

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Champix® 0.5 mg
Champix® 1.0 mg
Film-coated tablets**

varenicline (as tartrate) 0.5 mg, 1 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is intended for adults over the age of 18.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Champix is indicated as a medicinal aid to smoking cessation in adults over 18.

Therapeutic group:

selective partial agonist of nicotinic receptor.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine, listed in section 6.
Signs of this could be swelling of the face, tongue, lips, gums, throat or neck, trouble breathing, rash including skin peeling, blisters in your mouth.

Special warnings regarding use of the medicine

Before treatment with Champix, tell your doctor if:

- You are pregnant, plan to become pregnant and/or are breastfeeding.
- You have or have had in the past impaired function of the heart and/or blood vessels, kidney/urinary system, seizures, or any other medical condition.
- You have had in the past depression or other mental health conditions. Tell your doctor about symptoms you had during previous times you tried to quit smoking, with or without Champix.
- You are sensitive to any food or medicine, tell your doctor before taking the medicine.
- There is a change in your mood and behavior.
There have been reports of suicide attempts or suicidal thoughts in patients treated with Champix. Pay attention to changes in mood, anxiety, psychoses, violent behavior, depression, or worsening of existing depression.
- This is a repeated attempt to quit. Tell your doctor about any sign that occurred, even if it is an attempt to quit smoking with or without Champix.
- If you consume alcohol. If you consume alcohol during treatment with Champix, decrease the amount you consume until you know what the combined effect of this medicine and alcohol is. Some patients who consumed alcohol when taking this medicine experienced increased drunkenness, aggressive or unusual behavior, forgetfulness.

When you try to quit smoking, with or without Champix, you may have signs that are related to nicotine withdrawal, such as the urge to smoke, depression, trouble sleeping, irritability, frustration, anger, feeling anxious, difficulty concentrating, restlessness, decreased heart rate, increased appetite and weight gain.

Some people have experienced suicidal thoughts when trying to quit smoking with or without medication.

Monitoring kidney function in the elderly is recommended.

If you experience any of these signs or any other worrying behavior pattern - stop the treatment and contact your doctor immediately!

Children and adolescents

There is no information regarding the safety and effectiveness of using this medicine in children. This medicine is intended for adults over the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking:

- cimetidine (used to reduce acidity in the stomach) as it may increase the activity of Champix in your body.
- other medicines to quit smoking (such as bupropion, nicotine). Using Champix with nicotine patches may cause nausea, headache, vomiting, tiredness, dizziness, and upset stomach to happen more often than if you just use nicotine patches alone. It is not known if Champix is safe and effective when used with other stop smoking medicines.
- stopping smoking (with or without Champix treatment) can affect the activity of medicines such as medicines for asthma, medicines for diabetes, digoxin, anticoagulants, therefore consult your doctor as dosage adjustment may be necessary.

Using this medicine and food

Take this medicine with a full glass of water after eating.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant or if you are breastfeeding, ask your doctor for advice about the risks of smoking for a pregnant woman and her unborn baby, the possible risks of taking Champix during pregnancy and breastfeeding, and the benefits of quitting smoking with or without Champix.

It is not known if Champix passes into breast milk. If you are breastfeeding and taking Champix, monitor your baby to see if seizures as well as spitting up or vomiting occur more often than normal.

Driving and using machines

Starting this medicine can impair alertness so caution is necessary when driving, operating dangerous machines and during any other activity that requires alertness until you know how you are affected by the medicine and/or by stopping smoking.

Important information about some of this medicine's ingredients

Champix contains sodium.

Champix contains less than 1 millimole sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

- Medicine dosage:

The dosage and treatment regimen will be determined by your doctor only.

For the 4-week starter pack:

The standard dosage is usually:

Days 1-3: Take one white tablet (0.5 mg) once a day.

Days 4-7: Take one white tablet (0.5 mg) twice a day (morning and evening).

Day 8 and on: Take one blue tablet (1.0 mg) twice a day (morning and evening).

For the pack that contains only the 0.5 mg dosage:

The standard dosage is usually:

Days 1-3: Take one white tablet (0.5 mg) once a day.

Day 4 and on: Take one white tablet (0.5 mg) twice a day (morning and evening).

For the pack that contains only the 1.0 mg dosage:

When you have finished taking the tablets from the starter pack, starting on Day 29 and on:
Take one blue tablet (1.0 mg) twice a day (morning and evening).

It is advisable to take this medicine at the same time each day.

• Quit date:

There are 3 ways that you can take Champix to help you quit smoking. Talk to your doctor about the following three possibilities:

1. Choose a quit date when you will stop smoking. Start taking Champix 1 week (7 days) before your quit date. Take Champix for 12 weeks.
- or
2. Start taking Champix before you choose a quit date. Pick a date to quit smoking that is between Day 8 and Day 35 of treatment. Take Champix for 12 weeks.
- or
3. If you are sure that you are not able or willing to quit smoking right away, start taking Champix and reduce smoking during the first 12 weeks of treatment, as follows:

Weeks 1-4	Reduce your smoking to reach one half of your starting daily number of cigarettes. For example: If you usually smoke 20 cigarettes each day, reduce your smoking to 10 cigarettes each day during weeks 1 through 4.
Weeks 5-8	Reduce your smoking to reach one quarter of your starting daily number of cigarettes. For example: If you usually smoke 20 cigarettes each day, reduce your smoking to 5 cigarettes each day during weeks 5 through 8.
Weeks 9-12	Keep reducing your smoking until you are no longer smoking (0 cigarettes each day).

