

Daylina 3 mg/0.02 mg Film-Coated Tablets

Drospirenone (3 mg) and Ethinylestradiol (0.02 mg)

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What *Daylina* is used for

Oral contraception. *Daylina* is used to prevent pregnancy.

Treatment of moderate acne vulgaris in women who elect to use oral contraception.

Treatment of symptoms of premenstrual dysphoric disorder (physical and emotional symptoms including acne, tender breasts, bloating, feeling tired, irritability, and mood changes that occur in the one to two weeks before a woman's period).

How *Daylina* works

The contraceptive effect of *Daylina* is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the endometrium.

Before you use *Daylina*

- When you must not use it

- if you have (or have ever had) a blood clot in a blood vessel of your legs, your lungs or other organs
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots')
- if you have ever had a heart attack or a stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or temporary stroke symptoms)
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
 - severe diabetes with blood vessel damage
 - very high blood pressure

- a very high level of fat in the blood (cholesterol or triglycerides)
- a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura'
- if you have (or have ever had) liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or drospirenone, or any of the other ingredients of this. This may cause itching, rash or swelling.
- if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir / pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir. *Daylina* can be restarted approximately 2 weeks after completion of this treatment.
- *Daylina* contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

Pregnancy and lactation

If you are pregnant, you must not take *Daylina*. If you become pregnant while taking *Daylina* you must stop immediately and contact your doctor.

Use of *Daylina* is generally not advisable when a woman is breastfeeding.

- Before you start use it

Before the use of the tablet, a thorough medical and gynaecological examination should be carried out to exclude pregnancy and diseases representing risks.

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

Warnings and precautions

Tell your doctor if any of the following conditions apply to you or gets worse while you are using *Daylina*:

- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor

- immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema;
- if you have gall bladder disease (gallstones);
- if you have diabetes
- if you have depressed mood (depression);
- if you have Crohn's disease or chronic inflammatory bowel disease;
- if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you suffer or have suffered from inflammation of the pancreas and this is associated with severe increase in blood fats (triglycerides);
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins
- if you have epilepsy
- if you suffer from a certain type of deafness (otosclerosis) that became worse during previous pregnancies;
- if you have the inherited disease called porphyria;
- if you have Sydenham's chorea (a disease of the nerves in which uncontrolled movements of the body occur);
- if you have brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.

BLOOD CLOTS

Using a combined hormonal contraceptive such as *Daylina* increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems. It is important to remember that the overall risk of a harmful blood clot due to *Daylina* is small.

Seek urgent medical attention if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke.

Symptoms of blood clots can include:

Deep vein thrombosis:

- unusual unilateral leg pain and/or

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swelling

Pulmonary embolism:

- sudden breathlessness or rapid breathing
- sudden onset of coughing
- sharp chest pain which may increase with deep breathing

Blood clot in the eye:

- sudden, partial or total loss of vision

Heart attack:

- chest discomfort, pressure, squeezing pain below the breastbone, sometimes radiating to the back, jaw, throat, arm and stomach
- rapid or irregular heartbeats
- anxiety, shortness of breath
- fullness, indigestion or choking feeling

Stroke:

- sudden weakness or numbness of the face, arm or leg, especially on one side of the body;
- sudden confusion, trouble speaking or understanding
- loss of consciousness with or without focal epileptic seizures

Blood clots blocking other blood vessels:

- swelling and slight blue discolouration of an extremity;
- severe pain in your stomach.

Factors that increase your risk of a blood clot in a vein and in an artery

- as you get older (particularly above about 35 years);
- smoking (women over 35 years should be strongly advised not to smoke if they wish to use a combined oral contraceptive)
- obesity (body mass index or BMI over 30 kg/m²);
- if one of your immediate family has had a stroke, heart attack or blood clot in the leg, lung or other organ at a young age;
- prolonged immobilisation, major surgery, any surgery on the legs, or major trauma;
- high blood pressure;
- migraine;
- if you, or someone in your immediate family, have a high level of fat in the blood;
- if you gave birth less than a few weeks ago;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm);
- if you have diabetes.

