

CHAMPIX[®]

Varenicline tartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CHAMPIX. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CHAMPIX against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What CHAMPIX is used for

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

CHAMPIX is a medicine prescribed by your doctor as a short term treatment to help you stop smoking. It can help to relieve the craving and withdrawal symptoms associated with stopping smoking.

Although it is not recommended that you smoke while taking treatment, CHAMPIX will reduce the enjoyment of cigarettes if you do smoke when on treatment.

Your doctor will also recommend that you undertake counselling to assist you further to stop smoking.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your

doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you take CHAMPIX

When you must not take it

You must not take CHAMPIX if you have an allergy to:

- any medicine containing varenicline tartrate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant. It may affect your developing baby.

Do not take CHAMPIX after the expiry date printed on the carton or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems or if you have to undergo haemodialysis treatment.
- repeated fits or convulsions.

CHAMPIX has not been studied in patients with these problems.

Tell your doctor if you have a history of mental illness.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you take CHAMPIX.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This includes other medications to help you stop smoking such as nicotine replacement treatments including patches gum or inhalers (eg. Nicorette, Nicabate, QuitX) and bupropion (Zyban) tablets.

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

Some medicines and CHAMPIX may interfere with each other.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

23/01/07

Use in children

CHAMPIX tablets are not recommended for use in children less than 18 years.

How to take CHAMPIX.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

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.

How much to take

Before starting your course of CHAMPIX you should decide on a date in the second week of treatment (between day 8 and day 14) when you will stop smoking. You should write this date on the pack as a reminder. You will need to keep taking the full 12-week course of CHAMPIX tablets even though you stop smoking in the second week.

Your doctor may recommend that you take a second course of treatment with CHAMPIX. This is usually for another 12 weeks. This may be the case where you have stopped smoking but your doctor feels that you would benefit by another course of CHAMPIX.

Week 1

Day 1 - 3. From Day 1 to 3, you should take one white CHAMPIX 0.5 mg tablet once a day.

Day 4 - 7. From day 4 to day 7, you should take one white CHAMPIX

0.5 mg tablet twice a day, once in the morning and once in the evening,

Week 2

Day 8 - 14. From day 8 to day 14, you should take one light blue CHAMPIX 1 mg tablet twice a day, once in the morning and once in the evening,

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 tablet twice a day, once in the morning and once in the evening. After 12 weeks of treatment, if you have stopped smoking, your doctor may recommend another 12 weeks of treatment with CHAMPIX. This will increase your chances of stopping smoking long term. For this course take one light blue CHAMPIX 1 mg tablet twice a day.

If you do not stop smoking during the first 12 weeks of treatment or if you start smoking again after treatment, you can make another attempt at stopping smoking. However, before you make another attempt, you should try to understand the reasons why your attempt to stop smoking failed, so that your next attempt has a better chance of success.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much CHAMPIX. Take your tablets with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using CHAMPIX

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CHAMPIX.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately. 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.

Things you must not do

Do not take CHAMPIX to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. It is important to keep taking CHAMPIX, according to the instructions described above.

Things to be careful of

Be careful driving or operating machinery until you know how CHAMPIX affects you. However, CHAMPIX should not affect your ability to drive or use machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CHAMPIX. This medicine helps most people give up smoking, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Headache, difficulty sleeping, sleepiness, abnormal dreams, dizziness, feeling weak.
- Constipation, feeling bloated, indigestion, flatulence, dry mouth
- Nausea (feeling sick), vomiting, stomach discomfort
- Increased appetite, changes in taste

The above list includes the more common side effects which may be

caused by your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Tremor, increased muscle tension, abnormal co-ordination
- Abnormal heartbeat, increased heartbeat, chest pain
- Disturbed vision, pain in the eye, shortsightedness, sensitivity to light
- Blood in vomit, red blood in stools, abdominal pain, mouth ulcers, pain in the gums;
- Skin rash, reddening of the skin, itching

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing, difficulty in breathing or shortness of breath
- severe chest pain
- seizures or fits
- fainting
- swelling of the face, lips, mouth, tongue or throat
- severe sudden onset of itchy swellings on the skin
- severe skin reaction with painful red blisters with chills, fever, aching muscles and generally feeling unwell

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After stopping CHAMPIX you may notice an increase in irritability, urge to smoke, depression, and/or trouble sleeping. This does not happen in

everyone. However, if this does occur you should talk to your doctor.

After using CHAMPIX

Storage

Keep your tablets in the pack until it is time to take them.

CHAMPIX should be stored in a cool dry place where the temperature stays below 30 degrees

Do not store CHAMPIX or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

CHAMPIX 0.5mg tablets are white, film-coated, modified capsular shaped tablets marked "Pfizer" on one side and "CHX 0.5" on the other.

CHAMPIX 1.0mg tablets are light blue, film-coated, modified capsular shaped tablets, marked "Pfizer" on one side and "CHX 1.0" on the other.

A combination pack containing 11 x CHAMPIX 0.5 mg tablets and 14 x CHAMPIX 1 mg tablets is available to assist with the initial

dose schedule required when commencing CHAMPIX.

For continuing treatment, CHAMPIX 1 mg tablets are available in a pack of 28 tablets.

Ingredients

Active Ingredients

CHAMPIX 0.5mg tablets contain the equivalent of 0.5mg of the active ingredient varenicline.

CHAMPIX 1.0mg tablets contain the equivalent of 1.0mg of the active ingredient varenicline.

Inactive Ingredients

Each tablet of CHAMPIX contains the following other ingredients

- Cellulose – microcrystalline
- Calcium hydrogen phosphate
- Croscarmellose sodium
- Silica-colloidal
- Magnesium stearate
- Opadry Blue, Opadry Clear and Opadry Clear as a coating

Supplier

CHAMPIX is supplied in Australia by:

Pfizer Australia Pty Ltd
 ABN 50 008 422 348
 38-42 Wharf Road
 West Ryde NSW 2114
 Australia.

Toll Free number: 1800 675 229

CHAMPIX is supplied in New Zealand by:

Pfizer New Zealand Ltd
 PO Box 3998
 Auckland, New Zealand.
 Toll Free Number: 0800 736 363

Australian Registration Numbers

Combination Pack containing CHAMPIX 0.5mg and 1.0mg Tablet Blisters: AUST R No. 124940

Champix 1.0mg Tablet Blister Pack: AUST R No. 124941

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