

## Package leaflet: Information for the user

### Desogestrel Mylan 0,075 mg, tabletten

desogestrel

#### **Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

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

1. What Desogestrel Mylan is and what it is used for
2. What you need to know before you take Desogestrel Mylan
3. How to take Desogestrel Mylan
4. Possible side effects
5. How to store Desogestrel Mylan
6. Contents of the pack and other information

#### **1. What Desogestrel Mylan is and what it is used for**

- Desogestrel Mylan is used to prevent pregnancy.
- There are 2 main kinds of hormone contraceptive:
  - The combined pill, “**The Pill**”, which contains 2 types of female sex hormone (an oestrogen and a progestogen).
  - The progestogen-only pill, **POP**, which doesn't contain an oestrogen.
- Desogestrel Mylan is a progestogen-only-pill (POP).
- Desogestrel Mylan contains a small amount of one type of female sex hormone, the progestogen **desogestrel**.
- Most POPs work primarily by preventing the sperm cells from entering the womb but they do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- Desogestrel is different from most POPs in having a dose that in most cases prevents the egg cell from ripening. As a result, desogestrel is a highly effective contraceptive.
- In contrast to the combined pill, Desogestrel Mylan 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 Desogestrel Mylan. On the other hand, you may not have any bleeding at all.

## 2. What you need to know before you take Desogestrel Mylan

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

### Do not take Desogestrel Mylan:

- 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 is still not working normally.
- if you have or if you are suspected of having a **cancer** that grows under the influence of sex-steroids, such as certain types of breast cancer.
- if you have any unexplained **vaginal bleeding**.

Tell your doctor before you start to use this medicine 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 this medicine.

### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you have ever had **breast cancer**.
- if you have **liver cancer**, since a possible effect of desogestrel cannot be excluded.
- if you have ever had a **thrombosis**.
- if you have **diabetes**.
- if you suffer from **epilepsy** (See section 'Other medicines and Desogestrel Mylan').
- if you suffer from **tuberculosis** (See section 'Other medicines and Desogestrel Mylan').
- if you have high **blood pressure**.
- if 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 this medicine 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.

### Breast cancer

- It is important to regularly check your breasts and you should 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, this reduces the risk, so that 10 years after stopping the Pill, 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 the woman gets older.

Therefore, the extra number of breast cancers diagnosed is higher if a woman continues to take the Pill when she is older. 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.
- 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 Desogestrel Mylan 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 the women were examined more often, so that the breast cancer is noticed earlier.

### **Thrombosis**

See your doctor immediately if you notice possible signs of a thrombosis (see also 'Regular check-ups').

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". A pulmonary embolism can cause chest pain, breathlessness, collapse or even death.

- 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 Desogestrel Mylan is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

### **Psychiatric disorders**

Some women using hormonal contraceptives including Desogestrel Mylan have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

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

### **Other medicines and Desogestrel Mylan**

Tell your doctor if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Desogestrel Mylan. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

#### Some medicines

- can have an influence on the blood levels of Desogestrel Mylan
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding.

These include medicines used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and phenobarbital),
- tuberculosis (e.g. rifampicin, rifabutin),
- HIV infection (e.g. ritonavir, nelfinavir, nevirapine, efavirenz),
- Hepatitis C virus infection (e.g. boceprevir, telaprevir),
- other infectious diseases (e.g. griseofulvin),
- high blood pressure in the blood vessels of the lungs (bosentan),
- depressive moods (the herbal remedy St. John's wort),
- certain bacterial infections (e.g. clarithromycin, erythromycin),
- fungal infections (e.g. ketoconazole, itraconazole, fluconazole),
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem),
- insomnia or anxiety (barbiturates – also used to produce sedation)

If you are taking medicines or herbal products that might make Desogestrel Mylan less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Desogestrel Mylan may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Desogestrel Mylan may also interfere with how other medicines work, causing either an increase in effect (e.g. medicines containing ciclosporin) or a decrease in effect (e.g. lamotrigine).

