

**IS DANGEROUS. Please pay attention to the fact that the two medicinal products were replaced, of which you were informed by either your doctor or pharmacist. If you are not sure about anything, please consult your doctor or pharmacist BEFORE TAKING THE MEDICINE.**

It is recommended that you copy from the package the name of the medicinal product, its strength and the regime of taking (for instance 1 tablet in the morning and 1 tablet in the evening), putting down the data in the table "My list of medicines", which is attached to this leaflet. This applies to all the medicines you are using, including those you only take occasionally (for sleeping, against pains, etc.) When you visit a general practitioner or a specialist, please bring this list with you. In such a way, health care professionals will always be aware of all the medicines you are taking. By so doing, you will improve the safety of treatment with medicinal products, as the possibility of inappropriate course of treatment (doubling of medicines, side effects) will be reduced significantly.

### Patient's Responsibility

During the treatment, the most important one is YOU. Your treatment will be successful and will bring the expected results if you comply with the instructions provided by health care professionals. When taking your medicines, pay due regard to both the **instructions for use**, which are contained in each package of medicines, and the instructions provided by the physician when prescribing the medicine and by the pharmacist when dispensing it. By dealing with your medicines prudently, you will participate significantly to successful treatment. Each individual is responsible, to a considerable degree, for his or her own health!

Should you require any detailed information, please ask your doctor or pharmacist, regional units or field offices of the Health Insurance Institute of Slovenia, or the Ministry of Health of the Republic of Slovenia.

### Legal bases:

Health Care and Health Insurance Act (Official Gazette of the Republic of Slovenia, Nos. 9/1992, 13/1993, 9/1996, 29/1998, 6/1999, 99/2001, 60/2002),  
 Medicinal Products and Medicinal Devices Act (Official Gazette of the Republic of Slovenia, Nos. 101/1999, 70/2000, 7/2002, 13/2002, 67/2002),  
 Pharmacies Act (Official Gazette of the Republic of Slovenia, Nos. 9/1992, 13/1993, 38/1999, 86/2002),  
 Rules on the classification, prescribing and dispensing of medicinal products for human use (Official Gazette of the Republic of Slovenia, No. 59/2003),  
 Compulsory health insurance rules (Official Gazette of the Republic of Slovenia, Nos. 30/2003 – consolidated version, 35/2003, 78/2003),  
 Decision on determining the list of mutually interchangeable medicinal products (Official Gazette of the Republic of Slovenia, No. 97/2003),  
 Decision amending the list of medicinal products on the basis of Decision on criteria for the classification of medicinal products in lists (Official Gazette of the Republic of Slovenia, No. 100/2003).

## The following may be described to you by physicians:

• a medicine which you have been receiving before and which is within the maximum attributed value  
**Medicine will be prescribed to you by the physician in the same way as before.**

• another equal medicine within the maximum attributed value, which requires  
**no additional payment.**

• a medicine which is included in the list of mutually interchangeable medicinal products and which exceeds the maximum attributed value  
**After consulting you, the physician will prescribe either of the following:**

• a medicine which is not included in the list of mutually interchangeable medicinal products  
**Medicine will be prescribed to you by the physician in the same way as before.**

• medicine exceeding the maximum attributed value, which requires  
**an additional payment.**

## How the pharmacist will now dispense a medicine to you?

• he/she will dispense a medicine **without additional payment.**

• should you persist, even after the consultation with the pharmacist, to receive the medicine exceeding the maximum attributed value, you will be referred **back to the physician who will give you a new prescription.**

• in agreement with you, he/she will dispense to you a medicine which requires **an additional payment.**

• he/she will dispense a medicine **without additional payment.**

• if you refuse to make an additional payment, he/she will dispense to you an equal medicine within the maximum attributed value **without an additional payment.**

# Cheaper Medicinal Products for More Health!

November 2003 saw the introduction of groups of mutually interchangeable medicinal products having a maximum attributed value which is covered out of compulsory and voluntary (supplementary) health insurance (hereinafter: health insurance).

**Changes are necessary in order to efficiently manage the expenditure for medicinal products, whereby considerable funds will be saved within the health insurance system, without thereby adversely affecting access to quality, safe and effective medicinal products.**

Measures similar to those now taken in Slovenia have been long used by several EU Member States for the good of their citizens.



