

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

Internal

Revised: 09/2022

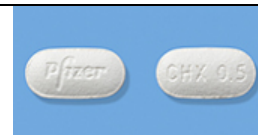
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:CHAMPIX Tablets 0.5mg

Active ingredient:Varenicline tartrate

Dosage form:white tablet, major axis: 8 mm, minor axis: 4 mm, thickness: 3 mm

Imprint or print on wrapping:チャンピックス 0.5mg, CHAMPIX 0.5mg, CHX 0.5,
pfizer



Effects of this medicine

This medicine shows a partial agonist effect (stimulating and antagonistic actions) by binding to $\alpha_4\beta_2$ nicotine receptors in the brain instead of nicotine. It helps to decrease withdrawal symptoms due to smoking cessation and desire to smoke by enhancing a small amount of free-dopamine with the stimulating action. It also suppresses a feeling of satisfaction due to smoking by inhibiting the binding of nicotine to $\alpha_4\beta_2$ nicotine receptors with the antagonistic action when you smoke while taking this medicine.

It is usually used for helping smokers with nicotine addiction to quit smoking.

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: mental disorders such as schizophrenia/bipolar disorder/depression or renal dysfunction.
If you are on hemodialysis.
- 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))
- In general, for adults, start with taking 0.5 mg of varenicline at a time, once a day, after a meal on the first to third day. From the fourth to the seventh day, take 0.5 mg at a time, twice a day, after breakfast and supper. After the eighth day, take 1 mg at a time, twice a day, after breakfast and supper. Medication period should be 12 weeks. This preparation contains 0.5 mg of varenicline in a tablet. Strictly follow the instructions.
- When you start taking this medicine, you will be asked about smoking conditions, health status while smoking and others in a medical interview. And then, your intention to discontinue smoking will be confirmed.
- Consult with your doctor and set a date for starting smoking cessation. Then, start this medicine from 1 week before the date and continue the treatment for 12 weeks.
- If you do not tolerate the dosage, it may be decreased to one tablet (0.5 mg of varenicline) at a time after the eighth day. Also, if you have any severe renal dysfunction, start with taking one tablet (0.5 mg) at a time, once a day. Then, the dose frequency may be increased up to twice a day, as necessary.
- Before taking this medicine, Tobacco Dependence Screener (TDS) is performed.
- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- To maintain smoking cessation, you will receive anti-smoking education from doctors based on smoking cessation treatment.
- During smoking cessation, discomfort, depressed mood, insomnia, irritability, frustration, anger, anxiety, difficulty in concentration, restlessness, decreased heart rate, increased appetite and weight gain are frequently observed. It has been reported that the same symptoms also occur or worsen while taking this medicine. In addition, patients with mental illness may experience aggravation of the symptoms.
- Symptoms such as depressed mood, anxiety, irritated feeling, easily excited, change in behavior and thought, mental disorder, mood alteration, aggression, hostility and feeling like dying may occur, though relationship with this medicine is unknown. If any of these symptoms occur, discontinue the use of this medicine and contact your doctor immediately.
- This medicine may cause dizziness, sleepiness or consciousness disorder and there is a case resulted in car

accident. Do not operate dangerous machinery, such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, insomnia, abnormal dream, headache, flatulence and constipation. 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.

- skin eruption, fever, skin redness [oculomucocutaneous syndrome, erythema multiforme]
- swelling of the face/tongue/lips/throat, hives, breathing difficulty [angioedema]
- decreased consciousness, difficulty in thinking, poor judgment [consciousness disturbance]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]

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 direct sunlight 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.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.