PATIENT INFORMATION
BIOSIMILARS

- Biosimilars are the follow-on products of complex biological drugs. They are equivalent to their reference products in terms of efficacy, safety and quality. Biosimilars are indicated for the treatment of the same severe diseases as the reference biologic drug.
- Numerous studies have confirmed the safety of switching from a reference product to a biosimilar and vice versa.
- The decision for switching to a biosimilar is the responsibility of the treating physician or the hospital in which is the therapy administered.

BIOSIMILARS AT A GLANCE

Biological drugs (biologics) are produced by living cells and have a complex structure. They are prescribed for the treatment of cancer, rheumatism, certain skin diseases or intestinal disorders.

A biosimilar is a follow-on medicine of a certain original biological drug. The manufacturers of biosimilars must prove in specific studies that the biosimilar drug is highly comparable in efficacy, safety and quality to the respective original medicine.

You can only receive a biosimilar if prescribed by a physician.

WHAT ARE FOLLOW-ON DRUGS?

Each development of a new drug costs a lot of time and money. That is why originator drugs have a patent protection up to 20 years. As soon as the patent expires, other manufacturers may then produce and market a follow-on drug. There are different types of follow-on drugs:

- **GENERIC DRUGS:** These drugs, identical to their originals are chemically manufactured and thus easier to replicate. For example, generic drugs of most well known painkillers have been available for many years in your pharmacy.
- **BIOSIMILARS:** These are the successors (follow-on) of complex biological drugs. Biologics and biosimilars are manufactured by a rather complex procedure in living cells. The development of biosimilars is substantially more difficult and takes longer than the development of a generic drug.

EQUAL IN EFFICACY AND SAFETY

Most biological drugs are proteins produced in living cells and are very similar to endogenous substances. Due to their complicated structure, natural variations in production are non-evitable and expected. However, these variations are only acceptable if neither the efficacy nor the safety of the drug are compromised. This strict rule applies to all biological medicinal products; the original medicinal products and the biosimilars.

This means: Biosimilars differ minimally from respective original medicinal product. This also applies to all biological medicinal products – both the original medicinal product and biosimilars. Even with each new batch of an original medicinal product there are unavoidable small variations. The active ingredient produced later is very similar to the previous one, but not one hundred percent identical.

HOW ARE BIOSIMILARS USED COMMONLY

In 2006, the first biosimilar drug was approved in Europe. Currently, more than 40 biosimilars are available in Austria. These are, for example, blood cell growth factors used in frame of chemotherapy or so-called monoclonal antibodies, which are applied for treatment of cancer or chronic inflammatory diseases.

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Most frequently, the administration of these medicines is performed with a ready-to-use syringe with an applicator (e.g. pen) or as an intravenous infusion. The drug administration follows the strict physician's prescription.

FOR MARKETING AUTHORISATION BIOSIMILARS MUST COMPLY WITH STRICT REQUIREMENTS

- Prior to marketing approval, experts examine very carefully the product quality, efficacy and safety.
- Independent conducted studies confirm that a biosimilar is effective and safe. The biosimilar is approvable only if in direct comparison, it is tantamount to the (original) reference biological.
- A company wishing to place a biosimilar on the market must prove in clinical studies for a defined disease that it is just as effective and safe as the original biological drug.
- If this is confirmed, the biosimilar is considered approvable along with the other indications authorized for the original biologic.

CONSULTATION WITH A MEDICAL SPECIALIST

It is possible that for the initiation of your treatment your doctor recommends a biosimilar medicine. They could also consider switching to a biosimilar during the course of your treatment. Switching to a biosimilar is safe. The clinical studies and positive experience accumulated in the past 10 years of biosimilars' everyday use, show that after switching, the therapeutic efficacy is comparable to that of the original biological.

There can be several reasons to offer you a therapy with a biosimilar. Besides the lower costs, the biosimilar might have a more suitable pack size or more convenient, individual dosage form, or it may be easier to handle. Some people get along better with a ready-to-use syringe, others prefer an injector, pen injector or infusion.
If you are treated with a biological medicine, you should discuss the procedure with your doctor.

ARE THERE SIDE EFFECTS?

Like any drug, biologicals also can have side effects. A biosimilar can have the same side effects as the original. Biosimilars must prove with carefully conducted studies that they are as safe as the reference biological.

People with certain intolerances or allergies should inform their doctor so that scrutiny of all ingredients is considered. Inform your medical team or your pharmacist about any abnormalities and side effects occurring during the treatment. Do not stop taking your medicine without consulting your doctor.

IF YOU HAVE ANY ADDITIONAL QUESTIONS?

Please do not hesitate to send us an
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Find more information:
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This patient information is available in different languages. Please scan the QR-Code.

This patient information has been produced in collaboration with the Austrian Biosimilars Association, the Austrian Federal Office for Safety in Health Care (BASG), the Austrian Medical Association and the Austrian Chamber of Pharmacists.

Further information: www.biosimilarsverband.at

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