**INDICATIONS AND USAGE**

Sildenafil is indicated for the treatment of pulmonary arterial hypertension (PAH). PAH is a form of pulmonary hypertension in which there is an abnormal increase in blood pressure in the pulmonary arteries. It is characterized by sustained vasoconstriction of pulmonary arteries and increased resistance to pulmonary blood flow. Sildenafil, a phosphodiesterase type 5 (PDE-5) inhibitor, is used to relax the smooth muscles of the pulmonary arteries, thereby reducing pulmonary vascular resistance and improving right ventricular function.

**CONTRAINDICATIONS**

Sildenafil is contraindicated in patients with a hypersensitivity to sildenafil or any of its components. It is also contraindicated in patients with a known history of nitrate use within the past 24 hours, as well as in those with a severe hypotensive state or severe bleeding.

**WARNINGS AND PRECAUTIONS**

- **Hypotension**: Sildenafil can cause a sudden drop in blood pressure, which may be exacerbated by certain medications such as nitrates. Patients with a history of hypotension or anemia may be at higher risk for this effect.
- **Combination Use**: Avoid concomitant use of sildenafil with nitrates, as this combination can lead to a severe and potentially fatal decrease in blood pressure.
- **Priapism**: Priapism can occur with the use of sildenafil. This is a persistent and painful erection that cannot be easily corrected with aspiration. It is important for patients to report this symptom immediately to their healthcare provider.
- **Hypersensitivity Reactions**: Sildenafil can cause severe allergic reactions, including anaphylaxis.

**SIDE EFFECTS**

Sildenafil is generally well tolerated. However, like other PDE-5 inhibitors, it can cause side effects such as headache, flushing, and nausea. More serious side effects include priapism, hypotension, and changes in vision.

**DOSE AND ADMINISTRATION**

Sildenafil is typically administered as a tablet or oral suspension, depending on the patient's preference and the healthcare provider's recommendation. The starting dosage is often 25 mg, with adjustments made based on the patient's response and tolerability. The maximum recommended dosage is 100 mg. It is important to follow the dosing instructions provided by the healthcare provider.

**PATIENT INFORMATION**

Before prescribing sildenafil, the healthcare provider should inform the patient about the potential risks and benefits of the medication. Patients should be instructed to discontinue the use of sildenafil if they experience side effects, such as headache, flushing, or priapism. Patients should also be made aware of the importance of regular medical follow-up to monitor their response to therapy.

**ADDITIONAL INFORMATION**

Sildenafil is marketed under various brand names, including Viagra and SILDENAFIL. The medication is available in several formulations, including tablets, oral suspensions, and intracavernosal injections. It is important to use sildenafil as prescribed by the healthcare provider to ensure the most effective treatment and minimize the risk of side effects.
What are the possible side effects of Sildenafil for oral suspension?

- Low blood pressure, Low blood pressure may cause you to feel faint or dizzy. Lie down if you feel faint or dizzy.
- More shortness of breath than usual. Tell your doctor if you get more shortness of breath after you start Sildenafil for oral suspension. More shortness of breath than usual may be due to your underlying medical condition.
- Decreased eyeglas or loss of sight in one or both eyes (RAUD). If you notice a sudden decrease or loss of eyeglas, talk to your doctor right away.
- Sudden decrease or loss of hearing. If you notice a sudden decrease or loss of hearing, talk to your doctor right away. It is not possible to determine whether these events are related directly to this class of oral medicines, including Sildenafil for oral suspension, to other diseases or medicines, to other factors, or to a combination of factors.
- Heart attack, stroke, irregular heartbeats, and death. Most of these happened in men who already had heart problems.
- Erections that last several hours. If you have an erection that lasts more than 4 hours, get medical help right away. It is not treated right away, priapism can permanently damage your penis.

The most common side effects with Sildenafil for oral suspension include:

- Nosedlebl, headache, upset stomach, getting red or hot in the face (flushing), trouble sleeping, as well as a few, erection increased respiratory infection, nausea, vomiting, bronchitis, pharyngitis, rash, and pruritus in children.

Tell your doctor if you have any side effect that bothers you or doesn’t go away:

- These are not all the possible side effects of Sildenafil for oral suspension. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Sildenafil for oral suspension?

- Store Sildenafil for oral suspension in a well-shielded bottle at a temperature of 30°C (86°F) or in a refrigerator between 2°C to 8°C (36°F to 46°F).
- Do not freeze Sildenafil for oral suspension.
- Throw away Sildenafil for oral suspension after 60 days.
- Keep Sildenafil for oral suspension and all medicines away from children.

General information about Sildenafil for oral suspension

Medicines are sometimes prescribed for purposes that are not in the patient leaflet. Do not use Sildenafil for oral suspension for a condition for which it was not prescribed. Do not give Sildenafil for oral suspension to other people. Even if you think you have the same condition, you should not use this medicine. It could harm them.

This patient leaflet summarizes the most important information about Sildenafil for oral suspension. If you would like more information about Sildenafil for oral suspension talk with your doctor. You can ask your doctor or pharmacist for information about Sildenafil for oral suspension that is written for health professionals.

For more information go to www.novitiumpharma.com/products or call 1-855-204-1431.

What are the ingredients in Sildenafil for oral suspension?

Sildenafil for oral suspension

Active ingredient: sildenafil citrate

Inactive ingredients: arbistic, citric acid anhydrous, sucrose, sodium citrate dibehydrate, xanthan gum, titanium dioxide, sodium benzoate, colloidal silicon dioxide anhydrous and grape flavor

Manufactured by:
Novitium Pharmaceuticals LLC.
70 Lake Drive
East Windsor, New Jersey-08520

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