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PACKAGE LEAFLET INFORMATION FOR THE USER
DANYA 75 microgram film-coated tablets
Desogestrel

Using Danya: summary of key points

If this is your first time using Danya, you must read all of this leaflet carefully before you start taking it. If you have already used Danya, you must check this medicine is still right for you.

Here are some **key points to consider** before taking Danya:

- Danya is a contraceptive pill for women who want to prevent pregnancy.
- **Take one tablet at the same time every day without any break between packs.** Always read "When and how to take the tablets" before starting Danya.
- **If you forget to take Danya:**
 - If you are **less than 12 hours late**, take the delayed pill straight away and take your further pills as usual. Danya will still protect you from pregnancy.
 - If you are **more than 12 hours late**, take the most recently missed pill straight away and leave any earlier missed pills in the strip. Take your further pills as usual. Use extra contraception (e.g. condoms) for the next 7 days. Missing tablets at any time in the cycle can reduce the efficacy of Danya and risk pregnancy. But if you have missed one or more tablets in the first week of taking Danya and had sex in the week before missing the tablets, the risk you may get pregnant is higher. Ask your pharmacist for advice.

For full details, see the chart in section 3, under "If you forget to take Danya".

It is common for women taking Danya to have bleeding patterns which are different from their usual periods, but to have no periods at all for some time.

In some circumstances it may not be appropriate to take Danya or it may be necessary to consult a doctor before taking Danya (see section 2 "Do not take Danya" and "Warnings and precautions").

Some medicines may reduce the efficacy of Danya. Tell your pharmacist if you are taking, or may start taking any other medicines (see section 2 "Other medicines and Danya").

Now read the rest of this leaflet. It includes other key points on the safe and effective use of this medicine that might be especially important for you.

This leaflet was last revised in August 2024.

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.

Ask your pharmacist if you need more information or advice.

If you get any side effects, talk to your pharmacist, doctor or family planning nurse. This includes any possible side effects not listed in section 4 of this leaflet.

Talk to your doctor if you find Danya doesn't suit you, or you're finding it difficult to take as instructed.

What is this leaflet:

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

1. WHAT DANYA IS AND WHAT IT IS USED FOR

Danya is a daily contraceptive used to prevent pregnancy for women of childbearing age. It is an oral hormonal contraceptive (often called "the pill"). Danya works primarily by preventing a woman's egg cell from ripening (prevents ovulation); it also has effects on cervical mucus which makes it more difficult for sperm to enter the womb. Danya contains two active ingredients: desogestrel, a progestogen, and ethinylestradiol, an oestrogen. For this reason Danya is called a progestogen-only pill (POP), or a mini-pill. Unlike the combined pill, Danya does not contain an oestrogen hormone in addition to the progestogen.

Other methods of contraception are available with a prescription that might suit you better – see section 6 "More about contraception and women's health screening" at the end of this leaflet. Talk to your pharmacist, doctor or family planning nurse if you want more information.

Unlike the combined pill, Danya can be used by women who cannot take oestrogens and by women who are breast-feeding.

If you think you are post-menopausal, talk to your doctor. You may not need to take contraceptives.

Hormonal contraceptives, including Danya, do not protect you against HIV infection (AIDS) or any other sexually transmitted disease. Only condoms protect you from sexually transmitted infections.

This product does not work as an emergency contraceptive. If it's taken every day it will protect against a pregnancy in the future.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DANYA

Do not take Danya:

- if you are **allergic** to desogestrel or any of the other ingredients of this medicine (listed in section 6).
- if you have a **blood clot** in the legs (deep vein thrombosis) or lungs (pulmonary embolism) (see section "Blood clot" in section 2 "Warnings and precautions").
- if you have or have had **jaundice** (yellowing of the skin or whites of the eyes) or **severe liver disease** and blood tests show your liver is not working properly.
- if you have or are suspected to have a **cancer** that is affected by sex-hormones, such as certain types of breast cancer, ovarian cancer and uterine cancer.
- if you have any **unexplained vaginal bleeding** between your periods, or if you repeatedly have bleeding after sex.
- if you are pregnant or think you may be pregnant.

Talk to your doctor or family planning nurse if any of these apply to you. Your doctor or family planning nurse may advise you to use a different method of contraception.

Warnings and Precautions

Talk to your pharmacist, doctor or family planning nurse before taking Danya, if:

- you have had cancer that is affected by progestogen hormones, such as certain types of breast cancer, ovarian cancer, endometrial (uterine) cancer.
- you have liver cancer or other liver problems.
- you have had a blood clot in the legs (deep vein thrombosis) or lungs (pulmonary embolism).
- you suffer from epilepsy (see section 2 "Other medicines and Danya").
- you have diabetes.
- you have high blood pressure.
- you have or have had **chloasma** (yellowish-brown pigmentation patches on the skin, particularly of the face)

If any of these apply to you, you may still be able to take Danya but your doctor may want to see you from time to time.

It is common for women taking Danya to have bleeding patterns that are different from their usual periods. Some women will have bleeding less often, or none at all, some will have bleeding more often. Bleeding patterns may settle with time. A change in your bleeding pattern is not something you should normally be worried about if you are taking your pill as directed – see section 4 "Changes to your periods".

