studied; therefore, the use of such combinations is not recommended.
- The safety of Sildenafil is unknown in patients with bleeding disorders and patients with active peptic ulceration.
- Sildenafil has systemic vasodilatory properties that result in transient decreases in blood pressure, so the physicians, before prescribing Sildenafil, should carefully consider whether their patients with underlying cardiovascular disease could be affected adversely by this vasodilatory effect, especially in combination with sexual activity.
- There is no controlled clinical data on the safety or efficacy of Sildenafil if prescribed in the following groups, so should be done with caution:
 - Patients who have suffered from myocardial infarction, stroke or life-threatening arrhythmia within the last 6 months.
 - Patients with resting hypotension (B.P.<90/50) or hypertension (B.P.>170/110).

- Patients with cardiac failure or coronary artery disease causing unstable angina.
- Patients with retinitis pigmentosa (a minority of these patients have genetic disorders of retinal phosphodiesterases).
- As dizziness and altered vision were reported in clinical trials with Sildenafil, patients should be aware of how they react to it, before driving or operating machinery.
- Prolonged erection greater than 4 hours and priapism have been reported infrequently, the patient should seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency could result.
- Patients should advise patients to stop taking PDE5 inhibitors, including Sildenafil, and seek prompt medical attention in the event of sudden decrease or loss of hearing. These events, which may be accompanied by tinnitus and dizziness, have been reported in temporal association to the intake of PDE5 inhibitors, including Sildenafil. It is not possible to determine whether these events are related directly to the use of PDE5 inhibitors or to other factors.

Use during pregnancy and lactation:

Pregnancy Category B

Sildenafil is not indicated for women. There are no adequate and well controlled studies of Sildenafil in pregnant women.

Lactation: Sildenafil is not indicated for use in women.

Drug interactions:

- Sildenafil metabolism is principally mediated by the cytochrome P450 isoform 3A4 (major route). Therefore, inhibitors of this isoenzyme (e.g. Ketoconazole, Erythromycin, Clmefidine, HIV protease inhibitor or grape fruit juice) may reduce Sildenafil clearance.
- Sildenafil does not potentiate the hypotensive effect of Alcohol.
- Caution is required in patients taking Sildenafil concomitantly with multiple antihypertensive medications; for possibility of additional blood pressure reduction.
- Simultaneous administration of Sildenafil with alpha-blockers, may lead to symptomatic hypotension in some patients. Therefore, Sildenafil doses above 25 mg should not be taken within 4 hours of taking an alpha-blocker.
- Sildenafil has no effect on bleeding time when taken alone or with aspirin. But in vitro studies, Sildenafil shows potentiation the antiaggregatory effect of sodium nitroprusside, so caution is recommended.

Side effects:

- Side effects are mild to moderate in nature and the incidence and severity increase with increasing the dose.
- The most commonly reported side effects were: Headache, flushing, dyspepsia and nasal congestion.
- Other side effects: Urinary tract infection, abnormal vision (mild and transient, predominantly color tinge to vision, but also increased sensitivity to light or blurred vision), diarrhea, dizziness, rash, respiratory tract infection, back pain, flu syndrome, antralgia, face edema, photosensitivity reaction, pain, chills, abdominal pain, allergic reaction, chest pain, migraine, tachycardia, palpitation, hypotension, abnormal electrocardiograph, vomiting, glossitis, colitis, dysphagia, gastroenteritis, esophagitis, stomatitis, dry mouth, abnormal liver function tests, anemia, leucopenia, thirst, gout, hyperglycemia, hypoglycemic reaction, hypernatremia, arthritis, arthrosis, myalgia, tendon rupture, tenosynovitis, synovitis, ataxia, hypertension, neuralgia, neuropathy, paresthesia, tremor, vertigo, depression, insomnia, somnolence, abnormal dreams, decrease in the reflexes, asthma, pharyngitis, sinusitis, bronchitis, increase in the sputum, increased cough, herpes simplex, sweating, mydriasis, conjunctivitis, photophobia, tinnitus, eye pain, ear pain, eye hemorrhage, cataract, dry eyes, cystitis, nocturia, urinary frequency, breast enlargement, abnormal ejaculation, genital edema and anorgasmia.

Overdosage:

- In studies with healthy volunteers of single doses up to 800 mg, side effects were similar to those seen at lower doses but incidence rates and severity were increased.
- In cases of overdosage, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as Sildenafil is highly bound to plasma proteins.

Storage conditions:

Store between 15 - 30°C.

Presentation:

BLUVISA® 50: Each film coated tablet contains Sildenafil Citrate equivalent to 50 mg Sildenafil in packs of 4 tablets.

Hospital packs are also available.

This is a medication

- Medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- 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 medication out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

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