

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Zinnia P \*

ethinylestradiol/levonorgestrel 30µg/150 µg coated tablets

**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, health care provider 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, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

#### What is in this leaflet:

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

#### 1. WHAT ZINNIA P IS AND WHAT IT IS USED FOR

Zinnia P is a low dose combined contraceptive pill that protects against pregnancy (here generally designated as ‘Pill’).

Zinnia P contains 28 tablets per card

The active tablets (21 white tablets) contain a small amount of two female sex hormones, a progestogen (levonorgestrel) and an estrogen (ethinylestradiol). The active tablet is generally designated as the “Pill”.

The other tablets (7 yellow tablets) do not contain any active substance (placebo tablets).

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZINNIA P

##### 2.1 Do not take Zinnia P:

- if you are hypersensitive (allergic) to ethinylestradiol, levonorgestrel or any of the other components of Zinnia ,
- if you now have or have a history of venous blood clots (in deep veins or in lungs), whether you are on anticoagulant therapy or not,
- if you now have or have a history of arterial blood clots (e.g. heart attack) or diseases associated with the early stages of such blood clots in the arteries (such as tightness in the chest, so-called Angina pectoris, or sudden visual disturbances or muscle paralysis),
- if you have a known tendency to form blood clots or any other condition associated with clots, such as disease of heart valves or heart rhythm problems),
- if you have lupus, a disorder of the immune system,

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- if you have many risk factors for artery disease (such as older age, smoking, diabetes and high blood pressure),
- if you have had a stroke,
- if you smoke (also see 2.2.3 'The "Pill" and vascular disease'),
- if you suffer from high blood pressure above 160/100 mm Hg and it has not been satisfactorily treated,
- if you suffer from sugar diabetes (Diabetes mellitus) and your blood vessels have already been damaged as a result,
- if you have a history of migraines, which are accompanied by sensory, perceptual and/or motor disturbances (so-called aura),
- if you now have or have a history of pancreatic inflammation,
- if you now have or have a history of liver disorder, as long as liver function tests have not returned to normal,
- if you have acute hepatitis (liver inflammation) or a hepatitis flare: combined oral contraceptives should not be started during these; continuing use for those already taking combined oral contraceptives is usually possible.
- if you now have or have a history of liver tumors (benign or malignant),
- if you are now suspected of having or have a history of sex-steroid influenced cancer (e.g. of lining of the uterus or the breasts),
- if you have undiagnosed vaginal bleeding,
- if you miss menstruation, the cause of which has not been found.

Discontinue use immediately, if one of the above-mentioned diseases or conditions appears for the first time while taking Zinnia P .

## **2.2 Warnings and precautions**

### **2.2.1 Stop taking Zinnia P immediately (in addition to conditions specified in section 2.1)**

- if you suspect or know that you are pregnant,
- if there are signs that you have a blood clot, such as sudden sensation, perception or movement problems,
- if your blood pressure constantly rises to values above 140/90 mmHg (you can think of starting to take the 'Pill' again, as soon as your blood pressure values have returned to normal through antihypertensive therapy),
- if surgery is planned (at least 4 weeks in advance) and/or during longer periods of immobilisation (also see 2.2.3 'The "Pill" and vascular disease'). You can think of starting to take the "Pill" again at least two weeks after complete remobilization.
- if migraine appears for the first time or worsens,
- if headaches occur unusually frequently, persistently or in unusual severity,
- if severe upper abdominal pain or swelling occurs,
- if your skin and the whites of your eyes turn yellow, your urine turns brown and your stool very light in color (so-called jaundice), or if your skin itches over your entire body,
- if you suffer from sugar diabetes (Diabetes mellitus) and your blood sugar count is suddenly increased,
- if you suffer from a condition called porphyria, occurring in episodes, and which recurs while using Zinnia P .

### **2.2.2 You require special medical monitoring**

- if you smoke (especially if you are over age 35 and you smoke more than 15 cigarettes per day),
- if you are 40 years of age or older,
- if you are overweight,
- if you have a heart or kidney condition,
- if you are inclined to have inflamed superficial veins (phlebitis) or pronounced varicose veins,
- if you have circulatory problems in your hands and feet,
- if your blood pressure has been measured to be over 140/90 mmHg,

- if you suffer from migraine,
- if you suffer from depression,
- if you have epilepsy,
- if you have sugar diabetes (Diabetes mellitus) or if your body's ability to use glucose is reduced, (decreased glucose tolerance). It may be that the required dose of the drugs used to treat your diabetes will change while using Zinnia P .
- if you are known to have a disturbed lipid (fat) metabolism,
- if you are known to have sickle cell disease,
- if you have a movement disorder called chorea,
- if you have had a liver disorder,
- if you are known to have a gallbladder disorder,
- if you suffer from a benign tumor in the muscle layer of the uterus (uterine myoma),
- if you suffer from a chronic inflammatory bowel disease (Crohn's disease, ulcerative colitis),
- if you have a certain manifestation of deafness (otosclerosis),
- in the event of prolonged immobilization, e.g. following accidents (see 2.2.1),
- if you suffer from a certain disorder of the immune system, the so-called butterfly rash (systemic lupus erythematosus),
- if you are known to have haemolytic-uremic syndrome (a disorder of blood and kidneys).