## System of Mutually Interchangeable Medicinal Products

In terms of prices, there are considerable differences between mutually interchangeable medicinal products. It is in the public interest that the health insurance system only covers the full value of those medicinal products which, given that their quality, safety and efficiency are provenly equal, are the most price effective. This is why groups of mutually interchangeable medicinal products have been introduced. Savings generated by physicians increasingly prescribing those medicinal products which are essentially similar (equal) and therefore mutually interchangeable and, in addition, cheaper, will be spent, for the good of those insured, on new, modern medicinal products which are more effective but, as a rule, more expensive as well, and to reduce waiting times in the health system.

In order to better understand the changes, we would like to present several notions which you will be facing more often in the future:

**A group of mutually interchangeable medicinal products** includes those medicinal products containing the same active ingredient, same dosage and pharmaceutical form, which have provenly comparable quality, safety and efficiency. This implies that they are essentially similar and that they act in the same way. This is why such medicinal products are equal and mutually interchangeable. Groups of mutually interchangeable medicinal products will be determined and updated, presumably, twice a year by the Office of the Republic of Slovenia for Medicinal Products, by adopting a list of mutually interchangeable medicinal products (Official Gazette of the Republic of Slovenia, No. 97/2003). **Each medicinal product** which is being dispensed by pharmacies is a quality, safe and efficient medicinal product, which is established and guaranteed, subject to the relevant regulations, by the Office of the Republic of Slovenia for Medicinal Products, which is an expert body of the Ministry of Health.

**A medicinal product's maximum attributed value** is the value which, for an individual medicinal product from a group of mutually interchangeable medicinal products, is covered out of compulsory and voluntary (supplementary) health insurance, depending on the inclusion in one of the lists of medicinal products (the positive or the intermediate list). A medicinal product's maximum attributed value is determined by the Health Insurance Institute of Slovenia (Official gazette of the Republic of Slovenia, No. 100/2003). As regards those medicinal products included in the positive list, 75 per cent of that value is covered out of compulsory health insurance, and as regards those medicinal products included in the intermediate list, 25 per cent of the value is covered out of compulsory health insurance. In case of certain population groups or illnesses, the full value is covered out of compulsory health insurance. The remaining percentage making up the difference to the maximum attributed value is covered by voluntary (supplementary) health insurance.

The changes introduced in November 2003 only apply to those medicinal products which are included in the list of mutually interchangeable medicinal products. The following are included in the list of mutually interchangeable medicinal products: certain medicines for the treatment of cardio-vascular diseases, diabetes, gastro-intestinal diseases, anti-microbial medicines, medicines for the nervous system, skin diseases and allergies, and those for contraception. Health insurance does not cover the full value for all the medicinal products belonging to the same group of mutually interchangeable medicinal products any more, but only the full value for those mutually interchangeable medicinal products which do not exceed the maximum attributed value. As regards the other medicinal products belonging to the same group of mutually interchangeable medicinal products which exceed the maximum attributed value, the amount making up the difference between the price for such medicinal products and the maximum attributed value, which is covered out of health insurance, must be paid.

The process of prescribing those medicinal products which are not included in the list of mutually interchangeable medicinal products will remain

unchanged (medicinal products will not be interchanged, no extra payments will be needed). **The list of mutually interchangeable medicinal products with the maximum attributed value** will be changed periodically, presumably twice a year. The currently applicable version is available at the following web site <http://www.zzs.si/egradiva>.

## How Physicians Will Prescribe Medicines

In prescribing medicine and choosing appropriate treatment, physicians are autonomous within the framework of the professional doctrine and applicable regulations. If prior to 1 November 2003 your treatment involved a medicine which is now included in the list of mutually interchangeable medicinal products and which exceeds the maximum attributed value, your doctor will inform you accordingly. If you should decide to retain the same medicine which now exceeds the maximum attributed value, your doctor will inform you about the required additional payment making up the difference between the price for this medicine, which is more expensive, and the maximum attributed value. At the same time, your doctor will let you know that he or she can prescribe to you a cheaper medicine from the list of mutually interchangeable medicinal products, for which no additional payment will have to be made in the pharmacy. The decision whether you would like to get the medicine with an additional payment or a medicine without an additional payment, can therefore also be yours.