Hormonal contraceptive and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it

may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump. In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders

Some women using hormonal contraceptives including *Daylina* 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.

Bleeding between periods

During the first few months that you are taking *Daylina*, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.

Daylina contains lactose, sunset yellow and soya lecithin

In *Daylina* the white active film-coated tablets contain 48.53 mg of lactose monohydrate and the green inactive ones contain 37.26 mg of lactose anhydrous per film-coated tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The hormone-free film-coated tablets contain "sunset yellow" colouring agent which may cause allergic reaction. *Daylina* also contains 0.070 mg of soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines can have an influence on the blood levels of *Daylina* and can make it *less effective in preventing pregnancy* or can cause unexpected bleeding, such as medicines used for the treatment of:

- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidone, felbamate, oxcarbazepine, topiramate);
 - tuberculosis (e.g. rifampicin);
 - HIV and hepatitis C virus infections (e.g., ritonavir, nevirapin, efavirenz);
 - fungal infections (e.g. griseofulvin, ketoconazole);
 - high blood pressure in the blood vessels in the lungs (bosentan)
 - inflammation and pain of the joints (etoricoxib)
 - the herbal remedy St. John's wort (*Hypericum perforatum*).
- Daylina* may influence the effect of other medicines, e.g.,
- ciclosporin (to prevent transplant rejection);
 - lamotrigine (used for the treatment of epilepsy);
 - tizanidine (used for the treatment of muscle spasm);
 - theophylline (used to treat breathing problems).

How to use Daylina

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Each blister contains 24 active white tablets and 4 green hormone-free tablets. The two differently coloured tablets of *Daylina* are arranged in order. A strip contains 28 tablets.

Take one tablet of *Daylina* every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Do not confuse the tablets: take a white tablet for the first 24 days and then a green tablet for the last 4 days. You must then start a new strip straightaway (24 white and then 4 green tablets). There is therefore no gap between two strips.

Because of the different composition of the tablets it is necessary to begin with the first tablet at position 1 on the strip which is marked with "Start" and that you take the tablets every day. For the correct

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order, follow the direction of the arrows and the numbering on the strip.

Preparation of the strip

To help you keep track, there are 7 weekdays sticker strips marked with the 7 days of the week. Choose the weekday's sticker strip that starts with the day you begin taking the tablets.

For example, if you start on a Wednesday, use the weekday's sticker strip that starts with "Wed".

Fit the "☞" symbol on the strip to the same symbol on the blister card and place the strip into the area bordered with black line. Each day will line up with a row of pills.

There is now a day shown above every tablet and you can see whether you have taken a pill on a particular day. Follow the direction of the arrow on the wallet until all 28 tablets have been taken.

During the 4 days when you are taking the green hormone-free tablets, bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last white active tablet of *Daylina*.

Once you have taken the last green tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use *Daylina* in this manner, you are protected against pregnancy also during the 4 days when you are taking a hormone-free tablet.

- When to use it

Use as directed by your doctor or pharmacist.

When can you start with the first strip?

If you have not used a contraceptive with hormones in the previous month

Begin with *Daylina* on the first day of the cycle (that is, the first day of your period). If you start *Daylina* on the first day of your menstruation you are immediately protected against pregnancy.

Changing from a combined hormonal contraceptive, or combined contraceptive vaginal ring or transdermal patch)

You can start *Daylina* preferably on the day after the last active (hormone-containing) tablet of your previous pill, but at the latest on the day after the tablet-

free days of your previous pill finish (or after the last inactive tablet of your previous pill). When changing from a vaginal ring or patch, follow the advice of your doctor.

Changing from a progestogen-only method (progestogen-only pill (minipill), injection, implant or a progestogen-releasing intrauterine system (IUS)

You may switch any day from the minipill (from an implant or an IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet taking.

