

PATIENT LEAFLET: INFORMATION FOR THE CONSUMER
TABEX[®] 1.5 mg film-coated tablets

Please read carefully the leaflet as it contains important for you information.

This medication does not require physician's prescription. And despite of that, for the best results from treatment it is recommended that instructions for use are followed carefully for this medication.

- Save this leaflet. It may be necessary to read it again.
- If you need additional information or advice please ask your pharmacist.
- If some undesired side effects occur and becomes serious, or you note other side effects not mentioned in this leaflet please notify your physician or pharmacist.

In this leaflet

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2. Before you start taking Tabex.
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1. WHAT IS TABEX AND WHAT IT IS USED FOR

Tabex contains active ingredient Cytisine, which is acting on the body of the smoker similarly to Nicotine. Taking Tabex leads to gradual reduction of smoking without the unpleasant effects and discomfort usually related to smoking cessation. Tabex is used in people addicted to smoking tobacco products (chronic tabacosis) desiring to stop smoking.

2. BEFORE YOU START TAKING TABEX

Do not start Tabex in:

- Allergic reaction or increased sensitivity to the active ingredient Cytisine or some of the other ingredients in Tabex.
- If you have suffered from recent heart attack or stroke, unstable angina, disturbances of heart rhythm (cardiac arrhythmia), atherosclerosis.
- During pregnancy or lactation.

Other contraindications for use of Tabex are:

- Chromaffin Tumors of the Adrenal Medulla
- gastroesophageal reflux disease (reflux of stomach juices in the lower esophagus causing burning sensation).

- Mental diseases (some forms of schizophrenia)

Special precautions for the use of Tabex

There is no sufficient clinical experience for safe application of Tabex and special cautions are required in patients with:

- Ischemic heart disease (impaired blood supply to the heart muscle)
- Heart failure (weakness of heart muscle)
- Arterial hypertension (increased blood pressure)
- cerebrovascular diseases
- occlusion of blood vessels
- kidney and liver diseases
- hyperthyroidism (overactive thyroid gland)
- ulcer
- diabetes

There is no sufficient clinical experience for application of Tabex as well in children under 18 years of age and adults of over 65 years of age.

Application of Tabex is not recommended in these categories of patients without prior consultation with a physician and evaluation of the benefits and risks.

When patients are taking other medications

Inform your physician if you are using other medications such as fizostigmin, Galantamine, statin medications, medications lowering the blood pressure, tuberculosis medications because of the potential increase of their undesired side effects in simultaneous use with Tabex. Please inform your physician or pharmacist if you are using or have recently used other medications including non-prescription medications.

Simultaneous use of Tabex with foods and beverages foods and beverages do not affect or interact with the action of Tabex.

Pregnancy or lactation

Please consult with your physician or pharmacist before use of any medication. If pregnancy is established or when lactating, treatment with Tabex should not be undertaken.

Driving and operating machinery

There is no data for adverse effects of Tabex when carrying out activities requiring increased attention and responsiveness.

Important information for some of the ingredients in Tabex.

This product contains lactose. If you are lactose intolerant it is necessary to inform your physician before starting a course with Tabex.

3. HOW TO TAKE TABEX

Please accept Tabex as it is described in this insert. If you are unsure about anything, please inquire with your physician or pharmacist.

Application: tablets are taken orally with sufficient amount of liquids.

Dosage: treatment is applied according to the following regimen:

- Day 1 to 3: one tablet six times daily (every two hours). In days one to three it is expected reduction of the cigarettes smoked. If the result is unsatisfactory the treatment is to be discontinued and may make another attempt in 2 – 3 months. If results are satisfactory (significant reduction of cigarettes smoked) following day 3 treatment is continued according to the following regimen.
- Days 4 to 12: one tablet every 2.5 hours (5 tablets per day);
- Days 13 to 16: one tablet every 3 hours (4 tablets per day);
- Days 17 to 20: one tablet every 5 hours (3 tablets per day);
- Days 21 to 25: one to two tablets per day

Smoking of cigarettes should have been discontinued by the 5th day of treatment. When treatment course is concluded the patient will have to demonstrate willpower and abstain from smoking even a single cigarette.

If you have taken more than the prescribed dose

If you have accidentally taken a dose larger than the prescribed patients may experience nausea, accelerated heart beats, difficulties breathing. It is possible to experience vomiting and increase of pupils. In these cases discontinue the Tabex intake and consult a physician or seek help with your physician or medical facility.

If you have missed a dose of Tabex

If you have missed your dose take it as soon as possible. If it is time for your next dose take it as usual, and skip the missed dose. Do not take double dose to compensate for the missed dose. Continue to take the medication as described in this insert.

If you have additional questions related to the intake of this product, please inquire with your physician and pharmacist.

4. POSSIBLE UNDESIRE SIDE EFFECTS

As with any medication Tabex may cause some undesired side effects, but not everyone will experience side effects.

When undertaking treatment with Tabex especially in the beginning these are the possible undesired side effects:

- Dryness in the mouth, changes of taste and appetite, nausea, vomiting, abdominal pains, constipation, diarrhea;

- Headache, lightheadedness
- Heart palpitations, chest pains, increased heart rate, mild increase of blood pressure;
- Drowsiness, sleeplessness, increase in irritability;
- Difficulties breathing;
- Muscle aches;
- Loss of weight, sweating.

If some of the undesired side effects become serious or if you notice others not mentioned in this insert, please inform your physician and pharmacist.

5. HOW TO STORE TABEX

Store in the original packaging in order to protect from moisture. Store in temperature under 25°C. Store in place inaccessible for children.

This medication should not be used after the expiration date marked on the packing. The expiration term marked on the packaging includes the last day of the specified month.

Medications should not be discarded in drain systems, or in the garbage containers. Please inform yourself from your pharmacist how to destroy unneeded medications. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

What is the Tabex content?

- Active ingredient: Cytisine 1.5 mg
- Other ingredients: lactose monohydrate (tablettose70), microcrystalline cellulose (type 102), talc, magnesium stearate.
- Content of the film coating: Opadry II brown (polyvinyl alcohol – partially hydrolyzed, titanium dioxide (E171), Macrogol 3350, talc (E553b), iron dioxide yellow (E172), iron dioxide red (E172), iron dioxide black (E172).

What is the appearance of Tabex packaging and contents?

Tablets are beige in color, round, double convex with diameter 6 mm. Twenty tablets in blister sheets of PVC/aluminum foil, with 5 blister sheets in retail box, accompanied by insert.

Holder of use permit and manufacturer
Sopharma AD

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