**It is important to know that differences in prices of mutually interchangeable medicinal products are only due to the fact that they are made by different producers. Such medicinal products are provenly interchangeable in terms of their quality, safety and efficiency. It is therefore the best to leave your doctor and pharmacist to choose the appropriate medicinal product.**

As a result of the changes, the following two cases might happen after 1 November 2003 in the physicians' office (either general practitioner or specialist):

### Case A

*Prior to 1 November 2003, you had been receiving either a medicine which is included in the list of mutually interchangeable medicinal products and which does not exceed the maximum attributed value or a medicine which is not included in the list of mutually interchangeable medicinal products.*

In this case, no change applies to you. Your doctor will prescribe to you the same medicine which will not be interchanged by the pharmacist and for which no additional payment will be required (no interchange, no additional payment).

### Case B

*Prior to 1 November 2003, you had been receiving a medicine which is included in the list of mutually interchangeable medicinal products and which does exceed the maximum attributed value.*

In this case, your doctor will draw your attention to this fact, talk with you about that and propose to replace the medicine exceeding the maximum attributed value with an equal medicine belonging to the same group of mutually interchangeable medicinal products whose price is fully covered out of health insurance. If you should agree, your doctor will prescribe such a medicine to you and you will receive it in the pharmacy at no additional payment.

If after consultation with your doctor you should still want to receive the medicine exceeding the maximum attributed value, he or she will prescribe such a medicine to you, drawing your attention to the fact that in the pharmacy you will have to **make an additional payment** for the difference between the price for the prescribed medicine, which is more expensive, and the maximum attributed value, which is covered out of health insurance.

## How Pharmacists Will Dispense Medicines

Pharmacists are authorised to dispense medicinal products both in accordance with what is prescribed by physicians and subject to applicable regulations. The latter allow a medicine which is more expensive to be replaced by a cheaper one, provided that the two medicines concerned are both included in the same group of mutually interchangeable medicinal products and are thus provenly equal. It is important to know, however, that it is your doctor who is authorised to choose the appropriate treatment. Therefore, interchanging two equal medicines with the same active ingredient, dosage and pharmaceutical form does not mean infringing physicians' autonomous decision on choosing the appropriate treatment.

As a result of the changes, the following two cases might happen after 1 November 2003 in the pharmacy:

### Case A

*In the pharmacy you submit a prescription either for a medicine which is included in the list of mutually interchangeable medicinal products and does not exceed the maximum attributed value or for a medicine which is not included in the list of mutually interchangeable medicinal products.*

In this case, no change applies to you. You will receive your medicine without being required to make an additional payment (no interchange, no additional payment).

Or maybe you have already arranged with your doctor about a prescription for a medicine which does not require an additional payment.

Should you decide later, i.e. in the pharmacy, to replace the prescribed cheaper medicine with another, equal but more expensive medicine from the same group of mutually interchangeable medicinal products and to make an additional payment for it, such replacement will not be possible in the pharmacy; you will have to see your doctor again to get a new prescription.

### Case B

*In the pharmacy you submit a prescription for a medicine which is included in the list of mutually interchangeable medicinal products and which does exceed the maximum attributed value.*

In this case, your pharmacist will inform you about an additional payment. Should you decide not to make an additional payment for such a prescribed medicine, which is more expensive, the pharmacist will suggest that instead of the medicine concerned you receive an appropriate other medicine from the list of mutually interchangeable medicinal products. This implies that you will be offered, instead of the prescribed medicine exceeding the maximum attributed value, another equal medicine from the same group of mutually interchangeable medicinal products for which no additional payment is required. If you agree, you will receive the medicine concerned.

Should you persist, even after the consultation with the pharmacist, to receive the medicine exceeding the maximum attributed value, you will have to make an additional payment making up the difference between the price for the prescribed more expensive medicine and the maximum attributed value, which is covered out of health insurance. In such cases, the pharmacist is not authorised to give you a medicine whose price exceeds the maximum attributed value without requiring an additional payment.

**Should you be receiving medicines included in the list of mutually interchangeable medicinal products, and should your medicine, which is more expensive, be replaced with another one, which is cheaper, by either your doctor or pharmacist, the latter will inform you accordingly, designating the names of the medicines replaced. Taking two equal medicines simultaneously**