U NOVARTIS

Adverse Event Reporting

An adverse event (or side effect) is any unwanted medical occurrence in a patient who has been given a medicinal product. This can be any unfavourable and unintended sign, symptom, or disease associated with the use of the product.

Reporting suspected side effects of the medicinal product is important to Novartis and the Health Products Regulatory Authority (HPRA). It allows continued monitoring of the benefit/risk profile of the medicinal product.

If you experience a side effect that concerns you, please tell your healthcare professional immediately.

Patients and healthcare professionals should report adverse events to the HPRA. Reporting forms and information can be found on the <u>HPRA website</u>.

Adverse events associated with a Novartis product could also be reported to Novartis via <u>www.report.novartis.com</u>.

If you cannot report your side effect online, please phone or email: +353 01 2080 612 drugsafety.dublin@novartis.com

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