

DAISY-30 TABLETS

Desogestrel/Ethinyl estradiol (150 mcg/30mcg)

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What DAISY-30 is used for

DAISY-30 is for oral contraception. You take it to stop you from getting pregnant.

How DAISY-30 works

This contraceptive contains two types of female sex hormones, oestrogen and progesterone. These hormones prevent an egg being released from your ovaries so you can't get pregnant.

Before you use DAISY-30

- When you must not use it

Tell your doctor or family planning nurse if you have any medical problems or illnesses.

Do not take DAISY-30 if any of the following apply to you. Taking DAISY-30 would put your health at risk:

- If you are pregnant or might be pregnant,
- If you have cancer affected by sex hormones – such as some cancers of the breast, womb lining or ovary
- If you have vaginal bleeding that has not been explained by your doctor
- If you have excessive thickening of the womb lining
- If you have ever had a severe liver disease
- If you are allergic (hypersensitive) to any of the ingredients in DAISY-30
- Presence or a history of arterial blood clot such as heart attack, stroke.
- Presence of any risk factor for blood clot.
- If you have moderate or severe high blood pressure
- If you have gall stones

- If you have had any of the following problems while pregnant or while using steroids:
 - severe itching -pregnancy-associated autoimmune blistering skin disease
 - jaundice (yellowing of the eye and skin)
 - a hearing problem called otosclerosis
- If you have ever had the disease systemic lupus erythematosus (a hypersensitivity reaction where the system attacks the body's cells and tissue, resulting in inflammation and tissue damage).

- If you have high fat levels in your blood (high cholesterol or triglyceride levels)
- blood vessel damage due to diabetes

- Before you start use it

DAISY-30 can make some illnesses worse. Some of the conditions listed below can be made worse by taking the Tablet. Or they may mean it is less suitable for you. You may still be able to take DAISY-30 but you need to take special care and have checkups more often.

- If you have any gynaecological problems, such as enlargement of fibroids or endometriosis
- If you have ever had kidney or liver problems,
- If you have ever had depression. In certain condition, taking of vitamin B₆ might be of therapeutic value.
- If you have ever had epilepsy or migraines
- If you have brown patches on your face or body (chloasma). Chloasma prevention requires sun avoidance and sun protection with hats and sunscreen.
- If you have infection
- if you have heart failure
- if you have high blood pressure

- if you have severe enlargement of veins

Tell your doctor that you are taking an estrogen-containing preparation if you are undergoing major surgery or prolonged immobilization

- Taking other medicines

If you ever need to take another medicine at the same time as being on the Tablet, always tell your doctor, pharmacist or dentist that you're taking DAISY-30. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop DAISY-30 from working properly – for example:

- certain antibiotics (example ampicillin, chloramphenicol, penicillin V, tetracyclines, neomycin)
- certain tranquilizers, tricyclic anti-depressants and maprotiline
- Certain laxatives and activated charcoal.
- Medicines that increase risk of liver damage
- Bromocriptine
- coumarin or indandione derivatives (medicines that help to prevent your blood from clotting)
- Dihydroergotamine (used to treat migraines)
- Sulphonamides

If you do need to take one of these medicines, DAISY-30 may not be suitable for you, or you may be able to take DAISY-30 and use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

The use of steroid may influence the results of certain laboratory tests.

DAISY-30 can also affect how well other medicines work. For example, if you have diabetes, you may need to

Take more insulin or other anti-diabetic medicines while you take DAISY-30. Your doctor will tell you if this is necessary.

Taking DAISY-30 with food and drink

There are no special instructions about food and drink while on DAISY-30.

Pregnancy and breast-feeding.

Do not use DAISY-30 if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking DAISY-30.

If you are breast-feeding, you should not take DAISY-30. Ask your doctor or family planning nurse about alternative contraception. Breastfeeding will not stop you getting pregnant.

DAISY-30 contains lactose If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using DAISY-30.

How to use DAISY-30*- How much to use*

To prevent pregnancy, always take DAISY-30 exactly as described below. Check with your doctor or family planning nurse if you are not sure.

1. Take DAISY-30 every day for 21 days
2. Then have seven tablet-free days
3. Then start your next strip

- When to use it

Take DAISY-30 every day for 21 days DAISY-30 comes in strips of 21 tablets, each marked with a day of the week.

- Take your tablet at the same time every evening..
- Start by taking a tablet marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one tablet each day, until you have finished all 21 tablets.
- Swallow each tablet whole, with water if necessary.
- Do not chew the tablet.

Then not required to take tablets for seven days. After you have taken all 21 tablets in the strip, you have seven days free from tablets. So if you take the last tablet of one pack on a Friday, you will take the first tablet of your next pack on the Saturday of the following week. Within a few days of taking the last tablet from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of tablets. You don't need to use extra contraception during these seven tablet-free days – as long as you have taken your tablets correctly and start the next strip of tablets on time.

Then start your next strip after the seven tablet-free days – even if you are still bleeding. Always start the new strip on time. As long as you take DAISY-30 correctly, you will always start each new strip on the same day of the week.

*- How long to use it***Starting DAISY-30****As a new user or starting the Tablet again after a break**

Either take your first DAISY-30 tablet on the first day of your next period. By starting in this way, you will have contraceptive protection with your first tablet.

Or if your period has already begun start taking DAISY-30 on day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must also use extra contraception, such as condoms, until you have taken the first seven tablets correctly.

