



چینٹکس

CHANTIX®

(Varenicline Tartrate)

0.5 mg and 1 mg FILM-COATED TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER



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INFORMATION FOR THE USER**



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CHANTIX®
(Varenicline Tartrate)
(ورنيسلين ٹارٹریٹ)

**0.5 mg and 1 mg
FILM-COATED TABLETS**

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 CHANTIX is and what it is used for
2. Before you take CHANTIX
3. How to take CHANTIX
4. Possible side effects
5. How to store CHANTIX
6. Further information

1. WHAT CHANTIX IS AND WHAT IT IS USED FOR

CHANTIX is a non-nicotine medicine which is used to help you stop smoking.

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

Although you are not recommended to smoke while taking treatment, CHANTIX can also reduce the enjoyment of cigarettes if you do smoke when on treatment.

2. BEFORE YOU TAKE CHANTIX

CHANTIX tablets should be swallowed whole with water.

The usual dose for adults which you should follow from day 1 is described in the following table:

Week 1	Dose
Day 1 - 3	From day 1 to day 3, you should take one white CHANTIX 0.5 mg film-coated tablet once a day.
Day 4 - 7	From day 4 to day 7, you should take one white CHANTIX 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 CHANTIX 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 CHANTIX 1 mg film-coated tablet twice daily, once in the morning and once in the evening, at about the same time each day.

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 CHANTIX 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 CHANTIX at the end of treatment.

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

If you take more CHANTIX than you should

If you accidentally take more CHANTIX 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 CHANTIX

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

Take special care with CHANTIX

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 stopping smoking

The effects of changes in your body resulting from stopping smoking, with or without treatment with CHANTIX, may alter the way other drugs 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.

For some people stopping smoking has been associated with an increased chance of experiencing feelings such as depression and anxiety.

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

Effect of CHANTIX on other drugs

CHANTIX is not expected to affect the way other drugs work.

Effect of other drugs on CHANTIX

Due to the way in which varenicline tartrate is removed from the body, it is not expected that other drugs will affect the way in which CHANTIX works.

Use of CHANTIX with other therapies for smoking cessation

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

CHANTIX is not recommended for use in children or adolescents below 18 years.

Taking CHANTIX with food and drink

CHANTIX can be taken with or without food.

Pregnancy

You should not take CHANTIX while you are pregnant.

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

Breast-feeding

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

Driving and using machines

CHANTIX may produce dizziness and sleepiness. You should not drive, operate complex

the tablet that you have missed.

If you stop taking CHANTIX

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 CHANTIX, 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, CHANTIX can cause side effects, although not everybody gets them.

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
- 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

machinery or engage in any other potentially hazardous activities until you know whether this medication affects your ability to perform these activities.

3. HOW TO TAKE CHANTIX

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 CHANTIX 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 CHANTIX 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.

- 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

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 CHANTIX

Keep out of the reach and sight of children.

Do not use CHANTIX 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 CHANTIX contains

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

Tablet Core - CHANTIX 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 - CHANTIX 0.5 mg film-coated tablets

Hypromellose
Titanium dioxide (E171)
Macrogols
Triacetin

Tablet film coating - CHANTIX 1 mg film-coated tablets

Hypromellose
Titanium dioxide (E171)
Macrogols
Indigo Carmine Aluminium Lake (E132)
Triacetin

What CHANTIX 0.5 mg and 1 mg film-coated tablets looks like and contents of the pack

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

CHANTIX is available in the following pack presentations:

- A treatment initiation pack containing 2 blisters; 1 clear blister of 11 x CHANTIX 0.5 mg film-coated tablets and 1 clear blister of 14 x CHANTIX 1 mg film-coated tablets in card packaging.
- A follow-on (maintenance) pack containing 2 clear blisters of 14 x CHANTIX 1 mg film-coated tablets in card packaging.

Dosage:

Use as directed by the physician.

Oral use.

Avoid exposure to heat and sunlight.

Store at room temperature.

Keep all medicines out of the reach and sight of children.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو گرمی اور دھوپ سے بچائیں۔ دوا کو کمرے کے درجہ حرارت پر رکھیں۔

تمام دوائیں بچوں کی پہنچ اور نظر سے دور رکھیں۔

Manufactured by:

Pfizer Manufacturing Deutschland GmbH

Heinrich-Mack-Str. 35

D-89257 Illertissen

Germany

Imported by:

Pfizer Pakistan Limited.

B-2, S.I.T.E., Karachi, Pakistan.

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