

What is VigiAccess?

VigiAccess is the public representation of VigiBase, the World Health Organization's global database of individual case safety reports (ICSRs) – i.e. reports of suspected adverse effects of medicinal products that have been spontaneously reported for individual patients by for example patients themselves, doctors, nurses, pharmacists or other health care professionals. Data has been collected in VigiBase since 1968 for the WHO Programme for International Drug Monitoring, World Health Organization's response to the thalidomide tragedy of the early 1960s. The purpose was to collect information about the adverse effects of medicines from as many sources as possible across the world, to ensure that the first signs of possible danger from medicines would not be missed. Uppsala Monitoring Centre, UMC, is the WHO Collaborating Centre for International Drug Monitoring and has developed and maintained VigiBase on behalf of the member countries since 1978. Over 130 countries contribute to this database and it covers over 100,000 different medicinal products. For more information, see www.who-umc.org.

What do I need to know about VigiAccess information?

A report in VigiAccess represents a *suspicion* that an adverse effect *could* have occurred as a result of treatment with a medicinal product, but it is *not* a systematic register of adverse effects. Therefore, it cannot be concluded that the medicinal product in question, or the active ingredient(s), generally causes the observed effect or is unsafe to use.

VigiAccess data is heterogeneous, due to e.g. differences in national legislation and policies. Reporting may be influenced by many different factors, such as the availability and extent of use of the product, and the nature of the adverse effects.

Spontaneous reports must be interpreted with caution; it is not possible to calculate the frequency of any adverse effect, as only a small proportion of occurring events are reported and there is no information available on the total number of patients that have been using the product, so comparisons between various medicinal products based on spontaneous reports are misleading.

The balance between the benefit and risk of a specific medicinal product varies between individual patients, and benefit-risk analysis always requires a detailed evaluation and scientific assessment of all available data.

If you think that you may be experiencing a side-effect from a medicinal product, please seek advice from a health professional as soon as possible. **Never stop or change the dose for prescription medicines without consulting your physician.**

To maintain patient confidentiality and comply with data protection laws, the public VigiAccess information is aggregated, i.e. with information on the continent or WHO Region instead of the country, and age groups instead of the patient's age.

If you want to know more about how you can use this data for research or other purposes, please visit www.who-umc.org/vigibase/vigibase

About the release of this data:

The UMC takes great care to ensure that the data contained herein is an accurate record of data collected by the national drug authorities and transmitted to the UMC. The UMC does, however, not guarantee, warrant or make any representation whatsoever regarding the data contained herein, including but not limited to guarantees, warranties or representations of accuracy, reliability, completeness, currency, suitability, fitness or usefulness for any particular purpose or with respect to non-infringement of any third-party rights. In no event shall the UMC be liable for any loss, damage, cost or other expense whatsoever (whether direct, indirect, punitive, incidental, special or consequential) arising out of or in any way connected with the use of or reference to any data contained herein. In no event shall the UMC be liable other than i) under Swedish substantive law and ii) subject to the courts of Sweden with the district court of Uppsala as first instance.