Breast Cancer

Breast cancer is rare in women under 40 years old. The risk increases as women get older. See your doctor as soon as possible if you feel any lumps or see a change in your breasts.

The risk of breast cancer is slightly higher in women taking any contraceptive pill, compared to women of the same age not on the pill. The risk with progestogen-only pills, such as Danya, is thought to be similar to that in women on the combined pill. It may be lower, though more research is needed to be certain.

A woman's risk while on the combined pill is more affected by how old she is, rather than for how long she takes the pill.

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 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.

Compared to the risk of getting breast cancer ever in life, the increased risk associated with the combined pill is low. It may be that women on the combined pill were examined more often, so that the breast cancer was noticed earlier.

When women stop taking the pill, their risk of breast cancer gradually reduces so that, within 10 years of stopping, their risk is the same as for those who have never taken it.

Blood clots

Blood clots in major arteries and veins are rare but can cause serious health problems. The risk of a blood clot is higher in women on any type of contraceptive pill, but no higher than in non-pregnant women. The risk with progestogen-only pills, such as Danya, is thought to be lower than in women on the combined pill, but this has yet to be confirmed.

A clot in the deep veins of the leg (called a deep vein thrombosis, or DVT) can cause the following symptoms, usually in the calf:

- swelling of the leg
- redness and warm skin
- severe pain in the leg

A clot in the leg can travel to the lungs and stop there (a pulmonary embolism), which can be fatal. Signs of a blood clot in the lungs include:

- chest pain
- breathlessness
- coughing up blood

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3. HOW TO TAKE DANYA

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or family planning nurse tells you. Check with your doctor, pharmacist or family planning nurse if you are not sure.

Danya will not prevent pregnancy unless taken exactly as directed.

Take one tablet at the same time every day, without a break between packs.

Follow the tablet while choosing a convenient time of day. It is best to link this to something you always do at the same time every day. For example, when you wake up, or when you brush your teeth. Never skip your daily tablet. Take it every day, even when you bleed or have spotting (see Section 4, "Possible side effects").

The Danya 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 arrows between two tablets. If you follow these instructions, make sure you use extra contraception (for example, condoms) for the first 7 days of taking Danya.

If you haven't had your usual break from a combined pill, start taking Danya on the day after you take the last tablet from your present pill pack. Even if your other pill pack contains inactive tablets, you can start Danya on the day after taking the last active tablet. If you are not sure which this is, ask your pharmacist. If you follow these instructions, you do not need extra contraception.

Changing from a vaginal ring or skin patch

If there has been a break between removal of the vaginal ring or skin patch file, you are not starting Danya on the day of removal of the ring or patch), make sure you use extra contraception (for example, condoms) for the first 7 days of taking Danya.

If you start taking Danya on the day of removal of the vaginal ring or skin patch, you do not need extra contraception.

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

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

When changing from an injection, implant or hormone-containing coil (IUS)

When changing from an injection, start using Danya on the same day the injection is due. You do not need extra contraception.

When changing from an implant or hormone-containing coil (IUS), start Danya the same day the IUS or implant is removed. Your doctor will advise you when the IUS should be removed and whether you need any extra contraception.

Starting or resuming Danya following emergency contraception

Ask your pharmacist for advice on how to start taking or resuming taking Danya following emergency contraception. If you have taken emergency contraception, it is advisable to wait until day 1 of your next menstrual period before taking Danya.

Emergency contraception containing **levonorgestrel** can be used with Danya. If you have used emergency contraception containing levonorgestrel during your cycle, you can start or continue taking Danya the same day, but you must use additional contraception (for example, condoms) every time you have sex for the next 7 days.

Using Danya and emergency contraception containing **ulipristal acetate** together can alter the effect of both these medicines, resulting in reduced contraceptive effect and increased risk of pregnancy. If you have used emergency contraception containing ulipristal acetate during your cycle, you must wait 5 days after taking ulipristal acetate before taking Danya and you must also use additional contraception (for example, condoms) every time you have sex during the 5 days while you wait to start or resume taking Danya and for the first 7 days of taking Danya (ie, for a total of 12 days).

After having a baby

You can start Danya any day between day 1 and day 21 after the birth of your baby. If you start later, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet taking. If you have already had unprotected sex, take a pregnancy test or talk to your doctor before starting Danya. Additional information for breast-feeding women can be found in "Pregnancy and Breast-feeding" in section 2, "Your doctor can also advise you".

After a miscarriage or abortion

You can start Danya immediately or within 5 days of a miscarriage or an abortion. You do not need extra contraception. If in doubt, your doctor or family planning nurse will advise you.

If you forget to take Danya

When were you due to take this missed pill?

- **Less than 12 hours ago**
 - Take the delayed pill straight away.
 - Take your further pills as usual. This may mean taking two pills in one day.
 - Don't worry, your contraceptive protection should not be reduced.
- **More than 12 hours ago**
 - Take the most recently missed pill straight away.
 - Leave any earlier missed pills in the strip.
 - Take your further pills as usual.
 - Use extra contraception (e.g. condoms) for the next 7 days.
 - If you have missed one or more tablets in the very first week of taking Danya, the risk of getting pregnant is higher than at any other time in your cycle. Ask your pharmacist for advice and if you need to use emergency contraception.

