



23 September 2021
EMA/522543/2021 rev.1¹

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	Batches of Champix (varenicline) that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set for the EU are being recalled. An earlier recall of several batches took place in June 2021 due to the presence of nitrosamine impurity and led to shortages of the medicine. The latest recall will lead to further shortages of the medicine. Based on the available data, there is no immediate risk to patients taking this medication. More information about the risk of nitrosamine impurities in human medicines can be found here: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities
Member States affected²	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 is recalling batches of Champix that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set for the EU.• An earlier recall of several batches took place in June 2021 and led to shortages of the medicine. The latest recall will lead to further shortages of the medicine.• Based on the available data, there is no immediate risk to patients taking this medication.• Healthcare professionals should consider alternative treatment for their patients. Alternatives will vary from market to market but may include nicotine replacement therapy (NRT) and bupropion.• People who are currently on Champix may not be able to complete treatment and healthcare professionals may need to consider switching treatment to an alternative.• Healthcare professionals should also take into account the need to consider gradually reducing the dose (dose

¹ This document was modified on 21 September 2021 to update in line with the latest DHPC.

² 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>tapering) at the end of treatment. This is because discontinuation of Champix was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients (please refer to Champix product information).</p> <ul style="list-style-type: none"> Healthcare professionals 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 is recalling batches of Champix due to the presence of a nitrosamine impurity. The recall affects all batches that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set at EU level. An earlier recall of several batches took place in June 2021 due to the presence of nitrosamine impurity and led to shortages of the medicine. The latest recall will lead to further shortages of the medicine. Based on the available data, there is no immediate risk to patients taking this medication. More information about the risk of nitrosamine impurities in human medicines can be found here: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/referral-procedures/nitrosamine-impurities Alternatives are available and your healthcare provider may 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 healthcare professional. Additional advice may be available from the national competent authority.
<p>Status</p>	<p>Ongoing³</p>

³ Further updates will be published as needed.