



8 July 2021
EMA/373269/2021

Shortage of Champix (varenicline) Film-coated tablets, 0.5 mg, 1 mg

Indication	Champix is used in adults to help them stop smoking.
Reason for shortage	The company that markets Champix is recalling several batches of the medicine that were found to contain the nitrosamine impurity N-nitroso-varenicline at levels above the company's acceptable level of daily intake. As a precaution, the company is pausing distribution of Champix pending further testing, which will result in shortages worldwide. Based on the available data, there is no immediate risk to patients taking this medication.
Member States affected¹	All EU Member States where Champix has been marketed (all Member States except Bulgaria)
Information to healthcare professionals	<ul style="list-style-type: none">• The company for Champix is recalling several batches and pausing distribution, as a precaution, due to the presence of a nitrosamine impurity.• Based on the available data, there is no immediate risk to patients taking this medication.• While EU authorities assess the data, healthcare professionals should, as a precaution, not start new patients on Champix.• Alternatives will vary from market to market but may include nicotine replacement therapy (NRT) and bupropion.• As a result of the recall and the interruption in the distribution there will be a global shortage.• People who are currently on Champix may not be able to complete treatment and healthcare professionals may consider switching treatment to an alternative.• Healthcare professionals should also take into account the need to consider dose tapering at the end of treatment. The product information for Champix states that "At the end of treatment, discontinuation of Champix was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to

¹ This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.



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	<p>3% of patients.”</p> <ul style="list-style-type: none"> • Healthcare providers should advise patients undergoing treatment not to discontinue Champix without consulting them, and to discuss any questions or concerns with their healthcare provider, if needed. • A direct healthcare professional communication (DHPC) informing about these measures will be sent to relevant healthcare professionals and will also be published on the EMA website. • Additional advice may be available from the national competent authority.
<p>Information to patients</p>	<ul style="list-style-type: none"> • The company for Champix is recalling several of its batches and pausing distribution. This is a precaution, due to the presence of a nitrosamine impurity. • Based on the available data, there is no immediate risk to patients taking this medication. • Alternatives are available and your healthcare provider will start you on such an alternative if you are about to start smoking cessation treatment. • If you are currently being treated with Champix, your doctor may switch you to a different treatment. You should not stop taking Champix without speaking with your healthcare professional. • If you have any questions, you should speak to your doctor or pharmacist. • Additional advice may be available from the national competent authority.
<p>Status</p>	<p>Ongoing</p>