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Clinicians' perspective on frequent generic switching?

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Dasatinib Zentiva®
100 mg Filmtabletten
Packungsbeilage beachten.
30 Filmtabletten
imatinib axios
100 mg Hartkapseln
imatinib
axios
Wirkstoff: Imatinib
60 Hartkapseln (N2)
ZENTIVA
Dasatinib Zentiva®
80 mg Filmtabletten
Dasatinib
Zum Einnehmen
30 Filmtabletten
ALIUD PHARMA®
DASATINIB AL
50 mg Filmtabletten
Zur Anwendung bei Erwachsenen
Dasatinib
Zytostatikum
60 Filmtabletten
Imatinib Devatis
400 mg Filmtabletten
Imatinib
30 Filmtabletten/N1
Imatinib HEXAL® 400 mg Filmtabletten
Imatinib
400 mg
HEXAL
90 Filmtabletten N3
Dasatinib - 1 A Pharma® 80 mg
Filmtabletten
Dasatinib
80 mg
1A PHARMA
30 x 1 Filmtablette N1
Imatinib-ratiopharm® 400 mg
Filmtabletten
Imatinib
ratiopharm
30 x 1 Tabletten
IMATINIB BASICS 400 mg
Filmtabletten
Wirkstoff: Imatinib
Basics
90 Filmtabletten
Dasatinib-ratiopharm®
100 mg Filmtabletten
Dasatinib
ZYTOTOXISCH
30 x 1 Filmtablette N1
ratiopharm

Chronic myeloid leukemia patients call for quality and consistency when generics are introduced to treat their cancer

J Geissler, G Sharf, J Cugurovic, R Padua, Š Narbutas, M Remic & V Venkatesh for the CML Advocates Network

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1. No generic drug to treat CML should be provided to patients without reliable proof of quality as well as bioequivalence (equivalent bioavailability/pharmacokinetics) to the originator drug. Generic drugs should be approved by the appropriate authorities of the respective country or region, and a narrow therapeutic range of some cancer drugs should be considered before acceptance of bioequivalence.

2. When generic drugs are intended for the treatment of severe diseases like leukemia, further comparative clinical data should be demanded by regulatory bodies and published to ensure that the generic drug is therapeutically equivalent (same safety and efficacy) to the original product in patients.

3. A CML patient should not be switched between different products with the same active substance for non-medical reasons provided this patient already responded optimally to the current product and tolerates it well.

4. If a switch for non-medical reasons between products with the same active substance is enforced, this should not happen more frequently than once a year. Sufficient follow-up is necessary to assess safety and efficacy to estimate drug response. If a patient experiences loss of drug response or experiences a significant increase in toxicity after switching to another product containing the same active substance, the patient must have the option to return to the previous treatment or switch to another treatment, if available.

5. After switching between products with the same active substance, more frequent molecular monitoring should be conducted to detect potential differences in effectiveness or side effects early after the switch.

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 prescibe generics, if available

”aut idem”

Exceptions possible, selection of specific generics possible