### 2.2.3 The 'Pill' and blood vessel disease

Using the 'Pill' gives an increased risk of blood clots. The additional risk is at its highest during the first year a woman ever uses the 'Pill'. This increased risk when using the 'Pill' is lower than the risk of clots developing during pregnancy, which is estimated at 60 cases per 100,000 pregnancies. In 1 - 2% of the cases, such clots result in death. The frequency of a clot, caused by 'Pills' containing the amounts in Zinnia P is about 20 cases in every 100,000 women who have been using the 'Pill' for one year.

In rare cases, clots can also occur in an artery, such as in heart vessels or the arteries that supply the brain, resulting in a heart attack or stroke. In very rare cases, clots can also occur in the blood vessels of the liver, intestines, kidneys or eyes.

The following signs can point to a clot. If you notice any of these signs in yourself, stop taking the tablets immediately and see your doctor, at once:

- unusual pain or swelling in a leg,
- pain and tightness in the chest, possibly radiating into the left arm,
- sudden difficulty in breathing,
- heavy cough without a clear cause,
- unusual, strong or persistent headaches,
- sudden partial or complete loss of vision,
- seeing double,
- indistinct speech, problems with speaking or loss of speech,
- dizziness,
- collapse, possibly in connection with an epileptic seizure,
- sudden weakness or numbness on one side of the body or in one part of the body,
- problems with movement,
- severe abdominal pain.

The risk of clots increases:

- with increasing age,
- with a history of blood clots in close family members (parents or siblings) at a relatively early age,
- with prolonged immobilization, major surgery, surgery to the legs, or major trauma. In these situations it is advisable to discontinue use of the 'Pill' (at least four weeks in advance of elective surgery as well as in the event of prolonged immobilisation) and not to resume until

two weeks after complete remobilization. If Zinnia P was not discontinued in time, a prevention for clots should be considered.

- if you are clearly overweight (Body Mass Index over 30 kg/m<sup>2</sup>),
- in the first three to four weeks following delivery or a miscarriage in the second trimester of pregnancy.

The risk of arterial occlusion increases with:

- smoking. With heavier smoking and increasing age, the risk further increases. It is advisable not to smoke, especially if you are over 35 and using hormones to prevent pregnancy. If you cannot stop smoking, you are advised to use other methods of contraception, especially if there are other risk factors.
- increasing age,
- the occurrence of blood clots in close family members (parents or siblings) at an early age,
- disturbances in lipid (fat) metabolism,
- high blood pressure,
- sugar diabetes (Diabetes mellitus),
- heart conditions (such as valve disease, irregular beats),
- obesity (body mass index over 30 kg/m<sup>2</sup>),
- migraine, especially migraine with aura.

Further diseases with possible blood vessel involvement include lupus, (an immune system disorder) haemolytic-uremic syndrome (a blood disorder causing kidney damage) and chronic inflammatory bowel disease (Crohn's disease and ulcerative colitis).

The presence of a severe or multiple risk factor(s) for vein or artery clots may also constitute a reason not to use Zinnia P.

The increased risk of blood clots just after giving birth must be considered.

#### **2.2.4 The 'Pill' and cancer**

Some studies have indicated that long-term use of combined oral contraceptives represents a risk factor with respect to developing cervical cancer in women, whose cervix is infected with a certain sexually transmitted virus (human papillomavirus). It has not yet been established, however, to which extent this finding is attributable to other factors (e.g., differences in the number of sex partners or in the use of barrier contraceptives).

There is a slightly increased risk of having breast cancer diagnosed in women who are currently using the 'Pill' as compared to women of the same age who do not use the 'Pill' for contraception. This excess risk gradually disappears after cessation of the 'Pill', and during the course of 10 years, there is no difference between previous 'Pill' users and other women of the same age. Because breast cancer is rare in women under 40 years of age, the excess number of cases in current and recent users of the 'Pill' is small in relation to the overall risk of breast cancer.

In very rare cases, benign, but nonetheless dangerous, liver tumors can occur, which can rupture causing severe internal bleeding. In case of severe upper abdominal pain, please contact your doctor immediately. Studies have suggested an increased risk of developing liver-cell cancer with long-term use of the 'Pill'; this type of cancer is, however, very rare.

#### **2.2.5 Other conditions**

##### **High blood pressure**

An increase in blood pressure has been reported in women taking the 'Pill'. This occurs more frequently in older users and with continued use. The frequency of high blood pressure increases with the content of the progestogen. If you have already contracted any disorders due to high blood pressure, or if you suffer from certain kidney disorders, it is advisable for you to use another method

of contraception (see also 2.1 'Do not take Zinnia P, 2.2.1 'Stop taking Zinnia P immediately' and 2.2.2 'You require special medical monitoring').

