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Using generic drugs: an informed choice about quality, safety and efficacy at a lower cost.

You might need to take medicines on various occasions. Being familiar with them will help you to choose the most effective and safe solution for your health problem, together with your doctor or pharmacist.

However, the issue goes far beyond that.

On the one hand, data from the Italian National Institute of Statistics (ISTAT) confirm that 9.5% of the population gives up healing while on the other reports sent to the Tribunal for Patients' Rights state that the most difficult costs to bear for families are those related to the purchase of drugs.

Before purchasing a medicine you should always seek the advice of your doctor or pharmacist. For our part, the development of the ***“ioequivalgo”*** App will help you obtain all the information you need about drugs and, eventually, find out whether or not generics are also available. It is an easy and fast consultation on your smartphone, always to hand, to be used whenever and wherever you want: all you have to do is type in the name of the medicine or its active substance, in order to find all the different formulations (granules, pills, etc. . .) and select the specific dosage recommended by the doctor or pharmacist. Your research will result in a complete list of all the medicines available on the market, grouped by price band. They may be patent protected (branded) or off-patent (generics). All the generics that you find in the App have been set up by the Italian Medicines Agency (AIFA) into specific lists named **“Transparency Lists”**. The ***“ioequivalgo”*** App will also help you to be properly informed and to evaluate whether it might be possible to get the same treatment, while saving money.

To learn more, please, check out this guide: you will discover what generics really are, to what extent they can help you and how to use medicines correctly.

1. Generic drugs: let's take a closer look.

A generic drug has the same pharmacological and therapeutic characteristics as a branded, off-patent medicine that is already on the market.

IT HAS THE SAME EFFECT AND ACTION AS THE BRANDED ONE BECAUSE IT HAS:

1. The **SAME ACTIVE SUBSTANCE**, the ingredient in charge of its pharmacological (therapeutic) effect
2. The **SAME QUANTITY** of ACTIVE SUBSTANCE
3. The **SAME NUMBER** of DOSAGE UNITS (i.e. : number of tablets per package)
4. The **SAME PHARMACEUTICAL FORM** (i.e.: tablets, capsules, solution for injection, etc.)
5. 5. The **SAME ADMINISTRATION ROUTE**.

It is safe because:

Active substances are already well-known, with many years of marketing consolidating their clinical use. This means they have already been evaluated as safe and authorized for





release onto the market by the Italian Medicines Agency based on the positive outcomes resulting from scientific research and the ongoing monitoring of various parameters such as toxicity, carcinogenesis, ability to have children and so forth.

- The therapeutic equivalence with the branded medicine has been demonstrated after AIFA's evaluation and approval of the studies presented by the drug manufacturing company.
- Production, distribution and storage processes undergo the same checks as for branded drugs.
- As for all medicines, controls are carried out even after they have been put onto the market.

On average, it is less expensive because:

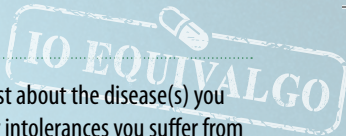
- Resources have already been invested into research, with the active substance being well-known and already in use for twenty years at least.
- Preclinical and clinical studies have already been conducted in order to demonstrate both efficacy and safety in human beings. Moreover, the manufacturers of branded drugs have previously completed the procedures for certain active substances.

In addition, putting generic drugs onto the market creates a sort of competition, thus reducing the average price of branded medicines which, in some cases, finally have the same cost as generics.

2. Branded and generic drugs: a comparison.

For your health's sake, always consider your doctor or pharmacist as points of reference. Despite this, remember that branded and generic drugs:

- a. have the **same** quantity of active substance
- b. have the **same** clinical efficacy
- c. have the **same** dosage
- d. have the **same** administration route
- e. have the **same** therapeutic indications
- f. have the **same** contraindications
- g. undergo the **same** controls
- h. undergo the **same** registration procedure
- i. undergo the **same** vigilance
- j. sometimes are produced in the **same** manufacturing company
- k. have a **different** name
- l. may have a **different** price
- m. may contain **different** excipients
- n. may have a **different** colour
- o. may have a **different** shape
- p. may have a **different** taste.