Changing to DAISY-30 from another contraceptive Tablet

- **If you are currently on a 21day Tablet:** start taking DAISY-30 the next day after the end of the previous strip. You will have contraceptive protection with your first tablet but you will not have a bleed until after you finish your first strip of DAISY-30.
- **If you are currently on a 28day Tablet:** start taking DAISY-30 the day after your last active tablet. You will have contraceptive protection with your first tablet. You will not have a bleed until after you finish your first strip of DAISY-30.

- **Or if you are taking a progestogen-only Tablet** (mini-Tablet or POP): start DAISY-30 on the first day of bleeding, even if you have already taken the POP for that day. You will have contraceptive cover straight away. If you don't usually have any bleeding while you are taking a progestogen-only Tablet, you can stop taking it any day and start DAISY-30 the next day. You will need to use extra
 - contraception, such as a condom, for seven days.

Starting DAISY-30 after a miscarriage or abortion If you have had a miscarriage or an abortion, your doctor may tell you to start taking DAISY-30 straight away. This means that you will have contraceptive protection with your first tablet.

Contraception after having a baby

If you have just had a baby, ask your doctor for advice about contraception.

If you are not breast-feeding:

- you can start taking DAISY-30 three weeks after the birth or,
- you can start taking DAISY-30 more than three weeks after the birth but you need to use extra contraception, such as a condom until you have taken the first seven tablets correctly.
- If you have had sex since the birth there is a chance that you could be pregnant, you should therefore use another form of contraception, such as a condom. In this case, take your first DAISY-30 tablet on the first day of your next period.

Additional Contraceptive Precaution

When additional contraceptive precautions are required you, either not to have sex, or to use a cap plus spermicide, or for her partner to use a condom. Rhythm methods is not advisable as the pill disrupts the usual cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus

- If you forget to use it

If you miss a tablet, follow these instructions:

- Less than 12 hours ago
 - Take the delayed tablet straightaway, and further tablets as usual. This may mean taking two tablets in one day.
 - Don't worry your contraceptive protection should not be reduced.

- More than 12 hours ago, or you have missed more than one tablet
 - Take the most recently missed tablet straight away
 - Leave any earlier missed tablets in the strip
 - Take your further tablets as usual. This may mean taking two tablets in one day. – Use extra precautions (condoms for instance) for the next 7 days.
 - Check how many tablets are left in the strip after the most recently missed tablet.

A lost tablet

If you lose a tablet,

Either take the last tablet of the strip in place of the lost tablet. Then take all the other tablets on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven tablet-free days you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a tablet from a spare strip. Then take all the other tablets from your current strip as usual. You can then keep the opened spare strip in case you lose any more tablets.

If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhea your body may not get its usual dose of hormones from that tablet. If you are better within 12 hours of taking DAISY-30, take another tablet from a spare strip. Carry on taking your tablets as normal. You won't need to use extra protection.

If you are still sick or have diarrhoea more than 12 hours after taking DAISY-30 follow the instructions for if you are more than 12 hours late.

Talk to your doctor if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.

Missed a period – could you be pregnant? Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your tablets correctly. Start your next strip at the normal time. If you think that you might

have put yourself at risk of pregnancy (for example, by missing tablets or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the pharmacy or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking DAISY-30 and see your doctor.

You can delay a period. If you want to delay having a period, take one strips of tablets. Start the second strips of tablets immediately without any break and take the tablet as usual way. After the second strip, give a break to tablet for seven days, then start your next strip of tablets in the normal way. When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the tablet, but don't worry.

- If you use too much (overdose)

Taking more than one tablet should not cause harm

It is unlikely that taking more than one tablet will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

While you are using it

- Things you must do

During prolonged treatment with estrogen and/or progestogen containing preparations periodic medical examination is advisable. See doctor immediately if experience any abdominal pain.

- Things you must not do

If you smoke, you are strongly advised to stop smoking when you use DAISY- 30 because the increasing of contracting blood vessel disease is probably slightly greater, especially if you are older than 35 years.

- Things to be careful of

Make an appointment to see your doctor if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking DAISY-30 for a while

- Carries on even after you've stopped taking DAISY-30.

Side effects

Like all medicines, DAISY-30 can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- **Migraine or headache**
- **Putting on weight or losing weight**
- Problems with blood sugar (reduced glucose tolerance)
- **Breast problems**, such as sore or larger breasts; producing discharge from the nipples
- **blood clot, rise the blood pressure.**
- **nausea, vomiting,**
- **Skin problem such as chloasma, erythema nodosum, rashes.**
- **Discomfort of the eyes** if you wear contact lenses
- Gall stones
- jaundice of the liver due to blocked bile duct

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of DAISY-30

- Storage

Keep all medicines out of the reach and sight of children.

Store DAISY- 30 below 30 ° C.

Store it in the original pack to protect it from light and moisture.

Do not use DAISY-30 after the expiry date shown on the packet. 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

Round, white to off-white, uncoated, biconvex tablets debossed with '227' on one side and other side plain

Ingredients

- Active ingredients

Desogestrel and Ethinylestradiol.

- Inactive ingredients

Anhydrous lactose, potato starch, vitamin E, polyvinyl pyrrolidone, isopropyl alcohol, colloidal silicon and stearic acid.

- MAL numbers:

MAL13015043AZ

Manufacturer

Jai Pharma Ltd.

Plot No. 20/21, Pharmez,

The Pharmaceuticals Special Economic Zone

Sarkhej – Bavla NH-08 A, Nr.

Village Matoda, Taluka: Sanand

Dist: Ahmedabad – 382 213, India

Product Registration Holder

Unimed Sdn Bhd

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Kuala Lumpur.

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