

Drospinon

Film Coated Tablets



Chemical Composition/Doses:

Each tablet contains: DROSPIRENONE 3 mg, and ETHINYLESTRADIOL 30 mcg.

Pharmacological Classifications: Hormones – Progestogens & Estrogens.

Chemical and Pharmacological Properties:

Drospinon film-coated tablets are a drug to prevent pregnancy occurring ("Pill").

"Pill" which contains two hormones is called combination preparations. Each tablet contains a small amount of two female sex hormones, to be precise Drospinon (a hormone that has an effect similar to the natural corpus luteum hormone) and Ethinylestradiol (a hormone with an estrogenic effect). Owing to the low content of hormones Drospinon film-coated tablets belong to the group of "Micro-pills". Since all the tablets of a calendar pack contain the same amount of the two hormones, this "Pill" is also called a "Monophasic preparation".

Indications: Hormonal contraceptive

Contra Indications:

- Combination preparations must not be taken under the conditions listed below. If any of these cases applies to you, you must inform your physician before using Drospinon film-coated tablets. Your physician may possibly then recommend another "Pill" or a different (non-hormonal) contraception method.
- When must you not take Drospinon film-coated tablets? You must not take Drospinon film-coated tablets if: There is a blood clot (venous thrombosis) in a leg, in the lungs or other parts of the body, if you have previously had such a disorder (cf. "Pill" and thrombosis).
- There is a disorder of the arterial blood vessels such as a cardiac infarction or stroke(cf. "Pill" and thrombosis)
- There is a significantly enhanced of thromboembolic events.
- This risk is significantly enhanced given the following conditions:
- present or past illnesses which may be the warning signs of a cardiac infarction (such as angina pectoris which is revealed by a severe pain in the chest) or of a stroke (such as a transient ischemic attack, a mild stroke without lasting symptoms),
- diabetes mellitus (sugar) with vascular damage.
- very high blood pressure.
- Severely enhanced blood lipids (cholesterol and triglycerides).
- present (possibly hereditary) blood clotting disorder such as APC (activated protein C) resistance, antithrombin III deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinemia and antiphospholipid antibodies.
- Present or past severe liver disease or jaundice, Jaundice (icterus) or itching (pruritus) over the whole body may be the first signs of a liver disease.
- Severe renal insufficiency or acute renal failure.
- Confirmed or suspected breast cancer or cancer of the sex organs.
- Present or past benign or malignant liver tumors.
- Unexplained, unusual vaginal bleeding.
- A history of migraine with focal neurological symptoms.
- Hypersensitivity to any of the medicinally active or other constituent contained in the Drospinon film-coated tablets.

If any of the above cases occurs when Drospinon film-coated tablets are being taken, you stop taking the drug immediately and see your physician. In the meantime you should use a different, nonhormonal contraception method. Also see the section "General remarks".

Side Effects:

What side effects can occur when using Drospinon film-coated tablets?

Serious side effects

The serious side effects associated with the "Pill" are listed in the section

"precautions for use and warning". You will find more details there. If needed consult your physician without delay.

Other possible side effects

The following side effects have been reported by users of the "Pill":

Organ /system		Common > 1/100	Frequency of undesired effects Uncommon < 1/100, < 1/1000	Rare > 1/1000
Immune system				asthma
Endocrine system	Cycle disturbances, intermenstrual bleeding, breast pain			Secretion from the nipples
Nervous system and psyche	Headache, mood swings		Reduced sex drive (libido)	
ears				Hardness of hearing
vessels	migraine		High blood pressure, low blood pressure	Thromboembolism
Gastrointestinal tract	nausea		vomiting	
skin			Acne, eczema itching	
Genital organs and breast	Changes in vaginal secretion, moniliasis		vaginitis	
Miscellaneous			Fluid retention, weight changes	

If you notice side effects yourself that are not listed in this package leaflet, please inform your physician or pharmacist.

