CABERGOL® 0.5 mg
Scored Tablet
Cabergoline

Read this entire leaflet carefully before you start taking this medicine, because it contains important information for you..
•Keep this leaflet. You may need to read it again.
•If you have any further questions, ask your doctor or pharmacist.
•This medicine has been prescribed for you only.. Do not pass it on to others.. It may harm them, even if their signs of illness are the same as yours.
•If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1.What CABERGOL® is and what it is used for
Pharmacotherapeutic group: Prolactine inhibitors, ATC code: G02CB03
-Inhibition / suppression of physiological lactation.
-Treatment of hyperprolactinemic disorders.

2.What you need to know before you take CABERGOL® ?
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Do not take CABERGOL®:
-If you are allergic to cabergoline, to other medicines called ergot alkaloids, (e.g. pergolide, bromocriptine, lisuride, ergotamine or ergometrine) or to any of the other ingredients of this medicine (listed in section 6)
- in association with:
oneuroleptics: drugs used to treat agitation, anxiety and psychotic symptoms
oanti-emetic neuroleptics : medicines used to prevent nausea and vomiting
-If you have had fibrotic reactions (scar tissue) affecting your abdomen, heart or lungs.
-If you will be treated with CABERGOL® for a long period and have stiff and inflamed heart valves (cardiac valvulopathy).
IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

Warnings and precautions
If you are being treated with CABERGOL® for a long time, your doctor will check that your heart, lungs and kidneys are in good condition before you start treatment.
He will also have an echocardiogram (ultrasound heart examination) done before starting
treatment and at regular intervals during treatment. In case of fibrotic reaction or abnormalities of the valves, the treatment should be stopped.
If you experience excessive drowsiness or sudden onset of sleep when you are treated with
CABERGOL®, you must contact your doctor.
The consumption of alcohol increases the sedative effect of these substances. Altered alertness can make driving dangerous and the use of machinery dangerous. Avoid taking alcoholic drinks and drugs containing alcohol.
Blood pressure monitoring is recommended:
• during the first few days of treatment because of the risk of lowering blood pressure during changes of position;
• when used with other medicines that affect blood pressure.
Cabergoline will be administered with caution:
-If you have severe liver disease
-Disease that involves the heart and blood vessels (cardiovascular disease)
-Cold hands and feet (Raynaud's syndrome)
-Gnawing pain in the abdomen when hungry (peptic ulcer) or bleeding from the stomach and intestines (gastrointestinal bleeding)
-History of serious mental disease, particularly psychotic disorders.
Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
The use of this drug is not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose or galactose malabsorption syndrome (rare hereditary diseases).
In addition, if you are a woman:
Before you can start taking cabergoline, check that you are not pregnant. In addition, you should be careful not to become pregnant for at least one month after stopping the cabergoline.
Cabergoline can restore fertility, an adequate method of contraception should be adopted if you do not wish to become pregnant.
In case of pregnancy, if you have a pituitary adenoma, careful monitoring is essential, including monitoring signs that may correspond to a resumption of growth of the tumor (intense headaches, visual disturbances).
Talk to your doctor or pharmacist before taking CABERGOL® 0.5 mg tablets.

Children :
NA.

Other medicines and CABERGOL®
-Medicines used to treat mental illness (e.g. antipsychotic medicines like chlorpromazine, haloperidol)
-Medicines for nausea and vomiting (e.g. domperidone, metoclopramide)
-Medicines that can cause vasoconstriction (decreased blood vessel diameter) and high blood pressure,
-Medicines for severe migraine headaches (e.g. pergolide, bromocriptine, lisuride, ergotamine, dihydroergotamine, ergometrine or methysergide)
-Medicines for Parkinson's disease
-Medicines with a sedative effect (that is to say, causing drowsiness),
-Antibiotics (e.g. erythromycin).
-Medicine used in certain disorders caused by Huntington's chorea (tetrabenazine)

CABERGOL® with food and drink
Not applicable.

Pregnancy, breast-feeding and fertility
Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should also take care not to become pregnant for at least one month once you have stopped taking this medicine. If you become pregnant during treatment with CABERGOL®, stop taking CABERGOL® and inform your doctor who will then monitor your pregnancy as CABERGOL® can result in congenital abnormalities if you use it during pregnancy.
Breast-feeding
As CABERGOL® will stop you producing milk for your baby, you should not take this medicine if
you plan to breast-feed. If you need to take CABERGOL® you should use another method of feeding your baby.

Driving and using machines
At the beginning of treatment, patients should be cautious when performing tasks requiring rapid and accurate response.
The attention of drivers of vehicles and machine users is drawn to the risks of dizziness or drop in blood pressure related to the use of this drug, especially at the beginning of treatment.
CABERGOL® may induce drowsiness and sudden onset of sleep. In these cases, you should not drive or carry out any activity where an alteration in your alertness could expose you or others to the risk of a serious accident or death (for example, the use of machinery).and this until the disappearance of these episodes and this drowsiness.

