

Drug Information Sheet("Kusuri-no-Shiori")

Internal

Revised: 12/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:CABASER Tab. 0.25mg [for galactorrhea, etc.]

Active ingredient:Cabergoline

Dosage form:white tablet, diameter: 5.5 mm, thickness: 2.8 mm

Imprint or print on wrapping:CABASER 0.25mg, カバサーール 0.25mg, company's mark, Pfizer, カベルゴリン, C.



Effects of this medicine

This medicine stimulates dopamine D₂-receptors to suppress excess secretion of prolactin, a kind of hormone that is involved with milk secretion.

It is usually used to suppress milk secretion or to treat ovulation disorder or pituitary gland adenoma (limited to cases that do not require surgical treatment) caused by excessive prolactin secretion. Also it is used to suppress milk secretion in puerperal period.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: heart valve leaflet thickening, heart valve disease such as position limit or accompanying stenosis or its history, pregnant toxicosis, puerperal hypertension, pleurisy, pleural effusion, pleural fibrosis, pulmonary fibrosis, pericarditis, pericardial effusion, retroperitoneal fibrosis or its history, peptic ulcer or gastrointestinal bleeding or its history, Raynaud's disease, mental disease or its history, hypotension, cardiovascular disorder or its history, visual disorder caused by extensive pituitary gland tumor or liver dysfunction or its history.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For galactorrhea, hyperprolactinemic ovulation disorder or hyperprolactinemic pituitary gland adenoma (limited to cases that do not require surgical treatment): In general, for adults, take this medicine once a week (on the same day of the week) before bedtime. Start with taking 1 tablet (0.25 mg of the active ingredient) at a time, and increase the dose by 1 tablet (0.25 mg) in intervals of 2 weeks or more with monitoring the clinical condition, then the maintenance dose [normally 1 to 3 tablets (0.25 to 0.75 mg) at a time] is determined. The dosage may be adjusted according to the age or symptoms. However, the maximum single dose is 4 tablets (1.0 mg).
For suppression of milk secretion in puerperal period: In general, for adults, take 4 tablets (1.0 mg of the active ingredient) only once after delivery of fetus, after a meal.
In any case, strictly follow the instructions.
- Before using this medicine, the sella turcica should be examined for the presence or absence of pituitary gland adenoma. (In patients with galactorrhea or hyperprolactinemic ovulation disorder.)
- If you miss a dose, take the missed dose as soon as possible. Note that dose on the next week should be taken on the same day of the week as you remembered and took the previous dose. You should never take two doses at one time. (In patients with galactorrhea, hyperprolactinemic ovulation disorder or hyperprolactinemic pituitary gland adenoma.)
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist. You may experience nausea, vomiting, stomach discomfort, hallucination (feeling the presence of things that do not really exist), delusions (groundless belief in something untrue, unwillingness to accept logical persuasion), dull headache, dizziness, orthostatic hypotension (weakness, dizziness, lightheadedness, dizziness on standing up, losing consciousness). If some symptoms occur concurrently while taking this medicine, get immediate medical attention.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause sudden sleepiness or dizziness on standing up due to hypotension. Avoid performing dangerous operations such as driving a car, operating machinery or working at heights.
- This medicine may cause valvular disease of heart. If symptoms such as respiratory distress, shortness of breath, easy fatigability, edema, weight gain or palpitation occur, contact your doctor immediately. (In patients with

galactorrhea, hyperprolactinemic ovulation disorder or hyperprolactinemic pituitary gland adenoma.)

- Before using this medicine, the presence or absence of valvular disease of heart should be examined in echocardiographic study. Echocardiographic study should be performed within 3 to 6 months after the start of treatment and then every 6 to 12 months. In addition, physical examination such as auscultation, chest X-rays and CT should be periodically performed. (In patients with galactorrhea, hyperprolactinemic ovulation disorder or hyperprolactinemic pituitary gland adenoma.)
- In patients with hyperprolactinemic pituitary gland adenoma whose pituitary gland tumor has grown, cerebrospinal fluid rhinorrhea may occur and result in meningitis. If symptoms such as fever, headache, nausea or vomiting occur, contact your doctor immediately.
- In patients with hyperprolactinemic pituitary gland adenoma associated with visual field disorder, visual field disorder may improve and then reappear. If any abnormalities are observed, contact your doctor immediately.
- Supportive treatment such as ice pack method (cooling breasts with ice pack) may be concomitantly performed. (In patients with suppression of milk secretion in puerperal period.)
- If you want to become pregnant, you should perform pregnancy test periodically to confirm pregnancy early.
- Women who do not want to become pregnant should avoid pregnancy.
- If you take this medicine for a long period of time, general gynecological examination should be performed periodically. (In patients with galactorrhea, hyperprolactinemic ovulation disorder or hyperprolactinemic pituitary gland adenoma.)

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea and headache. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- feeling the presence of things that do not really exist, groundless belief in something untrue, losing consciousness [hallucination, delusions, syncope, delirium, confusion]
- fever, dry cough, dyspnea [interstitial pneumonia]
- chest pain, edema, dyspnea [pleurisy, pleural effusion, pleural fibrosis, pulmonary fibrosis, pericarditis, pericardial effusion]
- respiratory distress/shortness of breath, edema, palpitation [valvular disease of heart]
- back pain, edema of feet, decreased urine output [retroperitoneal fibrosis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius), away from light and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.
- [To family members] Impulse control disorders (pathological gambling, pathological increase in sexual desire, excessive unplanned shopping and gluttony) may appear to the patients. Please pay attention to language and behavior of patients. If any of these symptoms occur, consult with the doctor.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.