Package leaflet: Information for the user

TUXERDIV 1.5 mg film-coated tablets
cytisinicline

Read all of this leaflet carefully before you start using 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 TUXERDIV is and what it is used for

TUXERDIV contains the active substance cytisinicline, also known as cytisine.

TUXERDIV is used for smoking cessation and the reduction of nicotine cravings in adult smokers who are willing to stop smoking. The treatment goal of TUXERDIV is the permanent cessation of the nicotine-containing products use.

Using of medicinal product TUXERDIV allows to gradually decrease nicotine dependence and disaccustom of tobacco smoking without nicotine withdrawal symptoms (e.g. depressed mood, irritability, anxiety, difficulty concentrating, insomnia, increased appetite).

2. What you need to know before you use TUXERDIV

Do not use TUXERDIV:
- if you are allergic to cytisinicline or any of the other ingredients of this medicine (listed in section 6).
- if you have unstable angina (chest pain),
- if you have a history of recent myocardial infarction (heart attack),
- if you have clinically significant cardiac arrhythmias (irregular heart beat),
- if you had stroke recently,
- if you are pregnant or breast-feeding (see section on pregnancy and breast-feeding below)

Warnings and precautions

TUXERDIV should be used with caution in case of ischemic heart disease, heart failure, hypertension, pheochromocytoma (a tumour of the adrenal gland), atherosclerosis (hardening of the

arteries) and other peripheral vascular diseases, gastric and duodenal ulcer, gastroesophageal reflux disease, hyperthyroidism (overactive thyroid), diabetes, schizophrenia, kidney and liver failure.

TUXERDIV should be taken only by those with a serious intention of weaning off nicotine. The use of TUXERDIV and continuation of smoking or use of products containing nicotine could lead to aggravated side effects of nicotine. Consult your doctor before using TUXERDIV in combination with other smoking cessation therapies.

Children and adolescents
Due to limited experience, the drug is not recommended for use in persons under 18 years of age.

Elderly population
Due to limited clinical experience, TUXERDIV is not recommended for use in elderly patients over 65 years of age.

Patients with kidney and liver impairment
There is no clinical experience of TUXERDIV in patients with kidney or liver impairment, therefore the medicine is not recommended for use in these patients.

Other medicines and TUXERDIV
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Do not take TUXERDIV with anti-tuberculosis drugs.

In some cases as a result of stopping smoking, with or without TUXERDIV, an adjustment of the dose of other medicines may be necessary. This is especially important if you use other medicines which contain theophylline (to treat asthma), tacrine (for Alzheimer's disease), clozapine (for schizophrenia) and ropinirole (to treat Parkinson's disease). If you are not sure, talk to your doctor or pharmacist.

It is currently unknown whether TUXERDIV may reduce the effectiveness of systemically acting hormonal contraceptives. If you are using systemically acting hormonal contraceptives, you should add a second barrier method (e.g. condoms).

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.

You must use effective methods of contraception if you are a woman of childbearing potential. Ask your doctor for advice.

TUXERDIV is contraindicated during pregnancy and breastfeeding.

Driving and using machines
TUXERDIV has no influence on the ability to drive and use machines.

Stopping smoking
The effects of changes in your body resulting from stopping smoking, with or without treatment with TUXERDIV, may alter the way other medicines act. Therefore, in some cases an adjustment of the dose may be necessary. See above under 'Other medicines and TUXERDIV 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 (rarely

including suicidal ideation and suicide attempt) 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.

TUXERDIV contains aspartame
This medicine contains 0.12 mg aspartame in each film-coated tablet.
Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to use TUXERDIV

Always use this medicine exactly as your doctor or pharmacist 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.

