

PACKAGE LEAFLET: INFORMATION FOR THE USER
CHAMPIX 0.5 mg film-coated tablets
CHAMPIX 1 mg film-coated tablets

Varenicline

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What CHAMPIX is and what it is used for
2. Before you take CHAMPIX
3. How to take CHAMPIX
4. Possible side effects
5. How to store CHAMPIX
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1. WHAT CHAMPIX IS AND WHAT IT IS USED FOR

CHAMPIX is a medicine which is used in adults to help them stop smoking.

CHAMPIX can help to relieve the craving and withdrawal symptoms associated with stopping smoking.

Although you are not recommended to smoke after your quit date, CHAMPIX can also reduce the enjoyment of cigarettes if you do smoke when on treatment. (The quit date is the day in the second week of treatment when you will stop smoking, see Section 3.)

2. BEFORE YOU TAKE CHAMPIX

Do not take CHAMPIX

- If you are allergic (hypersensitive) to varenicline tartrate or any of the other ingredients of CHAMPIX

Take special care with CHAMPIX

There have been reports of depression, suicidal ideation and behaviour and suicide attempts in patients taking CHAMPIX. If you are taking CHAMPIX and develop agitation, depressed mood, changes in behaviour that are of concern to you, your family or doctor or if you develop suicidal thoughts or behaviours you should stop your treatment and contact your doctor immediately.

The effects of stopping smoking

The effects of changes in your body resulting from stopping smoking, with or without treatment with CHAMPIX, may alter the way other medicines work. Therefore, in some cases an adjustment of the dose may be necessary. See below under 'Taking other medicines' for further details.

For some people, stopping smoking with or without treatment has been associated with an increased risk of experiencing changes in thinking or behaviour, feelings of depression and anxiety and can be associated with a worsening of psychiatric illness. If you have a history of psychiatric illness you should discuss this with your doctor or pharmacist.

Depressed mood may appear during smoking cessation with or without treatment. Depression, rarely including suicidal thoughts and suicide attempt, has been reported in patients undergoing a smoking cessation attempt. These feelings have also been reported while attempting to quit smoking with CHAMPIX. If these symptoms persist when you stop taking CHAMPIX, your doctor should continue to monitor you closely until you are feeling better.

Patients with cardiovascular disease

New or worse heart or blood vessel (cardiovascular) problems have been reported in people who already have cardiovascular problems. Tell your doctor if you have any changes in symptoms during treatment with CHAMPIX. Get emergency medical help right away if you have symptoms of a heart attack.

Stopping treatment with CHAMPIX

You may temporarily experience increased irritability, urge to smoke, depression and/or sleep disturbances when you stop taking CHAMPIX. Your doctor may decide to gradually lower your dose of CHAMPIX at the end of treatment.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effects of changes in your body resulting from stopping smoking, with or without treatment with CHAMPIX, may alter the way other medicines work. Therefore, in some cases an adjustment of the dose may be necessary. Examples include theophylline (a medicine to treat breathing problems), warfarin (a medicine to reduce blood clotting), and insulin (a medicine to treat diabetes). If in doubt, you should consult your doctor or pharmacist.

If you have severe kidney disease you should avoid taking cimetidine (a medicine used for gastric problems) at the same time as CHAMPIX as this may cause increased blood levels of CHAMPIX.

Use of CHAMPIX with other therapies for smoking cessation

The safety and benefits of taking CHAMPIX in combination with other medicines for stopping smoking have not been studied. CHAMPIX in combination with other smoking cessation therapies is therefore not recommended.

CHAMPIX is not recommended for use in children or adolescents below 18 years as safety and efficacy have not been established in this age group.

Taking CHAMPIX with food and drink

CHAMPIX can be taken with or without food.

Pregnancy and breast-feeding

You should not take CHAMPIX while you are pregnant.

Talk to your doctor if you are intending to become pregnant. If you want to start treatment with CHAMPIX, your treatment should be timed so that you have completed the course before becoming pregnant.

Although it was not studied, CHAMPIX may pass into breast milk. You should ask your doctor or pharmacist for advice before taking CHAMPIX.

Driving and using machines

CHAMPIX may produce dizziness and sleepiness. You should not drive, operate complex machinery or engage in any other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

3. HOW TO TAKE CHAMPIX

You are more likely to stop smoking if you are motivated to stop. Your doctor and pharmacist can provide advice, support and sources of further information to help ensure your attempt to stop smoking is successful.

