

Duralis® 5

Tadalafil

What is Duralis® 5?

Duralis® 5: Each film coated tablet contains Tadalafil 5mg; Box of 30 tablets.
Excipients: Lactose Monohydrate, Croscarmellose Sodium, Corn Starch, Povidone K-30, Colloidal Silicon Dioxide, Magnesium Stearate, Microcrystalline Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, Iron Oxide Yellow.

Why should you take Duralis® 5?

Duralis® 5 is prescribed for the management of erectile dysfunction (ED), a condition also known as male impotence. Erectile dysfunction is defined as the inability to achieve or maintain an erection sufficient for mutually satisfying intercourse. The effect of Duralis® 5 is achieved through dilation of blood vessels in the penis leading to an increased blood flow needed for an erection.

Duralis is also used for the treatment of signs and symptoms of benign prostatic hyperplasia. Symptoms include difficulty in starting to pass water, a feeling of not completely emptying the bladder and a more frequent need to pass water even at night. Duralis improves blood flow to, and relaxes the muscles of, the prostate and bladder which may reduce symptoms of benign prostatic hyperplasia. Duralis has been shown to improve these urinary symptoms as early as 1-2 weeks after starting treatment

What is the recommended dosage of Duralis® 5?

Erectile dysfunction

The recommended dose is one 5 mg tablet taken once a day at approximately the same time of the day. Do not take Duralis more than once a day. When taken once a day Duralis allows you to obtain an erection, when sexually stimulated, at any time point during the 24 hours of the day. Once a day dosing of Duralis may be useful to men who anticipate having sexual activity two or more times per week.

Benign prostatic hyperplasia

The dose is one 5 mg tablet taken once a day at approximately the same time of the day. If you have benign prostatic hyperplasia and erectile dysfunction, the dose remains one 5 mg tablet taken once a day. Do not take Duralis more than once a day.

For Men with renal impairment

Once-a-day dosing of 2.5 or 5 mg tadalafil both for the treatment of erectile dysfunction or benign prostatic hyperplasia is not recommended in patients with severe renal impairment

For Men with hepatic impairment

Once-a-day dosing both for the treatment of erectile dysfunction and benign prostatic hyperplasia has not been evaluated in patients with hepatic impairment; therefore, if prescribed, a careful individual benefit/risk evaluation should be undertaken by the prescribing physician

What to do if you miss a dose?

If you forget to take Duralis, take your dose as soon as you remember but do not double the dose to make up for a forgotten tablet. You should not take Duralis more than once a day.

What are the side effects of Duralis® 5?

Common (seen in 1 to 10 in every 100 patients) - headache, back pain, muscle aches, pain in arms and legs, facial flushing, nasal congestion, indigestion and reflux.

Uncommon (seen in 1 to 10 in every 1,000 patients) - dizziness, stomach ache, blurred vision, eye pain, increased sweating, difficulty in breathing, penile bleeding, presence of blood in semen and/or urine, pounding heartbeat sensation, a fast heart rate, high blood pressure, low blood pressure, nose bleeds and ringing in the ears.

Rare (seen in 1 to 10 in every 10,000 patients) - fainting, seizures and passing memory loss, swelling of the eyelids, red eyes, sudden decrease or loss of hearing and hives (itchy red welts on the surface of the skin).

What are the precautions to take during Duralis® 5 Treatment?

Before treatment with Duralis, a medical history and physical examination should be undertaken to diagnose erectile dysfunction or benign prostatic hyperplasia and determine potential underlying causes, before pharmacological treatment is considered.

Prior to initiating any treatment for erectile dysfunction, physicians should consider the cardiovascular status of their patients, since there is a degree of

cardiac risk associated with sexual activity. Tadalafil has vasodilator properties, resulting in mild and transient decreases in blood pressure and as such potentiates the hypotensive effect of nitrates.

Prior to initiating treatment with tadalafil for benign prostatic hyperplasia patients should be examined to rule out the presence of carcinoma of the prostate and carefully assessed for cardiovascular conditions

Cardiovascular

Serious cardiovascular events, including myocardial infarction, sudden cardiac death, unstable angina pectoris, ventricular arrhythmia, stroke, transient ischaemic attacks, chest pain, palpitations and tachycardia, have been reported either post marketing and/or in clinical trials. However, it is not possible to definitively determine whether these events are related directly to these risk factors, to Duralis, to sexual activity, or to a combination of these or other factors.

In patients receiving concomitant antihypertensive medicinal products, tadalafil may induce a blood pressure decrease. When initiating daily treatment with tadalafil, appropriate clinical considerations should be given to a possible dose adjustment of the antihypertensive therapy.

In patients who are taking alpha blockers, concomitant administration of Duralis may lead to symptomatic hypotension in some patients. The combination of tadalafil and doxazosin is not recommended.

Priapism and anatomical deformation of the penis

Patients who experience erections lasting 4 hours or more should be instructed to seek immediate medical assistance. If priapism is not treated immediately, penile tissue damage and permanent loss of potency may result.

Duralis 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 anaemia, multiple myeloma or leukaemia).

Use with CYP3A4 inhibitors

Caution should be exercised when prescribing Duralis to patients using potent CYP3A4 inhibitors (ritonavir, saquinavir, ketoconazole, itraconazole, and erythromycin), as increased tadalafil exposure (AUC) has been observed if the medicinal products are combined.

What are the cases in which you should not take Duralis® 5?

Do not take Duralis if you are

- allergic to tadalafil or any of the other ingredients of this medicine.
- taking any form of organic nitrate or nitric oxide donors such as amyl nitrite. This is a group of medicines ("nitrates") used in the treatment of angina pectoris ("chest pain").
- have serious heart disease or recently had a heart attack within the last 90 days.
- recently had a stroke within the last 6 months.
- have low blood pressure or uncontrolled high blood pressure.
- ever had loss of vision because of non-arteritic anterior ischemic optic neuropathy (NAION), a condition described as "stroke of the eye".
- are taking riociguat. This drug is used to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. PDE5 inhibitors, such as Duralis, have been shown to increase the hypotensive effects of this medicine.

How to store Duralis® 5?

Store below 30°C

Keep in original pack in intact conditions.

Date of revision: September 2015.

This is a medicament

- A medicament 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 medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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