Please, always inform your doctor or pharmacist about the disease(s) you are affected by as well as particular allergies or intolerances you suffer from before taking or purchasing any medicines, whether branded, generic or obtained without prescription. By doing this you will avoid those which might be unsuitable for your health.

3. Therapeutic adherence: an extra weapon for drugs.

In order to make the treatment effective it is essential that you follow the doctor's or pharmacist's indications carefully. Failure to do so may represent the main cause of inefficacy of the pharmacological treatment, which can lead to a worsening of health conditions and to unnecessary hospital admissions. Undergoing the treatment successfully means understanding and following the doctor's or pharmacist's recommendations about timing, dosage, frequency in taking a certain medicine for the entire course of the treatment, as well as understanding advice on your lifestyle.

If you think it is too difficult or stressful because the treatment consists of many and varied medicines to be taken every day, or because the information you were given is not adequate, ask your doctor, pharmacist or nurse. This confidence and dialogue based relationship with them will enhance a better understanding of their instructions. Health care professionals are at your disposal and will support your active participation in this process, which involves a new lifestyle, treatment and finally your healing.

If the therapy prescribed gives you any adverse reactions, please do not change or stop it, but instead consult your doctor or pharmacist immediately and decide with them what to do. Expensive and sometimes long-lasting treatments might force you to stop the therapy. Today, data shows that more

and more people are deciding to give up treatments because of their costs. Taking generic drugs, especially in case of chronic illness, can represent a suitable way of continuing the therapy and reaching the best health conditions possible. This is one of the reasons why you should talk to your doctor about this option.

Moreover, this would be of benefit not only to you and your family, but also to the National Health Service, as it will become more sustainable in terms of avoidable additional costs such as admissions, investigations, and so on.

4. A list you can always carry around

Special attention should be paid in cases of admissions or releases from hospital; in fact they can influence the course of your treatment.

For example, child births or scheduled surgeries represent crucial situations in which health professionals must take particular care, especially if you are already under treatment.

In cases like those above mentioned, **remember to bring a full list of the medicines you are taking with you.**

For each medicine, it shall contain: name, dosage and timing of administration throughout the day. Mentioning if you are taking homeopathic, herbal or phytotherapeutic products, supplements and other preparations purchased in authorized stores, is also essential.

5. Supporting quality through pharmacovigilance

If you are taking a branded medicine or a generic and the effects that you notice are different from those expected, or you simply think that the medicine is not working, please contact your doctor or pharmacist.

They will consider what is going on and, if necessary, report to AIFA all the possible negative effects observed in order to allow the necessary checks on the drug.

So please, play your part in this.

A form is also provided on the website www.agenziafarmaco.it, for all those citizens who want to report any adverse reactions.

Everyone should do it: you as a citizen have the right to report any allergic reactions, adverse events or inefficacies; for doctors or pharmacists that is a duty.



6. Therapeutic alliance: union is health for everyone

The therapeutic alliance is defined as the relationship built up between the patient, the doctor and all the other health professionals who are involved in the process according to their own skills. Being part of it means that the doctor explains all the pharmacological and therapeutic choices, while the patient expresses doubts, consent and preferences.

When face-to-face with your doctor or pharmacist you should be aware of all the recommendations given you and understand them properly. Therefore, always express your doubts and give your consent or dissent to what they suggest. This will help you to follow all the indications exactly.

In addition to that, the National Health System is able to provide you the cheapest generic drug, or more than one, if it is available on the market: at the chemist's you will decide if you wish to pay for it in full or not.

If the doctor's prescription says "NOT REPLACEABLE", the pharmacist will be required to provide you what was prescribed. Otherwise, the cheaper medicine will be offered.

If you choose the more expensive, you will pay the eventual price difference compared to the cheaper one out of your own pocket, together with the charge as well, if due.