Precautions:

When is it only permitted to take Drospinon film-coated tablets after consulting your physician?

Special monitoring may be needed in certain cases when a combination preparation is used. If any of these cases applies to you, you must inform your physician before starting to take Drospinon film-coated tablets. This mainly applies to the following conditions, and your physician can the risk in detail:

- Smoking
 - Sugar (diabetes mellitus)
 - Considerable overweight
 - High blood pressure
 - Diseases of the heart valves or certain heartbeat disturbances
 - Vein inflammation (superficial phlebitis)
 - Varicose veins (varices)
 - Occurrence of blood clots, heart attacks or stroke in a close relative
 - Migraine
 - Falling sickness (epilepsy)
 - High blood lipid levels (cholesterol or triglycerides), also in close relatives
 - Breast cancer in a close relative
 - Liver or gallbladder diseases
 - Crohn's disease or colitis ulcerosa (chronic inflammation of the intestines)
 - Systemic lupus erythematosus (a certain immune system disease)
 - Hemolytic- uremic syndrome (a certain blood disease that causes renal damage)
 - Present or past chloasma (yellowish brown pigment spots, Also known as "pregnancy mask", primarily in the face). In this case it is recommended to avoid direct sunlight or ultraviolet light.
- When you take Drospinon film-coated tablets and any of the cases described above occur or any of the diseases listed there deteriorates, you must see your physician.

What must be considered before taking Drospinon film-coated tablets?

Drug and Food Interactions

What other drugs influence the effect of Drospinon film-coated tablets

Several drugs can impair the effect of the "Pill". These include:

- drugs to treat epilepsy, such as hydantoins (e.g. phenytoin), barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate and felbamate
- drugs to treat tuberculosis (e.g. rifampicin)
- some antibiotics prescribed to treat certain infections (e.g. ampicillin, tetracycline, griseofulvin)
- ritonavir
- drugs containing St-john's-work (hypericinum)

other interactions

women using Drospinon film-coated tablets at the same time as other drugs with a potential for increasing serum potassium, e.g. same diuretics (potassium-sparing diuretics), some painkillers (nonsteroidal anti-inflammatory drugs) and a series of drugs to treat high blood pressure must their serum potassium checked in the first treatment cycle.

Please note that may also apply to drugs used recently.

Always inform your physician prescribing "Pill" what other drugs you are taking.

Likewise inform any other physician or dentist who prescribes drugs for you that you are taking Drospinon film-coated tablets. They will be able you whether and for how long you must use additional, no hormonal contraception.

Doses/Indications:

The following statements apply unless your physician has not prescribed Drospinon film-coated tablets otherwise. Please observe the prescription for use, us otherwise Drospinon film-coated tablets cannot work reliably!

When and how should you take Drospinon film-coated tablets?

Each calendar pack contains tablets. Each tablet is marked with the day of the week it must be taken. Take the tablets at the same time each day, with some liquid if needed.

Continue taking [the tablets] in the direction of the arrows until all 21 tablets have been used up.

Then stop taking the tablets for seven days. During this seven-day break bleeding should start (withdrawal bleeding). As a rule this happens on the second or third day after the last film-coated tablets has been taken. Starting taking [tablets] from next calendar pack on the eight day, irrespective of whether bleeding is still continuing or not. For one thing means that you will always be starting a new calendar pack on the same day of the week, and for another that your bleeding will be on about the same each month.

When should you start taking [tablets] from the first calendar pack?

• If you were not taking any "Pill" for contraception in the previous month:

Starting taking the Drospinon film-coated tablets on the first day of your cycle, i.e. on the first day of menstrual bleeding. Press a tablets out of the pack at the place marked with the appropriate day of the week.

• Switching from another combination preparation:

You can start taking Drospinon film-coated tablets on the day after the usual tablet-free break following the taking of the last tablet of previous preparation that contained an active ingredient. If the previous pill pack also contained tablets without an active ingredient, you must start taking Drospinon film-coated tablets immediately after the last tablet without an active ingredient if you do not know which is the last tablets containing an active ingredient. ask your physician or pharmacist.