If your period is late after missing any pills in the last month, or if you think you may be pregnant, take a pregnancy test. Stop taking Danya and see your doctor if you become pregnant (see section 2 "Pregnancy and Breast-feeding").

If you vomit or have severe diarrhoea

If you vomit within 3 hours of taking Danya, the pill should be considered 'missed' and the advice under section 3 "If you forget to take Danya" followed. If you have severe or persistent vomiting or diarrhoea, Danya may not have been completely absorbed and contraceptive effect may be reduced. You should use additional contraception (for example, condoms) for the duration of the illness and for the first 7 days of normal pill taking. If you are not sure what to do, ask your pharmacist for advice.

If you take more Danya than you should

There have been no reports of serious harmful effects from taking too many Danya tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your pharmacist, doctor or family planning nurse.

If you stop taking Danya

You can stop taking Danya 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 pharmacist, doctor or family planning nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your pharmacist, doctor or family planning nurse if you notice any unwanted effect, especially if severe or persistent.

Serious side effects are rare

Severe allergic reactions

You may experience signs of a severe allergic reaction (hypersensitivity) including:

- unusual cough, or if you cough up blood (possibly a sign of a blood clot).
- difficulty swallowing or breathing.

Get medical advice immediately if you get any of these:

- **Emergency outside the womb (ectopic pregnancy)**: Rarely, women taking Danya have had an ectopic pregnancy, where the baby develops outside the womb. Symptoms might include:
 - a sudden or severe pain in the lower abdomen or stomach area with or without vaginal bleeding.
 - dizziness or fainting.
- if you have a sudden severe stomach ache or look jaundiced (you may notice yellowing of the skin and the whites of the eyes, or dark urine, possible signs of liver disease)

As soon as possible

- if you feel a lump or see changes in your breast (possibly a sign of breast cancer)
- if you have unusually heavy vaginal bleeding or if you repeatedly have bleeding after sex
- if you think you are pregnant

If you are due to have surgery that will make you immobile, consult your doctor at least four weeks in advance.

Common side effects

These may affect up to 1 in 10 women

- altered mood, depressed mood
- decreased sexual drive (libido)
- headache
- nausea
- breast pain
- irregular or no periods
- increased body weight

Uncommon side effects

These may affect up to 1 in 100 women

- irritation of the vagina
- difficulties in wearing contact lenses
- vomiting
- hair loss
- painful periods
- ovarian cysts
- tiredness

Rare side effects

These may affect up to 1 in 1,000 women

- hives
- painful blue-red skin lumps (erythema nodosum)

As well as these side effects, you may notice breast secretion or leakage.

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 to the national Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DANYA

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

One blister pack of Danya contains 28 tablets, which is stated on the carton label and blister foil after EXP. The expiry date refers to the last day of that month.

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 Danya contains

The active substance is Desogestrel.

Each film coated tablet contains 75 microgram desogestrel; stearic acid; hypromellose; macrogol 400; titanium dioxide (E 171); lactose monohydrate (see section 2).

What Danya looks like and the contents of the pack

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

Each blister contains 1 or 4 blister packs. Not all pack sizes may be available.

Marketing Authorisation Holder:

- 11 Boumpoulinas, Nicosia, 1060 Cyprus

Manufacturer:

- Pharm Walpurg GmbH
- Im Wirtgen 25, D-45731 Waltrop, Germany

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

- Danya 75 microgram film-coated tablets.

This leaflet was last revised in August 2024.

More about contraception and women's health screening

Regular contraception

Consider taking emergency contraception after unprotected sex, or if your contraceptive method has failed (for example, a condom fits split or you have missed a pill). Ask your pharmacist for advice.

Male and female sterilisation	Permanent method
Progestogen-only implant	Long-lasting method (3 years)
Hormone-containing coil (IUS)	Long-lasting method (5 years)
Copper-coil (IUD)	Long-lasting method (5 to 10 years)
Progestogen-only injectable	Long-lasting method (3 to 13 weeks)
Combined oral contraception (COCP) pill	Daily method (pill)
Transdermal patch (patch), vaginal ring	Daily or monthly method
Male and female condoms	With every episode of sex
Female diaphragm	With every episode of sex
Natural family planning	Avoid sex during fertile time

Emergency contraception

Consider taking emergency contraception after unprotected sex, or if your contraceptive method has failed (for example, a condom fits split or you have missed a pill). Ask your pharmacist for advice.

Women's health screening

Some tests (breast screening) are offered by the NHS to women aged 25 to 64 to check the health of cells in the breasts. Breast screening is also offered to women aged 50 to 71 to detect early signs of breast cancer. For cervical screening and breast screening, contact your doctor. You can also contact your local breast screening unit.

Other sources of information

For more information on all methods of contraception, emergency contraception or screening, go to <https://www.nhs.uk>

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