PROCTIN®
0.5 mg Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PROCTIN
PROCTIN tablets for oral use contain cabergoline 0.5 mg with the following excipients: lactose and leucine.
Cabergoline is an ergot derivative with a potent and long-lasting prolactin lowering activity due its direct stimulation of the D2-dopamine receptors.
PROCTIN is indicated in the following conditions:
- Inhibition of the physiological lactation soon after delivery.
- Suppression of already established lactation.
-Treatment of hyperprolactinemia, either idiopathic or due to pituitary adenomas or empty sella syndrome and the clinical manifestations of hyperprolactinemia in men (impotence, decreased libido, gynecomastia) and in women (galactorrhea, amenorrhea, oligomenorrhea and anovulation).

The way to take PROCTIN
Take PROCTIN as directed by your physician.
The duration of treatment is determined according to the condition under treatment.
It is recommended to take PROCTIN with food.

Indication	**Dosage**
Inhibition of the physiological lactation soon after delivery	1 mg (2 tablets of 0.5 mg) given as a single dose the first day post-partum
Suppression of already established lactation	0.25 mg (half a tablet of 0.5 mg) every 12 hours for two days
Treatment of hyperprolactinemia and its clinical manifestations	Recommended starting dose: 0.5 mg per week given in one (one tablet of 0.5 mg) or two doses (half a tablet of 0.5 mg) per week. The weekly dose should be increased gradually by adding 0.5 mg per week at monthly intervals. The therapeutic dosage is usually 1 mg per week and ranges from 0.25 mg to 2 mg and up to 4.5 mg per week. A maximum dose of 3 mg per day should not be exceeded.

The lowest dose that produces the therapeutic response should be determined during dose escalation.

In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose
Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications
This drug is contraindicated in the following conditions:
- Hypersensitivity to any of the components or to any ergot alkaloid
- Hepatic insufficiency
- Toxemia of pregnancy
- History of pulmonary, pericardial and retroperitoneal fibrotic disorders
- Evidence of presence of cardiac valvulopathy in case of long-term treatment

- Co-administration of antipsychotics, anti-emetic neuroleptics, phenylpropanolamine
- Women with history of puerperal psychosis

Precautions

- The safety and efficacy of this drug have not yet been established in patients with renal and hepatic disease.
- This drug should be given with caution to patients with severe cardiovascular disease, Raynaud's syndrome, renal insufficiency, peptic ulcer, gastrointestinal bleeding, or with a history of serious mental disorders.
- Caution is needed when using drugs known to lower blood pressure. It is recommended to have a periodic monitoring of blood pressure during the first days of treatment.
- Pregnancy should be excluded before taking this drug and should be prevented for at least one month after treatment. This drug must be discontinued if pregnancy occurs during treatment.
-Mothers with hyperprolactinemic disorders who are breastfeeding or planning to breastfeed should not take this drug as it affects lactation.
- This drug restores ovulation and fertility in women; therefore women not willing to become pregnant should use an appropriate method of contraception.
- A complete evaluation of the pituitary is indicated before initiating the treatment of hyperprolactinemic disorders and serum prolactin level should be monitored during the treatment.
- A regular gynecological assessment is advised in case of long-term treatment.
- An evaluation of the heart, lungs and kidneys is needed before initiating and during a long-term treatment.
- Caution should be taken when driving a car or operating dangerous machinery during treatment with cabergoline.
- Safety and effectiveness of this drug in pediatric patients under 16 years of age have not been established.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.
Concomitant use of macrolides antibiotics, antipsychotics, anti-emetic neuroleptics, and phenylpropanolamine is contra-indicated.
Concomitant use of ergot alkaloids, alcohol, tetrabenazine, alpha sympathomimetics and indirect sympathomimetics is not recommended.
Care should be exercised when administering this drug concomitantly with medicines for Parkinson’s disease, psychoactive medication, drugs known to lower blood pressure and other sedative drugs.

Adverse reactions

The most reported adverse reactions include: hypotension, dizziness, headache, sleep disturbances, somnolence, hot flushes, abdominal pain, dyspepsia, gastritis, nausea, constipation, vomiting, breast pain, asthenia, and fatigue.
Other reported adverse reactions include: depression, cardiac disorders, palpitations, epistaxis, blurred vision, paraesthesia, muscle weakness, cramps, pruritus and rash.
Please inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (below 25°C), protected from light and humidity, beyond the reach of children. PROCTIN tablets absorb moisture, so you should always replace the cap after taking out the tablets.
The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

PROCTIN, Cabergoline 0.5 mg, pack of 2 tablets
PROCTIN, Cabergoline 0.5 mg, pack of 8 tablets

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PRCT05/001
Manufactured by Mediphar Laboratories -Lebanon