CABERGOL® 0,5 mg tablet contains lactose
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3.How to take CABERGOL® ?
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage
• The dosage should be adapted:
o depending on the prolactin level used the day before taking a tablet;
o in the opinion of your doctor who will decide whether or not to break the weekly dose.
• The dosage will be maintained or increased in increments according to the measured prolactin level, until an optimal response to treatment is obtained.

Method and route of administration
Oral route.

Frequency of administration
Cabergoline should be taken once or several times a week, in the middle of a meal, preferably in the evening or at bedtime with a light snack.

Duration of treatment
IN ALL CASES, COMPLY STRICTLY WITH THE MEDICAL PRESCRIPTION.

If you take more CABERGOL® than you should
In case of overdose, notify a doctor immediately.

If you forget to take CABERGOL®
Do not take a double dose to make up for the single dose you forgot to take.

If you stop taking CABERGOL®
Your doctor will advise you how long to take CABERGOL®. You should not stop until your doctor
tells you.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4.Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

Very common side effects that may affect more than 1 in 10 people are listed below:
• heart valve disease (valvulopathy including regurgitation) and associated disorders (inflammation of the heart envelope and effusion around the heart),
• headache, dizziness,
• nausea, dyspepsia (difficult digestion), gastritis, abdominal pain,
• asthenia, tiredness.

Common side effects that may affect more than 1 in 100 people are listed below:
• drowsiness,
• depression,
• orthostatic hypotension (a drop in blood pressure when moving to a standing position that may be accompanied by vertigo), particularly during long-term treatment, hot flashes,
• constipation, vomiting,
• breast pain (breasts),
• asymptomatic decrease in blood pressure.

Uncommon side effects that may affect more than 1 in 1,000 people are listed below:
• palpitation,
• dyspnea (difficulty breathing), pleural effusion (abnormal presence of fluid between the lung and the membrane surrounding the lung), fibrosis (scar tissue) including pulmonary fibrosis, epistaxis (bleeding from the nose),
• hypersensitivity reaction (allergy),
• transient hemianopia (loss or loss of vision in one half of the visual field), syncope, paresthesia (tingling sensation, tingling sensation),
• increased libido,
•Raynaud's syndrome (circulatory disorder in the fingers), loss of consciousness,
• edema and peripheral edema,
• rash, alopecia (hair loss or hair loss),
• cramps in the legs,
• transient decline in hemoglobin after regaining menstruation.

Rare side effects that may affect more than 1 in 10,000 people are listed below:
• stomach pain.

Very rare side effects that may affect less than 1 in 10,000 people are listed below:
• pleural fibrosis.

The frequency of the side effects listed below is not known:
• angina pectoris,
• respiratory disorders, respiratory failure, chest pain,
• sudden access to sleep, shaking,
• abnormal vision,
•aggression, delirium, hypersexuality, pathological gambling (compulsive gambling), mental disorders, hallucinations,
• increased blood levels of muscle enzymes (phosphokinase), abnormal blood tests for liver function.
•Abnormal or unusual thoughts.
•Heart valve and related disorders e.g. inflammation (pericarditis) or leaking of fluid in the pericardium (pericardial effusion). This is a very common side effect (may affect more than 1 in 10 people). The early symptoms may be one or more of the following: difficulty breathing, shortness of breath, pounding heart, feeling faint, chest pain,
back pain, pelvic pain or swollen legs. These may be the first signs of a condition called pulmonary fibrosis, which can affect the lungs, heart/heart valves or lower
back.
•Development of a widespread itchy rash, difficulty breathing with or without wheezing, feeling faint, unexplained swelling of the body or tongue or any other symptoms which appear to come on rapidly after taking this medication and make you feel unwell. These may be indicative of an allergic reaction.

You may experience the following side effects:
•Inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
oStrong impulse to gamble excessively despite serious personal or family consequences.
oAggression and altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
oUncontrollable excessive shopping or spending.
oBinge eating (eating large amounts of food in a short time period) or
compulsive eating (eating more food than normal and more than is
needed to satisfy your hunger).
Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

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 national pharmacovigilance system : Tunisian National Pharmacovigilance Center (CNPV).By reporting side effects you can help provide more information on the safety of this medicine.

5.How to store CABERGOL® ?
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 on the bottle label after EXP. The expiry date refers to the last day of that month.
•Do not store above 25°C.
Do not throw away any medicines via waste water or house hold 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 CABERGOL® contains

	CABERGOL® 0.5mg
Active substance:	
Cabergoline	0.5 mg
Excipients :	
Leucine, anhydrous lactose, magnesium stearate	

What CABERGOL® looks like and contents of the pack:
Each bottle contains 2 scored tablets and is enclosed in an outer cardboard carton. M.A.N°:
Each bottle contains 4 scored tablets and is enclosed in an outer cardboard carton. M.A.N°:
Each bottle contains 8 scored tablets and is enclosed in an outer cardboard carton. M.A.N°:

Delivery condition: List I

Marketing authorisation holder : Les Laboratoires MédiS
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NO0159
V02
This leaflet was last approved in: 01/2020

MédiS

This is a Medicament

-Medicament is a product but not like the others.
-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.

Keep all medicaments out of reach of children