Package leaflet: Information for the user

Cuitvar 0,5 mg + 1 mg, filmomhulde tabletten
varenicline

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

1. What [PRODUCT NAME] is and what it is used for

[PRODUCT NAME] contains the active substance varenicline. [PRODUCT NAME] is a medicine which is used in adults to help them stop smoking.

[PRODUCT NAME] can help to relieve the craving and withdrawal symptoms associated with stopping smoking.

[PRODUCT NAME] can also reduce the enjoyment of cigarettes if you do smoke when on treatment.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]:
- If you are allergic to varenicline or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking [PRODUCT NAME].

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

The effects of stopping smoking
The effects of changes in your body resulting from stopping smoking, with or without treatment with [PRODUCT NAME], 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 [PRODUCT NAME]’ 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 disorder. If you have a history of psychiatric disorder you should discuss this with your doctor.

Heart 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 [PRODUCT NAME]. 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 your start [PRODUCT NAME] treatment. Some people have reported seizures while taking [PRODUCT NAME].

Hypersensitivity reactions
Stop taking [PRODUCT NAME] and tell your doctor immediately if you experience any of the following signs and symptoms that may indicate a serious allergic reaction: swelling of the face, lips, tongue, gums, throat or body and/or difficulty breathing, wheezing.

Skin reactions
Potentially life-threatening skin rashes (Stevens-Johnson syndrome and Erythema Multiforme) have been reported with the use of [PRODUCT NAME]. If you develop a rash or if your skin starts to peel or blister, you should stop taking [PRODUCT NAME] and seek emergency medical help.

Children and adolescents
[PRODUCT NAME] is not recommended for use in paediatric patients as efficacy was not demonstrated.

Other medicines and [PRODUCT NAME]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In some cases as a result of stopping smoking, with or without [PRODUCT NAME], an adjustment of the dose of other medicines 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 [PRODUCT NAME] as this may cause increased blood levels of [PRODUCT NAME].

Use of [PRODUCT NAME] with other therapies for smoking cessation
Consult your doctor before using [PRODUCT NAME] in combination with other smoking cessation therapies.

[PRODUCT NAME] with food and drink
There have been some reports of increased intoxicating effects of alcohol in patients taking [PRODUCT NAME]. However, it is not known if [PRODUCT NAME] actually increases alcohol intoxication.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is preferable to avoid the use of [PRODUCT NAME] while you are pregnant. Talk to your doctor if you are intending to become pregnant.

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

Driving and using machines
[PRODUCT NAME] may be linked with dizziness, sleepiness and transient loss of consciousness. 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 [PRODUCT NAME]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

Before starting your course of [PRODUCT NAME] 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.

[PRODUCT NAME] comes as a white tablet (0.5 mg) and a light blue tablet (1 mg). You start with the white tablet and then usually go to the light 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 [PRODUCT NAME] 0.5 mg film-coated tablet once a day.
Day 4 - 7	From day 4 to day 7, you should take one white [PRODUCT NAME] 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 [PRODUCT NAME] 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 [PRODUCT NAME] 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 [PRODUCT NAME] 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 [PRODUCT NAME] 1 mg 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 [PRODUCT NAME]. You may need a lower dose.

[PRODUCT NAME] is for oral use.
The tablets should be swallowed whole with water and can be taken with or without food.

If you take more [PRODUCT NAME] than you should
If you accidentally take more [PRODUCT NAME] 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 [PRODUCT NAME]
Do not take a double dose to make up for a forgotten tablet. It is important that you take [PRODUCT NAME] regularly at the same time each day. If you forget to take a dose, take it as soon as you remember. If, it is within 3-4 hours before your next dose, do not take the tablet that you have missed.

If you stop taking [PRODUCT NAME]
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 [PRODUCT NAME] according to the instructions described in the table above.

In smoking cessation therapy, risk of returning to smoking may be elevated in the period immediately following the end of treatment. You may temporarily experience increased irritability, urge to smoke, depression and/or sleep disturbances when you stop taking [PRODUCT NAME]. Your doctor may decide to gradually lower your dose of [PRODUCT NAME] at the end of treatment.