Aim to quit smoking by the end of the 12th week, or sooner if you feel ready. Continue to take Champix for another 12 weeks, for a total of 24 weeks of treatment.

- ❖ Starting Champix before your quit date gives Champix time to build up in your body. You can keep smoking during this time. Take Champix according to your doctor's instructions.
- ❖ You should try to stop smoking on your quit date. If you slip-up and smoke, try again. Some people need to take Champix for a few weeks for Champix to work better.
- ❖ Most people will take Champix for up to 12 weeks. If you have completely quit smoking by 12 weeks, your doctor may prescribe Champix for another 12 weeks to help you stay cigarette-free.
- ❖ This dosing schedule may not be right for everyone. Talk to your doctor if you are having side effects such as nausea, strange dreams, or sleep problems. Your doctor may want to reduce your dose.

Do not exceed the recommended dose.

Do not crush/split/chew because the tablets are film-coated.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package with you.

If you forget to take this medicine at the scheduled time

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember unless it is time for the next dose. Do not take a double dose!

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Champix may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using this medicine and get immediate medical attention:

if you experience a heart attack. The symptoms of this include:

- Pressure or pain or fullness in the chest that happens repeatedly or lasts more than a few minutes.
- pain or discomfort in one or both arms, back, neck, jaw or stomach pain.
- shortness of breath, sweating, nausea, vomiting, feeling lightheaded associated with chest discomfort.

Stop using this medicine and contact your doctor immediately if you experience any of the following symptoms:

- swelling of the face, tongue, lips, gums, throat or neck.
- trouble breathing.
- rash including peeling of the skin.
- blisters in your mouth.

Serious side effects:

- **Seizures** (in most cases occurring during the first month of taking the medicine). If you have a seizure during the treatment, stop the treatment and contact your doctor right away.
- **New or worse heart or blood vessel problems**, mostly in patients who already have a heart and blood vessel disease. Inform your doctor of any change in signs and symptoms.
- **Allergic reaction** - may be life-threatening.
- **Skin side effects** - rash, swelling, redness, or skin peeling - may be life-threatening.
- **Sleepwalking** can happen with Champix, and can sometimes lead to behavior that is harmful to you or other people, or to property. Stop taking Champix and contact your doctor if you start sleepwalking.
- **New or worse mental health conditions, such as changes in behavior or thinking, aggression, hostility, agitation, depressed mood, or suicidal thoughts or suicide attempts.** Some people get these symptoms when they begin taking Champix, and others develop them after several weeks of treatment, or after stopping the treatment. These symptoms happen more often in people who have a history of mental health conditions.

Stop taking Champix and call your doctor right away if you, your family or caregiver notice any of these symptoms. Decide with your doctor whether you should continue to take Champix. In many people these symptoms go away after stopping Champix, but in some people symptoms continue after stopping Champix. It is important for you to follow-up with your doctor until your symptoms go away.

Very common side effects:

nausea, sleeping problems (difficulty falling asleep, strange dreams), constipation, gas, vomiting.

Other side effects include:

changes in blood count, chest discomfort, disturbed hearing, ringing in your ears, thyroid function disorders, conjunctivitis, eye pain, disturbed vision, sensitivity to light, dry eyes, diarrhea, tooth pain, abdominal pain, indigestion, irritation of the stomach, heartburn, stomach ulcer, inflammation of the esophagus, mouth ulcers, altered sense of taste, increased or decreased appetite, dry mouth, red blood in your stools, belching, chest pain, flu-like illness, fever, changes in tests for liver and kidney function, weight gain, diabetes, reduced blood sugar level, changes in electrolyte balance, headache, dizziness, reduced sense of touch, difficulty speaking, joint pain, muscle pain, back pain, muscle cramps, reduced libido, passing urine frequently, urinating at night, increase in volume of urine and in frequency of passing urine, disturbed menstruation, problems with sexual function, inflammations of the respiratory tract, shortness of breath, inflammation of the nose, sinuses, and throat, increased discharge from the nose, acne, dry skin, eczema, itching, hot flushes, tiredness, tremor, sleepiness, lethargy, excessive sweating, feeling generally unwell or weakness.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

microcrystalline cellulose, dibasic calcium phosphate anhydrous, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, Opadry® White (in 0.5 mg tablets), Opadry® Blue (in 1.0 mg tablets), Opadry® Clear.

What the medicine looks like and contents of the pack:

Champix 0.5 mg: Creamy-white film-coated tablet with the word "Pfizer" imprinted on one side and "CHX 0.5" on the other.

Champix 0.5 mg is marketed in a blister of 11 tablets in a carton.

Champix 1.0 mg: Light blue film-coated tablet with the word "Pfizer" imprinted on one side and "CHX 1.0" on the other.

Champix 1.0 mg is marketed in a blister of 14 tablets, available in a pack of 56 tablets.

There is a combined pack of Champix 0.5 mg and 1.0 mg. The pack contains 11 tablets of 0.5 mg and 42 tablets of 1 mg.

Not all pack sizes and types may be marketed.

Registration holder's name and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Champix 0.5 mg: 137.66.31510.00

Champix 1.0 mg: 137.67.31511.00

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