Always take CHAMPIX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Before starting your course of CHAMPIX you should usually decide on a date in the second week of treatment (between day 8 and day 14) when you will stop smoking. If you are not willing or able to set a target quit date within 2 weeks, you may choose your own target quit date within 5 weeks after starting treatment. You should write this date on the pack as a reminder.

CHAMPIX tablets should be swallowed whole with water.

CHAMPIX comes as a white tablet (0.5 mg) and a blue tablet (1 mg). You start with the white tablet and then usually go to the blue tablet. See the chart below for the usual dosing instructions which you should follow from Day 1.

| Week 1 | Dose |
|---------------------|---|
| Day 1 - 3 | From day 1 to day 3, you should take one white CHAMPIX 0.5 mg film-coated tablet once a day. |
| Day 4 - 7 | From day 4 to day 7, you should take one white CHAMPIX 0.5 mg film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day. |
| Week 2 | |
| Day 8 – 14 | From day 8 to day 14, you should take one light blue CHAMPIX 1 mg film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day. |
| Weeks 3 - 12 | |

| | |
|---------------------------|---|
| Day 15 - end of treatment | From day 15 until the end of treatment, you should take one light blue CHAMPIX 1 mg film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day. |
|---------------------------|---|

If you have problems with your kidneys, you should speak to your doctor before taking CHAMPIX. You may need a lower dose.

Should you experience adverse effects that you cannot tolerate your doctor may decide to reduce your dose temporarily or permanently to 0.5 mg twice daily.

After 12 weeks of treatment, if you have stopped smoking, your doctor may recommend an additional 12 weeks of treatment with CHAMPIX 1 mg film-coated tablets twice daily.

In smoking cessation therapy, risk of returning to smoking may be elevated in the period immediately following the end of treatment. Your doctor may decide to gradually lower your dose of CHAMPIX at the end of treatment.

If you take more CHAMPIX than you should

If you accidentally take more CHAMPIX than your doctor prescribed, you must seek medical advice or go to the nearest hospital casualty department immediately. Take your box of tablets with you.

If you forget to take CHAMPIX

Do not take a double dose to make up for a forgotten tablet. It is important that you take CHAMPIX regularly at the same time each day. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the tablet that you have missed.

If you stop taking CHAMPIX

It has been shown in clinical trials that taking all doses of your medicine at the appropriate times and for the recommended duration of treatment described above will increase your chances of stopping smoking. Therefore, unless your doctor instructs you to stop treatment, it is important to keep taking CHAMPIX, according to the instructions described in the table above.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Giving up smoking with or without treatment can cause various symptoms. These could include changes of mood (like feeling depressed, irritable, frustrated or anxious), sleeplessness, difficulty concentrating, decreased heart rate and increased appetite or weight gain.

Like all medicines, CHAMPIX can cause side effects, although not everybody gets them.

If you are taking CHAMPIX and develop agitation, depressed mood, changes in behaviour or suicidal thoughts you should stop your treatment and contact your doctor immediately.

- Very common side effects which may affect more than 1 person in 10 are listed below:
 - Headache, difficulty sleeping, abnormal dreams
 - Nausea

- Common side effects which may affect more than 1 person in 100 are listed below:
 - Increased appetite, changes in the way things taste, dry mouth
 - Sleepiness, tiredness, dizziness
 - Vomiting, constipation, diarrhoea, feeling bloated, stomach discomfort, indigestion, flatulence

- Uncommon side effects which may affect more than 1 person in 1,000 are listed below:
 - Chest infection, discomfort or pain, inflammation of the sinuses,
 - Fever, feeling cold, feeling weak or unwell, viral infection, shortness of breath, cough, hoarseness, throat pain and irritation, congested sinuses, runny nose, snoring
 - Loss of appetite, feeling thirsty, increased weight
 - Depression, anxiety, hallucinations
 - Feeling of panic, difficulty thinking, mood swings
 - Tremor, difficulty with coordination, difficulty with speech, less sensitive to touch, increased muscle tension, restlessness,
 - Heart rhythm disturbances, increased blood pressure, increased heart rate
 - Disturbed vision, eyeball discolouration, eye pain, dilated pupils, shortsightedness, sensitivity to light, watery eyes
 - Ringing in the ears
 - Blood in vomit, irritated stomach and heartburn, abdominal pain, abnormal stools, red blood in stools, belching, mouth ulcers, pain in the gums, coated tongue
 - Skin rash, cyst, fungal infection, reddening of the skin, itching, acne, increased sweating
 - Chest wall and rib pain, stiff joints, muscle spasms
 - Glucose in urine, increased urine volume and frequency
 - Increased menstrual flow, vaginal discharge, changes in sex drive or ability

- Rare side effects which may affect less than 1 person in 1,000 is stroke.