After a miscarriage

Follow the advice of your doctor.

After having a baby

You can start taking *Daylina* between 21 and 28 days after having a baby. If you start later than day 28, you must use a so called barrier method (for example, a condom) during the first seven days of *Daylina* use. If, after having a baby, you have had sex before starting *Daylina* (again), you must first be sure that you are not pregnant or you must wait until your next period.

If you are breast-feeding and want to start taking Daylina (again) after having a baby

Read the section "Breast-feeding".

Ask your doctor what to do if you are not sure when to start.

- How long to use it

Continue taking *Daylina* for as long as your doctor recommends.

You can stop taking *Daylina* whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking *Daylina* and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

- If you forget to use it

The last 4 tablets in the 4th row of the strip are the hormone-free tablets. If you forget to take one of these tablets, this has no effect on the reliability of *Daylina*. Throw away the forgotten hormone-free tablet.

If you miss a white, active tablet (tablets 1-24 of your blister-strip), you must do the

following:

- If you are **less than 24 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 24 hours** late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a white tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules:

More than one tablet forgotten in this strip

Contact your doctor.

One tablet forgotten between days 1-7 (first row)

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.

One tablet forgotten between days 8-14 (second row)

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

One tablet forgotten between days 15-24 (third or fourth row)

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the green hormone-free tablets on this strip, throw them away, and start the next strip (the starting day will be different). Most likely, you will have a period at the end of the second strip - while taking the green hormone-free tablets - but you may have light or menstruation-like bleeding during the second strip.

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2. You can also stop the active white tablets and go directly to the 4 green hormone-free tablets (**before taking the hormone-free tablets, record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, take the hormone-free tablets for less than 4 days.

If you follow one of these two recommendations, you will remain protected against pregnancy. If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the hormone-free days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.

What to do in the case of vomiting or severe diarrhoea

Contact your doctor.

Delaying your period: what you need to know:

Consult your doctor.

Changing the first day of your period: what you need to know

Consult your doctor.

- If you use too much (overdose)

Consult your doctor.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Daylina*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

- Things to be careful of

Driving and using machines

There is no information suggesting that use of *Daylina* affects driving or use of machines.

Side effects

Like all medicines, *Daylina* can cause side effects, although not everybody gets them.

Serious side effects

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing.

Common side effects

Mood swings, headache, nausea, breast pain, problems with your periods, such as irregular periods, absence of periods

Uncommon side effects

For example: increased blood pressure, problems with your periods.

Rare side effects:

For example: Harmful blood clots in blood vessels. The chance of having a blood clot may be higher if you have any other conditions that increase this risk (see section "Before you use *Daylina*" for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Daylina

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Store in the original package in order to protect from light and moisture.

Shelf life: 3 years.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The active tablet is white or almost white,

round, biconvex film-coated tablet, diameter about 6 mm. Engraving on one side: "G73", the other side is without engraving.

The hormone-free tablet is green, round, biconvex film-coated tablet, diameter about 6 mm, without engraving.

- Ingredients

Active tablets:

Each tablet contains 3 mg drospirenone and 0.02 mg ethinylestradiol.

Tablet core (active):

Lactose monohydrate, Maize starch, Maize starch, pregelatinised, Macrogol, poly(vinyl alcohol) grafted copolymer, Magnesium stearate

Film-coating (active):

Poly(vinyl alcohol), Titanium dioxide (E171), Talc, Macrogol 3350, Lecithin (soya)

Hormone-free tablets:

Tablet core (hormone-free):

Cellulose, microcrystalline, Lactose anhydrous, Maize starch, pregelatinised, Magnesium stearate, Silica, colloidal anhydrous

Film-coating (hormone-free):

Polyvinyl-alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, Indigo carmine (E132), Quinoline yellow (E104), Iron oxide black (E172), Sunset yellow FCF (E110)

- MAL number:

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