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UK Supply Update – Champix® (Varenicline Tartrate)

Please find below an important update regarding the supply of Champix (varenicline tartrate).

In response to requests from various regulatory authorities globally, manufacturers across the pharmaceutical industry, including Pfizer, have been evaluating the potential for the presence or formation of nitrosamine impurities in pharmaceutical medicines. As part of Pfizer's evaluation, several lots of Champix were observed with nitrosamines above Pfizer's acceptable level of daily intake (ADI).

Pfizer places the utmost importance on patient safety and product quality. As a precautionary measure pending further testing, Pfizer have stopped distribution of all Champix under our control with immediate effect.

We currently anticipate this supply disruption will last several weeks, until the results of further testing are known. We are working to expedite the testing and progress discussions with regulators as quickly as possible.

For those patients currently prescribed Champix we believe the benefits outweigh the very low potential risks, if any, posed by nitrosamine exposure from varenicline on top of other common sources over a lifetime.

We understand the challenges that the situation poses and realise the importance of this medicine to our healthcare professionals and patients. Until the Champix shortage is resolved, patients will need to consult with their healthcare professional to discuss an alternative treatment option.

As more information becomes available, we will share this with you. Should you have further questions, please see below some additional ways of contacting Pfizer.

A Supply Disruption Alert (SDA/2021/006) has been issued regarding the current supply of Champix.

Yours faithfully,

Pfizer Ltd

Breakthroughs that change patients' lives®

[Pfizer.co.uk](https://www.pfizer.co.uk)

Stock / Ordering Queries

If there are any outstanding queries in relation to stock, please contact the Pfizer Customer Contact Centre on 0345 608 88 66.

Safety Reporting

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk. Adverse events should also be reported to Pfizer Medical Information on 01304 61 61 61.

Champix Summary of Product Characteristics (SmPC) can be found below

[https://www.medicines.org.uk/emc/search?q=%22varenicline%20tartrate%22&filters=attributes\[spc\]&offset=1&limit=50&orderBy=product&refreshFilters=true](https://www.medicines.org.uk/emc/search?q=%22varenicline%20tartrate%22&filters=attributes[spc]&offset=1&limit=50&orderBy=product&refreshFilters=true)

Company Contact Point

For any questions or medical queries related to Pfizer products, please contact Pfizer Medical Information on 01304 61 61 61 or visit <https://www.pfizermedicalinformation.co.uk/>