

Desomono 75 Microgram Film-Coated Tablets

**Informations for option:** Desomono 75 Microgram Film-Coated Tablets,

**Document:** leaflet MAH BRAND\_PL 40818-0001 [change](#)

Do not use Desomono if you are pregnant, or think you may be pregnant.

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

1 Desomono 75 microgram film-coated tablets

Desogestrel

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

[1. What Desomono is and what it is used for](#)

[2. What you need to know before you take Desomono](#)

[3. How to take Desomono](#)

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## **1. WHAT IS DESOMONO AND WHAT IS IT USED FOR**

Desomono is used to prevent pregnancy. Desomono contains a small amount of one type of female sex hormone, the progestogen **desogestrel**. For this reason Desomono is called a progestogen-only-pill (POP), or a **mini-pill**. Contrary to the combined pill, the POP or mini-pill does not contain an oestrogen hormone next to the progestogen.

Most POPs or minipills work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the primary action of combined pills. Desomono is distinct from other mini-pills in having a dose that in

most cases is high enough to prevent the egg cell from ripening. As a result, Desomono provides high contraceptive efficacy.

In contrast to the combined pill, Desomono can be used by women who do not tolerate oestrogens and by women who are breast feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Desomono. You also may not have any bleeding at all.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DESOMONO**

Desomono, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take Desomono

if you are allergic to desogestrel or any of the other ingredients of this medicine (listed in section 6). if you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel (e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)).

if you have or have had jaundice (yellowing of the skin) or severe liver disease and your liver function is still not normal.

if you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.

- if you have any unexplained vaginal bleeding.

Tell your doctor before you start to use Desomono if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control.

Consult your doctor immediately if any of these conditions appear for the first time while using Desomono.

### **Warnings and precautions**

[Talk to your doctor or pharmacist before taking Desomono, if

- you have ever had breast cancer.
- you have liver cancer, since a possible effect of Desomono cannot be excluded.
- you have ever had a thrombosis.
- you have diabetes.
- you suffer from epilepsy (see section "Taking other medicines").
- you suffer from tuberculosis (see section "Taking other medicines").
- you have high blood pressure.

- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation.

When Desomono is used in the presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

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### Breast cancer

- Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.

Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as<sup>1</sup>

the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the age until which the

woman continues to take the Pill is higher. How long she takes the Pill is less important.

- In every 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group
- Likewise, in 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra

cases in addition to the 44 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop

taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like Desomono is believed to be similar to that in women who use the Pill, but the evidence is less conclusive

Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill. It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that these women were examined more often, so that the breast cancer is noticed earlier

### Thrombosis

pee your doctor immediately, if you notice possible signs of a thrombosis (see also "When should you contact your doctor?")

thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". As a result, fatal situations may occur,

Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.

The risk is higher in Pill-users than in non-users. The risk with progestogen-only pills like Desomono is believed to be lower than in pills that also contain oestrogens (combined Pills).

### **Other medicines and Desomono**

Tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicine.

Some medicines may stop Desomono from working properly. These include medicines used for the treatment of-

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and phenobarbital)
- tuberculosis (e.g. rifampicin)
- HIV infections (e.g. ritonavir), or other infectious diseases (e.g. griseofulvin)
- stomach upset (medical charcoal)
- depressive moods (the herbal remedy St. John's wort).

Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Desomono may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

### **Pregnancy and breast-feeding**

#### Pregnancy

#### Breast-feeding

Desomono may be used while you are breast-feeding. Desomono does not influence the production or the quality of breast milk. However, a small amount of the active substance of Desomono passes over into the milk.

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'normal. When a pack is empty, you must start with a new pack of Desomono on the next day - thus without interruption and without waiting for a bleed.

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### **Starting your first pack of Desomono**

- **When no hormonal contraceptive has been used in the past month.**

Wait for your period to begin. On the first day of your period take the first Desomono tablet. You need not take extra contraceptive precautions.

[You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method, for example a condom) for the first 7 days of tablet-taking.

- **When changing from a combined pill, vaginal ring, or transdermal patch.**

You can start taking Desomono on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free break). If your present Pill pack also contains<sup>1</sup> inactive tablets you can start Desomono on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptive

You can also start at the last day following the tablet-, ring-, patch-free break, or placebo tablet interval, of your present contraceptive. **If you follow these instructions, make sure you use an additional contraceptive method (barrier method, for example a condom) for the first 7 days of tablet-taking.**

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- **When changing from another progestogen-only pill (mini-pill).**

You may stop taking it any day and start taking Desomono right away. You need not take extra contraceptive precautions.

- **When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD).**

[Start using Desomono when your next injection is due or on the day that your implant or your IUD is removed. You need not take extra contraceptive precautions.

- **After having a baby.**

You can start Desomono between 21 to 28 days after the birth of your baby. If you start later, make sure you use during the first cycle an additional contraceptive method (barrier method) for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before starting Desomono use. Additional information for breast-feeding women can be found in "Pregnancy and Breastfeeding" in section 2. Your doctor can also advise you

- **After a miscarriage or an abortion.**

Your doctor will advise you.