One package of TUXERDIV (100 tablets) is sufficient for a complete therapy. The duration of treatment is **25 days.**

TUXERDIV is for oral use and it should be taken with a suitable amount of water according to the following schedule:

Days of treatment	**Recommended dosing**	**Maximum daily dose**
Day 1 to 3	1 tablet every 2 hours	6 tablets
Day 4 to 12	1 tablet every 2.5 hours	5 tablets
Day 13 to 16	1 tablet every 3 hours	4 tablets
Day 17 to 20	1 tablet every 5 hours	3 tablets
Day 21 to 25	1-2 tablets a day	to 2 tablets

Smoking should be stopped no later than on the 5th day of treatment. Smoking should not be continued during treatment as this may aggravate adverse reactions. In case of treatment failure, the treatment should be discontinued and should not be restarted until after 2 to 3 months.

Taking this medicine
One pack of TUXERDIV (100 tablets) is sufficient for a complete therapy. Each pack contains two blisters of tablets. It is important that you start with the blister marked as **1** that contains the tablets needed from day 1 of the treatment through to part of day 10. The blisters are marked with the day number and every number of hours the tablets are to be taken for that day, for example **2h** means take 1 tablet every 2 hours up to a maximum of 6 tablets. When blister **1** is complete, start the blister marked **2**. Follow the day numbers on the pack from day 10 through to day 25.

The duration of treatment is 25 days.

Use in children, adolescents and the elderly
TUXERDIV should not be used in persons under 18 years or age or over 65 years of age due to limited clinical experience

If you use more TUXERDIV than you should
Symptoms of nicotine intoxication are observed in TUXERDIV overdose. Symptoms of overdose include malaise, nausea, vomiting, increased heart rate, fluctuations in blood pressure, breathing problems, blurred vision, convulsions.
If you have one of the described symptoms or a symptom which is not mentioned in this leaflet, stop taking TUXERDIV and contact your doctor or pharmacist.

If you forget to use TUXERDIV
Do not take a double dose to make up for a forgotten dose.

If you stop using TUXERDIV
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.

These side effects may occur with certain frequencies, which are defined as follows:

Very common may affect more than 1 user in 10: change in appetite (mainly increase), weight gain, dizziness, irritability, mood changes, anxiety, increased blood pressure (hypertension), dry mouth, diarrhoea, rash, fatigue, sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), headaches, increased heart rate, nausea, changes flavour, heartburn, constipation, vomiting, abdominal pain (especially in the upper abdomen), muscle pain.

Common may affect 1 to 10 users in 100: difficulty in concentration, slow heart rate, abdominal distension, burning tongue, malaise.

Uncommon affects 1 to 10 users in 1,000: feeling of heaviness in the head, decreased libido, tearing, dyspnoea, increased sputum, excessive salivation, sweating, decreased elasticity of the skin, tiredness, increase in serum transaminase levels.

Most of above side effects occur at the beginning of the therapy and resolve with duration. These symptoms could also be the result of smoking cessation (withdrawal symptoms), and not treatment with TUXERDIV.

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: HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TUXERDIV

Keep this medicine out of the sight and reach of children.
Store in the original package in order to protect from light.
This medicinal product does not require any special temperature storage conditions.

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

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 TUXERDIV contains

- The active substance is cytisinicline. One film-coated tablet contains 1.5 mg of cytisinicline.
- The other ingredients are:

Tablet core: hypromellose, mannitol, maize starch, magnesium aluminometasilicate, silica colloidal anhydrous and magnesium stearate.
Film-coating: AquaPolish P green [hypromellose (E464), cellulose microcrystalline (E460), talcum (E553b), glycerol (E422), titanium dioxide (E171), quinoline yellow lake (E104), indigo carmine lake (blue 2) (E132)], menthol flavour powder SC552873 and aspartame.

What TUXERDIV looks like and contents of the pack

Tuxerdiv 1.5mg film-coated tablets are round, biconvex, light green or greenish film-coated tablets with a 5 mm diameter.
Carton includes 100 film-coated tablets in PVC / PVDC / Aluminium blisters.

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