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 in concentrating, decreased heart rate and increased appetite or weight gain.

You should be aware of the possible emergence of serious neuropsychiatric symptoms, such as agitation, depressed mood, or changes in behaviour during a quit attempt with or without [PRODUCT NAME] and you should contact a doctor or pharmacist if you experience such symptoms.

Serious side effects of either an uncommon or rare frequency have occurred in people attempting to quit smoking with [PRODUCT NAME]: seizure, stroke, 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). 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).

- Very common: may affect more than 1 in 10 people

    - Inflammation of the nose and throat, abnormal dreams, difficulty sleeping, headache
    - Nausea

- Common: may affect up to 1 in 10 people

    - 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: may affect up to 1 in 100 people

    - 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
    - High blood sugar
    - Heart attack
    - Suicidal thoughts
    - Changes in thinking or behaviour (such as aggression)

- Rare: may affect up to 1 in 1,000 people

    - 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
    - Diabetes
    - Sleep walking
    - Loss of contact with reality and unable to think or judge clearly (psychosis)
    - Abnormal behaviour

- 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)
- Serious allergic reactions including angioedema (swelling of the face, mouth, or throat)

- Not known

- Transient loss of consciousness

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 via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [PRODUCT NAME]

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 carton and blister or bottle label after EXP. The expiry date refers to the last day of that month.

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 [PRODUCT NAME] contains
- The active substance is varenicline.
- Each 0.5 mg film-coated tablet contains 0.5 mg of varenicline (as citrate).
- Each 1 mg film-coated tablet contains 1 mg of varenicline (as citrate).
- The other ingredients are:
  Tablet core: cellulose, microcrystalline; starch, pregelatinized (maize starch); propyl gallate, magnesium stearate; citric acid anhydrous
  Tablet film coating - [PRODUCT NAME] 0.5 mg: hypromellose (E464); titanium dioxide (E171)
  Tablet film coating - [PRODUCT NAME] 1 mg: hypromellose (E464); titanium dioxide (E171); indigo carmine (E132)

What [PRODUCT NAME] looks like and contents of the pack
- [PRODUCT NAME] 0.5 mg are white, capsule-shaped, film-coated tablets, marked with 0.5 on one side.

- [PRODUCT NAME] 1 mg are light blue, capsule-shaped, film-coated tablets, marked with 1.0 on one side.

[PRODUCT NAME] is available in the following pack presentations:

PVC/PE/PVdC//Alu blister:

Pack of 25 film-coated tablets:

Each pack contains 25 film-coated tablets for a two-week treatment schedule containing 11 film-coated tablets of <Product name> 0.5 mg and 14 film-coated tablets of <Product name> 1 mg.

Pack of 53 film-coated tablets:
Each pack contains 53 film-coated tablets for a four-week treatment schedule containing 11 film-coated tablets of <Product name> 0.5 mg and 42 film-coated tablets of <Product name> 1 mg.

Pack of 165 film-coated tablets:
Each pack contains 165 film-coated tablets for an eight-week treatment schedule containing 11 film-coated tablets of <Product name> 0.5 mg and 154 film-coated tablets of <Product name> 1 mg.

PVC/PE/PVdC//Alu perforated unit dose blister:

Pack of 165 x 1 film-coated tablets:
Each pack contains 165 x 1 film-coated tablets for an eight-week treatment schedule containing 11 x1 film-coated tablets of <Product name> 0.5 mg and 154 x1 film-coated tablets of <Product name> 1 mg.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Houder van de vergunning voor het in de handel brengen
Teva B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Fabrikant
Delorbis Pharmaceuticals Ltd.
17 Athinon Str.
Ergates Industrial Area
Ergates, Lefkosia
Cyprus

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park
Paola, PLA 3000
Malta

In het register ingeschreven onder
RVG 132195

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland:	Cuitvar 0,5 mg +1 mg, filmomhulde tabletten
Portugal:	Cuitvar
Spanje:	Cuitvar 0,5 mg + 1 mg comprimidos recubiertos con película EFG

Deze bijsluiter is voor het laatst goedgekeurd in december 2024.