

Cytisine, 1.5 mg, tablets

Cytisine, 1.5 mg, tablets is a generic product, equivalent to the reference product TABEX (Sopharma) intended to be used in the treatment of nicotine dependence.

Cytisine, 1.5 mg, tablets obtained marketing authorization in the following countries: Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Ireland Netherlands, Poland, Romania, Sweden.

Smoking is the #1 cause of preventable deaths worldwide.

The current market for smoking cessation therapies is estimated to be \$2.3 billion. With only two non-nicotine-based prescription medications currently approved – varenicline and bupropion. Varenicline (Pfizer's Champix brand) leads the market with a share of 37.8%. Cytisine, 1.5 mg, tablets, being **safer and cheaper** alternative to varenicline will pose a strong challenge to Champix. Currently drug products containing cytisine are available only in Poland and Bulgaria, as OTC product.

ACTIVE SUBSTANCE

Cytisine is an alkaloid extracted from the plant Laburnum with a high binding affinity to the nicotinic acetylcholine receptor. Cytisine-containing product has been approved and marketed in Eastern Europe as an aid for nicotine treatment for 40 years.

MECHANISM OF ACTION

The active substance, cytisine, is a partial agonist of nicotinic receptors, characterized by a greater than nicotine affinity to the receptors. It reduces the satisfaction of smoking and prevents the central symptoms of nicotine withdrawal after the smoking cessation.

EFFICACY/SAFETY

The safety and efficacy of cytisine has been proven in many clinical studies.

Cytisine was superior to nicotine-replacement therapy for smoking cessation among smokers motivated to quit.

Cytisine was associated with lower rates of headache and nausea than varenicline.

Cytisine delivered more quality-adjusted life-years at a lower cost than varenicline.

THERAPY

Even one package of the CYTISINE 1.5 mg drug product may suffice for breaking the nicotine addiction.

Standard 25-day therapy of cytisine is 5 to 15 times cheaper than the 8-10 week course of nicotine-replacement therapy and even 15 to 20 times cheaper than 12 weeks of treatment with varenicline.