What to ask your doctor before taking medicines:

- What is it for ?
- How many "pills" every day ?
- When should I take it ?
- Can I take it together with other medicines, food, alcoholic beverages, etc. ?
- How long should the therapy be continued ?
- What should I do if I miss a dose ?
- What side effects can it cause ?
- How and where should it be stored ?

Information you should give before medicines are prescribed or recommended:

- If you are already taking medicines
- If you are allergic to some substances
- If you are planning a pregnancy
- If you are pregnant or breastfeeding
- If the medicine is going to be for children or geriatric patients
- If you have difficulties in moving any parts of your body easily during the administration of the medicine or in understanding the instructions.

After you left your doctor's office:

- If you have any doubts, feel free to call your doctor. He/she will appreciate your attention regarding the treatment
- If you have difficulties in taking the medicine or if it causes you problems do not stop taking it on your own initiative, instead talk to your doctor about it: he or she will look for alternatives or understand if the reported side effects are "normal"
- If you have medicines in you medicine chest which you think are similar to those prescribed, do not take them unless your doctor or pharmacist approves it!



What to ask the pharmacist:

- According to the law, it is your right to ask about the existence of cheaper generic drugs rather than branded, whether they belong to Group A (refund by the National Health System) or Group C, which are paid for entirely by the citizen and need a prescription

If the medicine prescribed is replaceable, the pharmacist will be required to provide you the less expensive medicine with the same active substance. Then, you will decide which one to purchase.

- To consult the Transparency List together. Transparency Lists will inform you about the cheapest generics, only by considering the medicine's trade name or active substance, its dosage unit (i.e. tablet) and package. You can easily verify the list on our App "ioequivalgo"
- To provide you all the useful information in order to take medicines in the most effective way possible
- All the relevant questions to avoid medicines that might be unsuitable for your diseases, allergies or particular needs
- To understand the price difference between the prescribed medicine and the cheaper possible alternative
- If devices (i.e. inhalers), blisters or packages are easy to open and operate.





Remember! Medicines are health partners only if...

- You make a correct use of them and only when strictly necessary
- They were prescribed by the doctor or suggested by the pharmacist
- You do not follow any advice from acquaintances and friends that might have used the same medicine for similar health problems: each person is different, therefore unique.

7. For you and those by your side, health is important.

Many people do not only take care of their own health. Sometimes, they are responsible for assisting those who are part of their lives: children, mothers, fathers, friends or partners.

As for yourself, always remember to:

- Check if they are following the therapy as prescribed by the doctor
- Check that timing and intake quantities are respected
- Help them to recognize and take medicines correctly in case of any variations.
- Check the medicine chest regularly so to dispose outdated drugs in the appropriate containers.

8. Online drugs: the future is upon us.

European Legislation for the online sale of drugs has recently been implemented in Italy.

The regulation identified this logo as common throughout the European Union and ensures the reliability of online retailers to all citizens. In particular, it guarantees that the

retailer has already obtained the authorization, under the law in force, for selling drugs to the public.

Currently, online sale is allowed only for those medicines without prescription called SOP (the Italian acronym for “Senza Obbligo di Prescrizione”, no prescription needed) and OTC (the English acronym for “Over the Counter”, “da banco” in Italian). They are both paid for entirely by the citizen.

Consequently, you will be able to purchase medicines in complete safety, but only on those websites where the logo previously released by the Ministry of Health is displayed. It shall be “clearly visible on each page of the websites specialized in the sale of over the counter medicines as well as in every pharmacy or authorized retailer”. In addition, if you want to verify the website reliability, all you have to do is click on the logo and you will immediately be redirected to the Ministry of Health website: here you can find out whether the online retailer is registered in the list of all authorised retailers, thus ensuring the safety of your purchase.



To learn more:

If you are willing to consider this matter further, you can dial the toll-free number “**800-571661 Farmaci-line**”, send an email to the following address “**farmaciline@aifa.gov.it**”, or fax us at this number **06.5978.4807**.

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www.ioequivalgo.it or downloading our App “**ioequivalgo**”.

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