



Generics: Example Germany

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Der Preis der Hoffnung

Neue Medikamente versprechen die Heilung tödlicher Leiden wie Krebs. Doch sie kosten ein Vermögen. Wem stehen sie zu? Und können die Kassen das leisten?

MAGAZIN



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Generics \neq Fake drugs



Germany:
Imatinib generics marketed
for adult patients with CML
since Dec 22, 2016

Outpatient situation (prescriptions)

Physician prescribes "Imatinib 400 mg"

Pharmacist chooses the type of generic
(according to

- price,
- discount contracts, depending on the individual insurance company of the patient)

A proven well tolerated generic might be preferred individually, but this is not the rule.

Inpatient situation (hospital pharmacy)

Physician may order "Imatinib 400 mg"

Hospital pharmacist in cooperation with a group of physicians chooses the type of generic for the next year (according to price and discount contracts)

In the hospital or during an recreation stay the generic may differ from the regular drug taken at home.

Physicians are forced to prescribe generics, if available

“aut idem”

Exceptions possible



What is a generic ?

A drug product that is comparable to a brand/reference listed drug product in dosage, form, strength, route of administration, quality and performance characteristics, and intended use.



Registration:

Statement on the composition of the pill,
tests for bioequivalence and bioavailability mandatory.

No data from prospective clinical trials are required.



Varying Degrees of Lactose Sensitivity

Lactose Maldigestion

Incomplete digestion of *lactose*, the natural sugar in milk, due to low activity of the *lactase* enzyme; may be asymptomatic

Lactose Intolerance

Gastrointestinal disturbances following the consumption of an amount of lactose greater than the body's ability to digest and absorb

Source: Lactose Intolerance, National Digestive Diseases Information Clearinghouse. December 15, 2011.

<http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance/>

J Natl Med Assoc. 2009;101:1S-24S



Lactose Intolerance vs Milk Allergy

Key differences...

Lactose intolerance	Milk allergy
A sensitivity	An allergy
Occurs in gastrointestinal system	Triggered by immune system
A sensitivity to milk carbohydrate (lactose)	A reaction to milk protein
Rare in young children	Generally impacts young children; may be outgrown*
Can enjoy milk and milk products with simple management strategies	Should avoid milk and milk products (unless allergy is outgrown)

Source: Lactose Intolerance, National Digestive Diseases Information Clearinghouse. <http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance/>. Accessed: December 15, 2011.

*Allergy and Asthma Foundation of America. Milk Allergy. <http://www.aafa.org/display.cfm?id=9&sub=20&cont=518>, Accessed: December 15, 2011

Place SR Logo Here

Imatinib in Germany, 23.5.2017

Glivec + 27 generics

Additions:

e.g. Lactose-1-H₂O 50mg;

Crospovidone;

microcrystalline Cellulose;

Talc;

Silica;

Magnesium stearate;

Gelatin;

Titanium dioxide;

Iron(III)oxide hydrate, black;

Iron(III)oxide

Price: 21.45 € - 112.32 € (Median 26.38 €) / 400 mg

Glivec 400 mg 112.32 €