### **If you forget to take Desomono**

- If you are **less than 12 hours** late in taking a tablet, the reliability of Desomono is maintained.

Take the missed tablet as soon as you remember and take the next tablets at the usual times.

- If you are **more than 12 hours** late in taking any tablet, the reliability of Desomono may be reduced.

The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the<sup>1</sup> last missed tablet as soon as you remember and take the next tablets at the usual times. This means that you possibly take 2 tablets on one day. Use an additional contraceptive method (barrier method, such as condoms) too for the next 7 days of tablet-taking. If you missed one or more tablets in the first week of tablet-intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

### **If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)**

follow the advice for missed tablets in the section above. If you vomit or use medical charcoal within 3-4 hours after taking your Desomono tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

### **If you take more Desomono than you should**

There have been no reports of serious harmful effects from taking too many Desomono tablets at one time. Symptoms that<sup>1</sup> may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your doctor for advice.

### **If you stop taking Desomono**

You can stop taking Desomono whenever you want. From the day you stop you are no longer protected against pregnancy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

serious undesirable effects associated with the use of Desomono are described in the paragraphs "Breast cancer" and "Thrombosis" in section 2 "Before you take Desomono". Please read this section for additional information and consult your doctor at once where appropriate.

Irregular bleeding may occur at irregular intervals during the use of Desomono. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Desomono is decreased. In general, you need not take any action; just continue to take Desomono. If, however, bleeding is heavy or prolonged you should consult your doctor.

Users of another desogestrel-only pill have reported the following side effects:

<b>Common</b> may affect up to 1 in 10 people	<b>Uncommon</b> may affect up to 1 in 100 people	<b>Rare</b> may affect up to 1 in 1,000 people
mood altered, depressed mood, decreased sexual drive	infection of the vagina rash,	hives, painful blue-red skin (libido) lumps (erythema nodosum) (these are skin conditions)
headache	difficulties in wearing contact lenses	
nausea	vomiting	
acne	hair loss	
breast pain, irregular or no menstruation	painful menstruation, ovarian cyst	
increased body weight	tiredness	

Apart from these side effects, breast secretion may occur.

You should see your doctor immediately if you experience symptoms of angioedema, such as (i) swollen face, tongue or pharynx; (ii) difficulty to swallow; or (iii) hives and difficulties to breathe.

### **Reporting of side effects**

If you get any side effects talk to your doctor, pharmacist or Family Planning Nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the national Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE DESOMONO**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original foil pouch to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Desomono contains**

The active substance is Desogestrel.

Each film coated tablet contains 75 microgram desogestrel.

The other ingredients are alpha-tocopherol; maize starch; povidone; stearic acid; hypromellose; macrogol 400; titanium dioxide (E 171); lactose monohydrate. |

The health of children breast-fed for 7 months whose mothers were using Desomono has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed. If you are breastfeeding and want to use Desomono, please contact your doctor.

### **Driving and using machines**

There are no indications of any effect of the use of Desomono on alertness and concentration.

### **What Desomono looks like and the content of the pack**

One blister pack of Desomono contains 28 biconvex, round, white film-coated tablets without break-marks. Each blister is enclosed in an aluminium foil pouch.

Each carton contains 1, 3, 6 or 13 blister packs. |

Not all pack sizes may be available.

### **Desomono contains lactose**

Desomono contains lactose (milk sugar). Please contact your doctor before taking Desomono if you have been told by your doctor that you are intolerant to some sugars.

### **Use in adolescents**

No clinical data on efficacy and safety are available in adolescents below 18 years. |

### **Regular Check-ups**

When you are using Desomono, your doctor will tell you to return for regular check-ups. In general, the frequency and<sup>1</sup> nature of these check-ups will depend on your personal situation.

### **Contact your doctor as soon as possible if:**

- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a **thrombosis**);

- you have a sudden, severe stomach ache or look jaundiced (possibly indicating **liver problems**);
- you feel a lump in your breast (possibly indicating **breast cancer**);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an **ectopic pregnancy**, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are **pregnant**.

### **3. HOW TO TAKE DESOMONO**

'Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you, are not sure.

#### **When and how to take the tablets?**

The Desomono pack contains 28 tablets. Each day corresponds with one tablet. On the back of the blister you will see the days of the week printed on the foil as well as arrows between each tablet. Every time you start a new pack of Desomono, i take a tablet from the top row. Do not start with just any tablet. For example if you start on a Wednesday, you must take the tablet from the top row marked (at the back) with Wed. Continue to take one tablet a day until the pack is empty, always following the direction indicated by the arrows. By looking at the back of your pack you can easily check if you have' already taken your tablet on a particular day. Take your tablet each day at about the same time. Swallow the tablet whole, |With water. You may have some bleeding during the use of Desomono, but you must continue to take your tablets as|

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#### **Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder:**

^edRx Developments Ltd 35-37 Ludgate Hill London, EC4M7JT, UK.

#### **Manufacturer:**

Pharbil Waltrop GmbH Im Wirrigen 25 D-45731 Waltrop

**This medicinal product is authorised in the Member States of the EEA under the following names:**

UK: Desomono 75 microgram film-coated tablets

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