

Package leaflet: Information for the user

CHAMPIX 0.5 mg film-coated tablets CHAMPIX 1 mg film-coated tablets Varenicline

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CHAMPIX is and what it is used for
2. What you need to know before you take CHAMPIX
3. How to take CHAMPIX
4. Possible side effects
5. How to store CHAMPIX
6. Contents of the pack and other information

1. What CHAMPIX is and what it is used for

CHAMPIX contains the active substance varenicline. 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. What you need to know before you take CHAMPIX

Do not take CHAMPIX:

- If you are allergic to varenicline tartrate or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 'Other medicines and CHAMPIX' 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.

Cardiovascular symptoms

New or worse heart or blood vessel (cardiovascular) problems have been reported primarily 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 or stroke.

Seizures

Tell your doctor if you have experienced seizures or have epilepsy before you start CHAMPIX treatment. Some people have reported seizures while taking CHAMPIX.

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.

Children and adolescents

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

Other medicines and CHAMPIX

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 with food and drink

CHAMPIX can be taken with or without food.

CHAMPIX may increase the effects of alcohol.

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 this medicine exactly as your doctor has told you. 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. |

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 to help avoid returning back to smoking.

If you are not able or willing to quit smoking straight away, you should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. You should then continue to take CHAMPIX 1mg film-coated tablets twice daily for a further 12 weeks resulting in a total of 24 weeks of treatment.

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.

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

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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.

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 in 10 people are listed below:

- Inflammation of the nose and throat, abnormal dreams, difficulty sleeping, headache,
 - Nausea
- Common side effects which may affect up to 1 in 10 people are listed below:
- Chest infection, inflammation of the sinuses
 - Increased weight, decreased appetite, increased appetite
 - Sleepiness, dizziness, changes in the way things taste
 - Shortness of breath, cough
 - Heartburn, vomiting, constipation, diarrhoea, feeling bloated, abdominal pain, toothache indigestion, flatulence, dry mouth
 - Skin rash, itching
 - Joint ache, muscle ache, back pain
 - Chest pain, tiredness
- Uncommon side effects which may affect up to 1 in 100 people are listed below:
- Fungal infection, viral infection
 - Feeling of panic, difficulty thinking, restlessness, mood swings, depression, anxiety, hallucinations, changes in sex drive
 - Seizure, tremor, feeling sluggish, less sensitive to touch
 - Conjunctivitis, eye pain
 - Ringing in the ears
 - Angina, rapid heart rate, palpitations, increased heart rate
 - Increased blood pressure, hot flush
 - Inflammation of nose, sinuses and throat, congestion of nose, throat and chest, hoarseness, hay fever, throat irritation, congested sinuses, excess mucous from nose causing cough, runny nose
 - Red blood in stools, irritated stomach, change of bowel habit, belching, mouth ulcers, pain in the gums
 - Reddening of the skin, acne, increased sweating, night sweats
 - Muscle spasms, chest wall pain
 - Abnormally frequent urination, urination at night
 - Increased menstrual flow,
 - Chest discomfort, flu like illness, fever, feeling weak or unwell
- Rare side effects which may affect up to 1 in 1,000 people are listed below:
- Excessive thirst
 - Feeling unwell or unhappy, slow thinking
 - Stroke
 - Increased muscle tension, difficulty with speech, difficulty with coordination, reduced sense of taste, altered sleep pattern
 - Disturbed vision, eyeball discolouration, dilated pupils, sensitivity to light, shortsightedness, watery eyes
 - Irregular heart beat or heart rhythm disturbances
 - Throat pain, snoring
 - Blood in vomit, abnormal stools, coated tongue
 - Stiff joints, rib pain
 - Glucose in urine, increased urine volume and frequency
 - Vaginal discharge, changes in sexual ability
 - Feeling cold, cyst

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, suicidal thoughts, loss of contact with

reality and unable to think or judge clearly (psychosis), changes in thinking or behaviour (such as aggression and abnormal behaviour), sleep walking, diabetes and high blood sugar. There have also been reports of severe 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) and serious allergic reactions including angioedema (swelling of the face, mouth, or throat). You should stop taking CHAMPIX and contact your doctor immediately if your skin starts to peel or blister, or if you develop swelling of the face, mouth or throat.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store CHAMPIX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the card packaging or carton. The expiry date refers to the last day of that month.

Blisters: Store below 30°C

Bottle: This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CHAMPIX contains

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

| 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 |

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

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

What CHAMPIX looks 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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Limited
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer

R-Pharm Germany GmbH
Heinrich-Mack-Str. 35
89257 Illertissen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Pfizer Limited
Tel: + 44 (0) 1304 616161

Ireland

Pfizer Healthcare Ireland

Tel: 1800 633 363 (toll free)
+44 (0) 1304 616161

Malta

V.J. Salomone Pharma Ltd.
Tel : +356 21220174

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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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