Patient Card

This medicine is an effective treatment but can take time to work.
You may experience some side effects before your symptoms improve.
Please read the leaflet provided in the box of your medicine for more information

Warning: Thoughts of self-harm and suicidal behaviour
Do not suddenly stop taking this medicine without talking to a healthcare professional.
Tell someone you trust you are taking this medicine.
Ask your trusted person to read the leaflet.

Contact your trusted person, go to a hospital or call NHS 111, or your local NHS mental health crisis team, if you have new or worse thoughts of harming yourself

16th November 2026

Direct Healthcare Professional Communication

Antidepressants: New safety measures for all patients to improve communication of the risk of suicidal thoughts and behaviours and persistent sexual dysfunction

Dear Healthcare Professional,

You are being contacted as you have been identified as a HCP who prescribes or dispenses antidepressants to patients. The approved Medicines and Healthcare products Regulatory Agency (MHRA) Direct Healthcare Professional Communication (DHPC) is below for your information. Medicines UK requests that this important safety information is disseminated to your colleagues.

Medicines UK, on behalf of the marketing authorisation holders of the 28 antidepressants[i] involved in the review of how the risks of suicidal thoughts and behaviours and persistent sexual dysfunction are communicated, and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

New safety measures are now being implemented for all patients taking antidepressants. This follows completion of a detailed review, involving patients and their families, into how the risks of suicidal thoughts and behaviours, and persistent sexual dysfunction are communicated in the patient information leaflets (PILs) that accompany antidepressant medicines.

These changes include:

- **a new boxed warning in the PILs** signposting to updated information on suicidal thoughts and behaviours
- **a new patient card** on suicidal thoughts and behaviours, available electronically now whilst we work with marketing authorisation holders on the introduction of printed warning formats
- **development of a supporting safety (ancillary) leaflet** expected to be available in 2027 to describe key risks and benefits in more detail. This leaflet is intended to support discussions about the benefits and risks of treatment and could be provided by the healthcare professional at the first consultation for new patients, or the next consultation for existing patients
- The **term post SSRI sexual dysfunction ("PSSD") is being added to the PIL** for certain antidepressant medications[ii]

Action for Healthcare professionals

Prescribers should ensure patients are aware of the updated information on the risks of suicidal thoughts and behaviour, and persistent sexual dysfunction.

Dispensing practices should provide patients with a link to the electronic version of the patient card, using the QR code included in this letter below. In due course, you can also direct patients to the electronic versions of the card available through the Electronic Medicines Compendium (eMC) at www.medicines.org.uk and/or individual company's website. Where possible, dispensing practices may print a copy of the card and provide it on request.



Background on the safety concern

A Commission on Human Medicines (CHM) Expert Working Group (EWG) on antidepressant risk minimisation was convened in response to concerns raised by patients and their families about whether patient information leaflets (PILs) adequately communicate the risks of suicidal thoughts and behaviours, and sexual dysfunction where symptoms may continue after stopping treatment. The EWG met between May 2024 and July 2025 and their recommendations were considered by the CHM in September 2025.

Central to the considerations of the EWG were the views of patients and families about the effectiveness of warnings in the current antidepressants' PILs. The EWG considered their views in the context of the literature published since 2019, when the regulatory position on suicidal thoughts and behaviours, and sexual dysfunction where symptoms continued were last reviewed at a committee level. They made recommendations to the CHM on regulatory options.

The CHM advised that updates to strengthen the wording on the risk of suicidal thoughts and behaviours in the PILs, should be developed through user testing with patients representing a range of mental health conditions. The MHRA subsequently worked with The Patients Association, a dedicated patient focus group, to refine and finalise the updated wording and format of the PILs.

The product information for the 28 antidepressants involved in the review will be updated in line with the new safety information. This includes revised warnings on suicidal thoughts and behaviours for all antidepressants involved in the review and the addition of the term "PSSD" for some antidepressants[ii].

We are working with marketing authorisation holders to introduce the warnings in printed formats. During the implementation period, the MHRA encourages dispensing practices and pharmacies, where feasible, to provide patients with a link to the electronic version. This can be done using the QR code included in this letter, or in due course, by directing patients to the electronic versions available through the Electronic Medicines Compendium (eMC) at www.medicines.org.uk and/or individual company's website. Where possible, pharmacies may print a copy of the card and provide it on request.

The MHRA will continue to work closely with healthcare system partners to review clinical guidance and communications, with the aim of improving the consistency of safety messaging relating to antidepressants.

Further information and updates are available on the MHRA antidepressants Drug Safety Update article at Antidepressants: use and safety
The MHRA will continue to monitor the impact of these measures through established pharmacovigilance and risk-management activities, including the proposed Clinical Practice Research Datalink (CPRD) study. The risks of suicidal thoughts and behaviours, and persistent sexual

dysfunction following antidepressant treatment will remain under close review, and further regulatory action will be taken where appropriate in light of emerging evidence.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contacts:
Reporting of adverse drug reactions can also be made to the relevant company using the details found on the Patient Information Leaflet provided with the medicine.

Yours sincerely,

RRP

Robert Russell-Pavier
Policy and Economics Director
Medicines UK
robert.russellpavier@medicinesuk.com

---

[i] fluvoxamine, fluoxetine, citalopram, escitalopram, sertraline, paroxetine, venlafaxine, duloxetine, reboxetine, amitriptyline, clomipramine, dosulepin, doxepin, imipramine, lofepramine, nortryptiline, trimipramine, trazodone, isocarboxazid, tranylcypromine, moclobemide, phenelzine agomelatine, vortioxetine, L-tryptophan, esketamine, mianserin, mirtazapine

[ii] amitriptyline, citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, nortriptyline, paroxetine, sertraline, venlafaxine