Caber®

Cabergoline

Description

Caber® is the preparation of Cabergoline which is a dopamine receptor agonist. The secretion of prolactin by the anterior pituitary is mainly under hypothalamic inhibitory control, likely exerted through release of dopamine by tuberoinfundibular neurons. Cabergoline is a long acting dopamine receptor agonist with a high affinity for D_2 receptors. Results of *in vitro* studies demonstrate that Cabergoline exerts a direct inhibitory effect on the secretion of prolactin by rat pituitary lactotrophs. Cabergoline decreased serum prolactin levels in reserpinized rats. Receptor binding studies indicate that Cabergoline has low affinity for dopamine D_1, α_1 and α_2 adrenergic and $5HT_1$, $5HT_2$ serotonin receptors.

Indications

Caber® is used to stop breast milk production (lactation) soon after childbirth, stillbirth, abortion or miscarriages. It can also be used if do not want to continue to breastfeed. **Caber**® can also be used to treat other conditions caused by hormonal disturbance which can result in high levels of prolactin being produced. This includes high levels of prolactin caused by tumors of the pituitary gland in both men and women.

Dosage and administration

The recommended dosage of **Caber**® for initiation of therapy is 0.25 mg twice a week. Dosage may be increased by 0.25 mg twice weekly up to a dosage of 1 mg twice a week according to the patient's serum prolactin level. Dosage increases should not occur more rapidly than every 4 weeks, so that the physician can assess the patient's response to each dosage level. If the patient does not respond adequately and no additional benefit is observed with higher doses, the lowest dose that achieved maximal response should be used and other therapeutic approaches considered. After a normal serum prolactin level has been maintained for 6 months, **Caber**® may be discontinued, with periodic monitoring of the serum prolactin level to determine whether or when treatment with **Caber**® should be reinstituted.

- To prevent milk production (lactation): 1 mg (two **Caber**® 0.5 mg tablets) on the first day after delivery.
- To stop lactation once have started to breastfeed: 0.25 mg (one half of **Caber**® 0.5 mg tablet) every 12 hours for two days.
- To reduce prolactin levels in other conditions: Initially take one **Caber**® 0.5 mg tablet (to be taken in two doses) spread out over a week (e.g., half a tablet on Monday and the other half of the tablet on Thursday). Dose will be increased up to a maximum dose of 4.5 mg or until have responded fully to treatment.

Use in pregnancy and lactation

Pregnant or planning to get pregnant, women must discuss with doctor before treatment though cabergoline is pregnancy category B. Pregnant for at least one month, one should stop taking cabergoline, as cabergoline will stop producing milk. If someone plan to breastfeed should not take cabergoline.

Side effects

Some common side effects of cabergoline are nausea, constipation, abdominal pain, dyspepsia, vomiting, headache, dizziness, paresthesia, vertigo, asthenia, fatigue, hot flashes, somnolence, depression, nervousness, postural hypotension, breast pain, dysmenorrhea, abnormal vision, acne, pruritus, pain, arthralgia and rhinitis. Some other less common side effects are facial edema, influenza-like symptoms, malaise, hypotension, syncope, palpitation, dry mouth, flatulence, diarrhea, anorexia, weight loss, weight gain, insomnia, anxiety, nasal stuffiness, epistaxis and increased libido.

Contraindications
Cabergoline is contraindicated in patients with known hypersensitivity to cabergoline or any components of this product. Cabergoline is also contraindicated in patients with uncontrolled hypertension or known hypersensitivity to ergot derivatives.

Warnings and precautions
Dopamine agonists in general should not be used in patients with pregnancy induced hypertension, for example, pre-eclampsia and eclampsia, unless the potential benefit is judged to outweigh the possible risk. Initial doses higher than 1.0 mg may produce orthostatic hypotension. Care should be exercised when administering cabergoline with other medications known to lower blood pressure. Cabergoline is not indicated for the inhibition or suppression of physiologic lactation. Use of bromocriptine, another dopamine agonist for this purpose, has been associated with cases of hypertension, stroke, and seizures. Since cabergoline is extensively metabolized by the liver, caution should be used when administering cabergoline to patients with hepatic impairment. Following diagnosis of pleural effusion or pulmonary fibrosis or valvulopathy, the discontinuance of cabergoline has been reported to result in improvement of signs and symptoms.

Drug interactions
Cabergoline should not be administered concurrently with D_2 antagonists such as phenothiazines, butyrophenones, thioxanthenes or metoclopramide as they can interfere with the effects of cabergoline. There are other medicines such as other ergot alkaloids, medicines to prevent vomiting (metoclopramide), medicines for reducing high blood pressure and macrolide antibiotics (such as erythromycin) that may affect the activity and tolerability of cabergoline.

Overdose
Overdosage might be expected to produce nasal congestion, syncope or hallucinations. Measures to support blood pressure should be taken if necessary.

Pharmaceutical precautions
Store in a cool and dry place protected from light. Keep away from the reach of children.

Presentation
Caber® tablet: Each tablet contains Cabergoline BP 0.5 mg.

Package quantities
Caber® tablet: Carton of 6 tablets is available in 3 Alu-Alu sachet and each sachet contains 2 tablets in Alu-Alu blister pack.

® Registered Trade Mark

Manufactured by
Popular Pharmaceuticals Ltd.
for

Advanced Chemical Industries Limited
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Narayangonj, Bangladesh