Other side effects have occurred in a small number of people attempting to quit smoking with CHAMPIX, but their exact frequency is unknown: heart attack, changes in thinking or behaviour (such as aggression and abnormal behaviour), suicidal thoughts, diabetes, high blood sugar and sleep walking. There have also been reports of serious allergic reactions including angioedema (swelling of the face, mouth, or throat) and skin reactions including Erythema Multiforme (a type of rash) and Stevens-Johnson Syndrome (a serious illness with blistering of the skin, mouth, around the eyes or genitals). You should stop taking CHAMPIX and contact your doctor immediately if you develop swelling of the face, mouth or throat, or if your skin starts to peel or blister.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CHAMPIX

Keep out of the reach and sight of children.

Do not use CHAMPIX after the expiry date which is stated on the card packaging or carton.

The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What CHAMPIX contains

- The active substance is 0.5 mg varenicline and 1 mg varenicline respectively
- The other ingredients are:

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|---|
| Tablet Core - CHAMPIX 0.5 mg and 1 mg film-coated tablets |
| Cellulose, Microcrystalline Calcium Hydrogen Phosphate Anhydrous Croscarmellose Sodium Silica, Colloidal Anhydrous Magnesium Stearate |

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| Tablet film coating - CHAMPIX 0.5 mg film-coated tablets |
| Hypromellose Titanium dioxide (E171) Macrogols Triacetin |

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|---|
| Tablet film coating - CHAMPIX 1 mg film-coated tablets |
| Hypromellose Titanium dioxide (E171) Macrogols Indigo Carmine Aluminium Lake (E132) Triacetin |

What CHAMPIX 0.5 mg and 1 mg film-coated tablets look like and contents of the pack

- CHAMPIX 0.5 mg film-coated tablets are white, film-coated, modified capsular shaped tablets, marked “Pfizer” and “CHX 0.5”
- CHAMPIX 1 mg film-coated tablets are light blue film-coated, modified capsular shaped tablets, marked “Pfizer” and “CHX 1.0”

CHAMPIX is available in the following pack presentations:

Not all pack sizes may be marketed.

- A treatment initiation pack containing 2 blisters; 1 clear blister of 11 x CHAMPIX 0.5 mg film-coated tablets and 1 clear blister of 14 x CHAMPIX 1 mg film-coated tablets in card packaging.
- A treatment initiation pack containing 2 blisters; 1 clear blister of 11 x CHAMPIX 0.5 mg and 14 x 1 mg film-coated tablets and 1 clear blister of 28 x CHAMPIX 1 mg film-coated tablets in card packaging.
- A follow-on (maintenance) pack containing 2 clear blisters of 14 x CHAMPIX 1 mg film-coated tablets in card packaging.
- A follow-on (maintenance) pack containing 2 clear blisters of 28 x CHAMPIX 1 mg film-coated tablets in card packaging.
- A follow-on (maintenance) pack containing 2 clear blisters of 14 x CHAMPIX 0.5 mg film-coated tablets in card packaging.
- A follow-on (maintenance) pack containing 2 clear blisters of 28 x CHAMPIX 0.5 mg film-coated tablets in card packaging.
- A treatment initiation pack containing 2 blisters; 1 clear blister of 11 x CHAMPIX 0.5 mg film-coated tablets and 1 clear blister of 14 x CHAMPIX 1 mg film-coated tablets in a carton.
- A follow-on (maintenance) pack containing 2 clear blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.
- A follow-on (maintenance) pack containing 4 clear blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.
- A follow-on (maintenance) pack containing 8 clear blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.
- A follow-on (maintenance) pack containing 10 clear blisters of 14 x CHAMPIX 1 mg film-coated tablets in a carton.
- A sealed blue white HDPE bottle pack, with a child resistant screw cap, in a carton, containing 56 x CHAMPIX 1 mg film-coated tablets.
- A sealed blue white HDPE bottle pack, with a child resistant screw cap, in a carton, containing 56 x CHAMPIX 0.5 mg film-coated tablets.

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Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>

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