*Ask your doctor or pharmacist for advice before taking any medicine.*

### **Pregnancy, breast-feeding and fertility**

#### Pregnancy

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

#### Breast-feeding

This medicine may be used while you are breast-feeding because it does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using Desogestrel Mylan. A small amount of the active substance desogestrel passes over into the milk.

The health of children who were breast-fed for 7 months while their mothers were using a desogestrel-only pill 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 breast feeding and want to use this medicine, please contact your doctor.

### **Driving and using machines**

There is no known effect on the ability to drive or use machines.

### **Desogestrel Mylan contains lactose**

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

### **Regular Check-ups**

When you are using this medicine, your doctor will tell you to return for regular check-ups. In general, the frequency and 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 (possible signs of a **blood clot**); possibly indicating a **thrombosis**;
- you have a sudden, severe stomach ache or **jaundice** (you may notice yellowing of the skin, the whites of the eyes, or dark urine, possibly a sign of **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 a sign of an **ectopic pregnancy**, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery
- you have unusual, heavy **vaginal bleeding**;
- you suspect that you are **pregnant**.

### **3. How to take Desogestrel Mylan**

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:**

Each blister strip of Desogestrel Mylan contains 28 tablets (this is 4 weeks' supply).

- **Take your tablet each day at about the same time. Swallow the tablet whole, with water.**

- Arrows are printed on the strip, between the tablets. The days of the week are also printed on the strip; each day corresponds with one tablet.
- Every time you start a new strip of Desogestrel Mylan, take a tablet from the top row. Don't start with just any tablet. For example, if you start on a Wednesday, you must take the tablet from the top row marked with WED.
- Continue to take one tablet every day until the pack is empty, always following the direction indicated by the arrows. By looking at the next day marked on the strip you can easily check if you have already taken your tablet on a particular day.
- You may have some vaginal bleeding during the use of this medicine (See section 4 Side Effects), but you must continue to take your tablets as normal.
- When a blister strip is empty, you must start with a new one on the next day - without interruption and without waiting for a bleed.

### Starting your first pack of Desogestrel Mylan

- **If you are not using hormonal contraception at present (or in the past month).**  
Wait for your period to begin. On the first day of your period take the first Desogestrel Mylan tablet. Additional contraceptive precautions are not necessary.  
  
If you take your first tablet on days 2 to 5 of your period, use an additional barrier method of contraception for the first 7 days of tablet-taking.
- **When you change from a combined pill, vaginal ring, or transdermal patch.**
  - If you don't have a tablet-, ring- or patch-free break:
    - Start taking Desogestrel Mylan 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 inactive (placebo) tablets you can start Desogestrel Mylan tablets 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 don't need to take extra contraceptive precautions.**
  - If you have a tablet-, ring- or patch-free break
    - You can also start on the day following the tablet-, ring-, patch-free break, or when you have taken all the inactive (placebo) tablets, of your present contraceptive.
    - **If you follow these instructions, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.**
- **When you change from another progestogen-only pill (mini-pill)**  
Switch on any day from another mini pill. Additional contraceptive precautions are not necessary.

- **When you change from an injection, implant or a hormonal Intrauterine device (IUS)**  
Start using Desogestrel Mylan when your next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.

- **After you have a baby**

You can start Desogestrel Mylan between 21 to 28 days after the birth of your baby.

If you start later, make sure that during the first cycle you use an additional barrier method of contraception until you have completed the first 7 days of tablet-taking. However, if you have already had sex, check that you are not pregnant before starting Desogestrel Mylan.

Information for breast-feeding women can be found in section 2 “What you need to know before you take Desogestrel Mylan” in the paragraph “Pregnancy, breast-feeding and fertility”. Your doctor can also advise you.

- **After a miscarriage or an abortion**

Your doctor will advise you.

#### **If you forget to take Desogestrel Mylan**

- **If you are less than 12 hours late:**

Take the missed tablet as soon as you remember and take the next one at the usual time. Desogestrel Mylan will still protect you from pregnancy.

- **If you are more than 12 hours late:**

If you are more than 12 hours late in taking any tablet, you may not be completely protected against pregnancy. The more consecutive tablets you have missed, the higher the risk that you might fall pregnant.

