

BIOLOGICAL MEDICINE AND BIOSIMILAR MEDICINE. WHO IS WHO?



– What is a biological medicine and a biosimilar medicine?

Biological medicines are those obtained from living cells and organisms. A biosimilar is a medicine equivalent to another biological medicine that already exists.

– Is a biosimilar medicine the same as a generic medicine?

A generic medicine contains exactly the same active substance as the reference medicine. Biosimilar medicines are very similar versions of the reference medicines, although they are not identical. In both cases, the safety and efficacy are similar to those of the reference medicine.

– Is there any difference in quality, safety and efficacy between a reference medicine and a biosimilar medicine?

No, as a biosimilar medicine must meet the same quality, safety and efficacy standards as its reference medicine.

– If I start a biological treatment, is there any difference between doing so with the reference medicine or with a biosimilar in terms of quality, safety and efficacy?

No, as both medicines (reference and biosimilar) are biological medicines subjected to the same quality, efficacy and safety requirements by the regulatory agencies.

– Can a biological medicine be changed for another?

Yes. Your doctor, based on his/her own criteria and having informed you beforehand, may change one biological medicine for another with the same therapeutic goal.

– Must the doctor inform me of a change of biological medicine?

Yes. As is the case when starting any treatment, your doctor will inform you about the new treatment, its administration and any other relevant information.

Biosimilar medicines contribute to the sustainability of the public health system while maintaining treatment safety and efficacy.

– Is the safety of biosimilar medicines monitored once they are marketed?

Yes. Safety is controlled permanently by official drug regulatory agencies. That is why it is important for you to notify any adverse reaction to your doctor, pharmacist or nurse, or directly via <https://www.ram.navarra.es>. If possible, save the package, as it is useful when notifying the adverse reaction.

– Are the side-effects of the reference medicine and the biosimilar medicine the same?

Yes. The possible side-effects of a reference biological medicine and its biosimilar are the same.

– What is the best way to obtain information about biosimilar medicines?

The main source of information should be your doctor, pharmacist or nurse.

