Adverse Event Reporting

An adverse event[1] (or side effect) is any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product/medical device and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product/medical device, whether or not considered related to the medicinal product/medical device.

By reporting adverse events for Novartis products, you help us to ensure the safety of our products and our patients. Your information will also enable Novartis to fulfill its reporting responsibilities to health authorities, which requires that we provide information on adverse events with our products - even in cases where a relationship between the product and the effect is not established.

The information that health care professional provides to Novartis Patient Safety will be treated in accordance with local privacy laws and the Novartis Privacy Policy and may be processed and stored on servers located in jurisdictions outside of the country in which it was collected. This information may be shared with health authorities, or other pharmaceutical companies with whom Novartis has a license agreement, and third parties we work with for the purpose of meeting the regulatory requirements for reporting safety information on Novartis products.

Adverse events associated with a Novartis product can be reported to Novartis via https://www.novartis.com/report

[1] Also reportable as Adverse Events are “Special Scenarios”, being: laboratory findings outside a published reference range (without symptom), drug-drug, drug-food interactions (with or without clinical symptoms), kinetic interactions in which the only effect is a change in drug plasma concentrations, transmission of infectious disease via medication, lack of efficacy, or lack of expected therapeutic effect (as defined in the product label), death without known cause, pregnancy exposure (with or without outcome) and drug use during lactation, overdose, drug abuse and misuse (with or without symptoms), drug dependence/addiction, medication errors such as accidental exposure, occupational exposure, dispensing/prescribing errors, drug maladministration (with or without symptoms), disease progression and aggravation (with or without symptoms), withdrawal reaction/syndrome and rebound effects, treatment non-compliance with clinical symptoms, unexpected beneficial effect (i.e. beneficial effect that is not related to the indications for which the product was given) and off-label use.