• Switching from a mini pill:

You can stop taking the mini pill on any day and start taking Drospinon film-coated tablets from the very next day.

• Switching from an injection or implant:

Start taking Drospinon film-coated tablets at the time the next injection would otherwise have to be done, or the day the implant is removed.

• After the birth of a child:

If you want to start taking Drospinon film-coated tablets very soon after childbirth, your physician will usually recommended that you wait until the first normal menstruation has occurred. Sometimes you can start even earlier. Your physician will advise you about it.

If you are breastfeeding and would like to take Drospinon film-coated tablets, you should likewise ask your physician.

• After a miscarriage or an abortion:

Ask your physician for advice.

What must be observed if you like to stop taking Drospinon film-coated tablets?

You can stop taking Drospinon film-coated tablets at any time. If you do not want to become pregnant, ask your physician about other reliable birth control methods.

If you stop taking [the product] because you would like to become pregnant, it is recommended that you wait for next natural period before trying to conceive. This helps you to calculate the date of birth.

Overdoses/Toxicity)

What is to be observed, if you have too many Drospinon film-coated tablets (overdose)?

There has been no experience to date of an overdose of Drospinon film-coated tablets.

Going by general experience with oral contraceptives ("Pills") the following symptoms can occur on overdose: nausea, vomiting or intermenstrual bleeding. If you discover that a child has taken several tablets by accident, obtain medical help.

you have forgotten to take the tablets?

• You are less than 12 hours late in taking one of the tablets; the contraceptive effect of Drospinon film-coated tablets is still maintained. You must take the missed tablet as soon as possible and take the subsequent tablets at their normal time.

• You are more than 12 hours late in taking one of the tablets; the contraceptive effect is no longer maintained. The risk of an ...

Reverse:

unwanted pregnancy high it a tablet was missed at the beginning or the calendar pack. You should then proceed as described below .

You have missed more than one tablet in the current calendar pack:

Ask your physician for advice.

You missed one tablet in week 1:

Take the missed tablet as soon as possible, even if this means taking two tablets at the same time. You can continue taking the tablets as normal, but for the next seven days you must use extra contraceptive precautions (e.g. a condom). If you had sexual intercourse in the week prior to the missed tablet, there is a risk of pregnancy. Tell your physician immediately in that case.

You missed one tablet in week 2:

Take the missed tablet as soon as possible, even if this means taking two tablets at the same time. Provided you took Drospinon film-coated tablets regularly on the seven days prior to the missed tablet, the contraceptive effect of the "Pill" is maintained and you need not take any extra precautions.

You missed one tablet in week 3:

you can choose between two options:

1- Take the missed tablet as soon as possible, even if this mean having to take two tablets at the same time. Take the subsequent tablets at the usual time again. Skip the tablet-free break and start taking tables from the next calendar pack right away. It is most likely that there will not be a proper withdrawal bleeding until you have used up this second calendar pack, but there may be spotting or breakthrough bleeding while the second pack is being taken. Or

2-You can immediately stop taking [tablets] from the current pack and after a tablet-free break of not more 7 days (you must also count the day the tablet was missed!) you can start taking from the next calendar pack right away. If you would like to start taking [tablets] from the new calendar pack on the day of the week you are used to, you can make the tablet-free break less than seven days.

• If you have forgotten to take several tablets and if no bleeding occurs in the first tablet-free break after a calendar pack has been used up, you have possibly become pregnant. In this case you must see your physician before starting on a new calendar pack.

Storage Conditions: Do not store above 25°C! Store in the original pack. Keep out of children's reach!

Other Observations

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THIS IS A MEDICAMENTS		
A medicament is a product but unlike any products. A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicines, their benefits and risks. Do not by yourself interrupt the period of treatment prescribed. Do not repeat the same prescription without consulting your doctor.		
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