

USER LEAFLET ON ORAL CONTRACEPTIVES

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Additional Notes	The following text is intended to indicate the information on oral contraceptives which should be provided for users of these products, for example in the packaging leaflet (Article 6 of Directive 75/319/EEC as amended).

CONTENTS

- 1. GENERAL**
- 2. NATURE OF THE PRODUCT**
- 3. CONSULTING YOUR DOCTOR**
- 4. CONSULTING YOUR DOCTOR**
- 5. HOW TO USE THIS PRODUCT**
- 6. GENERAL INFORMATION AND ADVICE**
- 7. ADVERSE REACTIONS**

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1. GENERAL

The following text is intended to indicate the information on oral contraceptives which should be provided for users of these products, for example in the packaging leaflet (Article 6 of Directive 75/319/EEC as amended).

It should be noted that:

- a) The present text is directed exclusively to the woman using the product, and is therefore selective and written in non-technical language. If a packaging leaflet is also supposed to provide information to the physician or pharmacist it will have to be considerably more extensive: in that case it will be advisable to separate this technical information from that directed to the user;
- b) The text is drawn up in the light of current knowledge and relates to oral contraceptives containing progestogens and oestrogens, employed to inhibit ovulation. For contraceptives of other types some adaptation of this text may be required;
- c) The text represents only a general standard; in some situations it may be considered more appropriate to provide more detailed or extensive information, or to omit points which in the national situation are irrelevant;
- d) The text should be presented in a manner which can be readily understood by the average user;
- e) The order in which the information is given need not necessarily follow that of the present notes for guidance.

2. NATURE OF THE PRODUCT

The nature of the product and the purpose(s) for which it is intended should be indicated. This means that where a product is destined both for use as an oral contraceptive and in gynaecological treatment this should be made clear.

3. CONSULTING YOUR DOCTOR

This section should include statements of the following type:

- a) You should consult a doctor before starting to take this preparation; only (s)he can determine whether it is suitable for you. You should also consult your doctor before changing from one oral contraceptive to another.
- b) There are some conditions in which it is generally inadvisable to take oral contraceptives. It is particularly important to tell your doctor if you have ever suffered from any of these illnesses:
 - clots in the legs or lungs,
 - strokes, heart attacks or angina pectoris,

- known or suspected cancer or tumours,
- unusual vagina bleeding, the cause of which has not been found,
- jaundice.

For the same reason you should also tell your doctor if there is any reason to think you may already be pregnant.

- c) In some conditions the doctor may wish to take special precautions or may advise you to use another type of contraception. Be sure that (s)he knows if you have been found to be suffering at any time from:
- any disorder of the breast, or discharge from the breast,
 - diabetes,
 - high blood pressure,
 - high blood fat levels,
 - migraine,
 - heart disease,
 - kidney disease,
 - epilepsy,
 - deafness,
 - mental depressions,
 - fibroids of the uterus,
 - gall bladder disease.

For the same reason you should tell the doctor about your smoking habits, (particularly since heavy smoking can increase the chance of certain adverse reactions), and about any medicines which you often need to take, including pain relievers.

4. HOW TO USE THIS PRODUCT

This section should include:

- a) Clear instructions as to:
- the day when the first tablet is taken,
 - the time of day when the tablet is to be taken (if relevant),
 - the duration of ingestion in each cycle,
 - the order in which the tablets are to be used (if these are arranged in a fixed order in the package),
 - the day when the second and subsequent cycles of treatment should start;
- b) Clear advice as to how the user should act:
- if a tablet (or more than one tablet) has been forgotten,
 - if no withdrawal bleeding occurs;

- c) Warnings as to conditions under which the reliability of the preparation may be impaired should be indicated. These will vary with the nature and dosage of the product but may include the first cycle of treatment (particularly if a preparation with a higher dose has previously been used), the simultaneous use of certain other substances, and the occurrence of vomiting and severe diarrhoea.

5. GENERAL INFORMATION AND ADVICE

- a) The degree of reliability of the preparation should be indicated in general terms.
- b) The user should be advised to inform any other doctor or surgeon whom she consults for any reason that she is taking oral contraceptives, since this may be important in diagnosis or treatment.
- c) The user should be recommended to consult once more the doctor who has prescribed the product at regular intervals, as agreed with him or her, and in addition:
- if any severe symptoms occur whilst using it,
 - if she has any reason to think that she has become pregnant,
 - before restarting treatment after interruption,
 - before restarting treatment after pregnancy or during lactation.
- d) The user should be informed as to the likely course of events if she stops taking the product (e.g. the time of onset of the next period and the resumption of fertility) and advised to see the doctor again if anything unusual happens at this time.
- e) A woman who wishes to become pregnant should be advised not to do so for three months after stopping the product, so that reproductive function can return completely to its previous pattern.

6. ADVERSE REACTIONS

- a) Commonly occurring adverse reactions should be listed, with some indication as to whether or not they are more common at the start of treatment. Effects listed here should include gastrointestinal symptoms, mild headache, mammary discomfort or swelling, some increase in weight, chloasma and mild depression. The effects on the menstrual cycle should be described in terms appropriate to the product concerned.
- b) Less common but severe adverse reactions should be mentioned, particularly thrombosis and cholestasis, and a list provided of those warning signs which justify consulting the doctor at once such as:
- mammary discharge and nodule formation,
 - severe changes in the monthly bleeding pattern,
 - marked vaginal secretion,
 - vertigo, faintness,
 - jaundice,
 - sudden impairment of vision,

- sudden pain in the chest or abdomen,
- pain or swelling in the legs,
- severe headache or migraine,
- any other unexpected symptom.