Take a tablet as soon as you remember and take the next one at the usual time. This may mean taking two in one day. Continue to take your tablets as usual but you must also use an extra method, such as a condom, for the **next 7 days**.

If you missed one or more tablets in the **very first week** of tablet-intake and had intercourse in the week before missing the tablets, you may fall pregnant. Ask your doctor for advice.

#### **If you vomit or have diarrhoea**

Follow the advice for forgotten tablets in the section above. If you vomit within 3-4 hours after taking your Desogestrel Mylan or have severe diarrhoea, the active ingredient may not have been completely absorbed.

#### **If you take more Desogestrel Mylan than you should**

There have been no reports of serious harmful effects from taking too many Desogestrel Mylan tablets at one time. Symptoms that may occur are nausea, vomiting and in young girls, slight vaginal bleeding.

For more information ask your doctor for advice.

#### **If you stop taking Desogestrel Mylan**

You can stop taking this medicine 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 product, ask your doctor or pharmacist.

#### 4. Possible side effects

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

Tell your doctor if you notice any unwanted effect, especially if severe or persistent.

#### Contact your doctor as soon as possible or seek immediate medical help:

**Rare** (may affect up to 1 in 1,000 people):

- if 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)
- if you develop a skin condition such as rash, hives, painful blue-red skin lumps (erythema nodosum).

**Not known** (frequency cannot be estimated from the available data):

- if you have swelling of the face, lips, tongue or throat leading to difficulty swallowing or difficulties breathing (possibly indicating angioedema)
- if you have severe pain or swelling in either of your legs, unexplained pain in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis or an embolism respectively) (see also section 2)
- if you have a sudden, severe stomach ache or look jaundiced (possibly indicating liver problems)
- yellowish-brown pigmentation patches on the skin, particularly of the face (chloasma)
- if you feel a lump in your breast (possibly indicating breast cancer) (see also section 2)

**Vaginal bleeding may occur at irregular intervals** while using this medicine. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period. You may need to use tampons or sanitary towels. You may also not have any bleeding at all. Irregular bleeding is not a sign that this medicine is not working. In general, you need not take any action; just continue to take this medicine. **If bleeding is heavy or prolonged you should consult your doctor.**

#### Other possible side effects

**Common** (may affect up to 1 in 10 women):

- mood changes
- depressed mood
- decreased sexual drive (libido)
- headache
- nausea (feeling sick)
- acne
- breast pain
- irregular or no periods
- increased body weight.

**Uncommon** (may affect up to 1 in 100 women):

- infection of the vagina



- difficulties in wearing contact lenses
- vomiting (being sick)
- hair loss
- painful periods
- ovarian cysts
- tiredness.

Apart from these side effects, breast secretion or leakage may occur.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Desogestrel Mylan**

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 blister, pouch or carton after "EXP:". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Desogestrel Mylan contains**

The active substance is desogestrel. Each tablet contains 75 micrograms of desogestrel.

The other ingredients are: lactose, all-rac- $\alpha$ -tocopherol, povidone, potato starch, silica colloidal anhydrous, stearic acid.

(See also 'Important information about some of the ingredients of Desogestrel Mylan' in section 2).

### **What Desogestrel Mylan looks like and contents of the pack**

Each tablet is round, white to off-white, uncoated, biconvex with approximately 5 mm of diameter and debossed with '152' on one side.

Desogestrel Mylan is available in blister packs of 28, 84 or 168 tablets, presented in strips of 28 tablets.

Each carton contains blisters packed separately in an aluminium laminated sachet.

Not all pack sizes may be marketed.

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

**Marketing Authorisation Holder:**

Mylan B.V.  
Dieselweg 25  
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**Manufacturers:**

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**In het register ingeschreven onder:**

RVG 120615

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

France: DESOGESTREL MYLAN PHARMA 75 microgrammes, comprimé  
Germany: Simonette 75 Mikrogramm Tabletten  
Netherlands: Desogestrel Mylan 0,075 mg, tabletten  
Poland: Demyrette  
Portugal: Myrazette

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