### **Pigmentation spots**

Yellowish-brown pigment spots may occasionally occur, especially in women with a history of chloasma gravidarum. It is therefore advisable for women with this tendency not to expose themselves directly to the sun or ultraviolet radiation (e.g. on sunbeds) while taking the 'Pill'.

### **Hereditary angioedema**

If you suffer from hereditary angioedema (a severe allergic condition), medicinal products containing estrogens, may worsen the condition. You should immediately consult your doctor if you notice you have symptoms such as swelling of the face, tongue and/or throat and/or difficulty swallowing or skin rash combined with breathing problems.

### **Irregular bleeding**

With all 'Pills', irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. If this irregular bleeding still occurs after three months or reappears after several months of regular cycles, please see your doctor.

It is possible that in some women withdrawal bleeding may not occur during the placebo period (yellow tablets). If you have taken Zinnia P according to the directions described in Section 3. 'How to take Zinnia P', it is unlikely that you are pregnant. However, if you have not taken the 'Pill' according to these directions prior to the first missed withdrawal bleed or if two withdrawal bleeds are missed, pregnancy must be ruled out before Zinnia P use is continued.

After discontinuing the 'Pill', it can take some time to return to a normal cycle.

### **2.2.6 Reduced efficacy**

The contraceptive effect can be reduced by forgetting to take the 'Pill', vomiting, gastrointestinal disturbances with diarrhoea or by some other medicines taken at the same time.

If Zinnia P and products containing St. John's wort are taken at the same time, it is advisable to use an additional barrier contraceptive (see Section 2.3, "Other medicines and Zinnia P").

### **2.2.7 Medical consultation / examination**

Before you use Zinnia P, your doctor will ask you detailed questions about your medical history and that of your close relatives. A thorough general medical checkup and a gynaecological examination, including an examination of the breast and a cervical smear, will be conducted. Pregnancy has to be ruled out. These examinations should be repeated regularly while you are taking the 'Pill'. Please tell your doctor whether you smoke and whether you are taking other medicines.

Zinnia P does not protect you against HIV infection or other sexually transmitted diseases. Among other safe sex practices consistent and correct use of condoms, male or female, is critical for prevention of HIV transmission.

Folic-acid deficiency can interfere with the development of the brain and spinal cord (neural tube defects) in the unborn child. If you stop taking Zinnia P because you want to become pregnant, you are advised to adhere to a diet rich in folic acid (vegetables, fruit, wholegrain products), and to take an additional 0.4 milligrams of folic acid daily. It should be taken four weeks prior to the planned conception and continued up to week 12 of pregnancy. Any woman, who has already been pregnant with a child who had a neural tube (spinal cord) defect, should take 4 milligrams or 5 milligrams of folic acid daily over the same period. You are advised to heed the contraindications and warnings contained in the patient information leaflet of folic acid preparations.

## **2.3 Other medicines and Zinnia P**

Talk to your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

### **2.3.1 Interactions between Zinnia P and other medicinal products can cause it to lose its contraceptive efficacy and/or can result in breakthrough bleeding.**

The following medicinal products can reduce the effect of Zinnia P:

- drugs, that increase intestinal motility (e.g. metoclopramide),
- drugs used in treating epilepsy such as phenytoin, barbiturates, barbexalone, primidone, carbamazepine, oxcarbazepine, topiramate and felbamate,
- some antibiotics for the treatment of tuberculosis (e.g. rifampicin, rifabutin), certain others against bacterial infections (e.g. ampicillin, tetracycline) or fungal infections (e.g. griseofulvin),
- certain drugs for the treatment of HIV infection (e.g. ritonavir, nevirapine, efavirenz),
- modafinil (agent for the treatment of narcolepsy, a nervous system disorder),
- herbal products, that contain St. John's wort (*Hypericum perforatum*).

If you are being treated with any of the drugs specified above, you are advised to use a barrier contraceptive (e.g. condom) in addition to Zinnia P. You are advised not only to use these additional methods of contraception during concomitant use with some of the drugs specified above, but for another seven to 28 days, depending upon the drug. If you have questions, ask your doctor or pharmacist.

If the use of these drugs extends beyond the last tablet in the current blister pack, then you should start taking the 'Pills' from the next pack of Zinnia P without a seven day interval.

If long-term treatment with any of the drugs specified above is necessary, it is preferable to choose a non-hormonal method of contraception.

### **2.3.2 Interactions between Zinnia P and other drugs can also cause more numerous and more pronounced side effects.**

The following medicinal products can impair the tolerance of Zinnia P:

- paracetamol (acetaminophen), a drug to relieve pain and fever),
- ascorbic acid (vitamin C)
- atorvastatin (a drug for lowering blood fat),
- troleandomycin (an antibiotic),
- imidazole, antifungal drugs (such as fluconazole),
- indinavir (an HIV drug).

### **2.3.3 Zinnia P and other 'Pills' can also affect the metabolism of other drugs.**

Zinnia P can impair the efficacy or tolerability of the following drugs:

- cyclosporine (drug used to suppress the immune system),
- theophylline (a drug used for the treatment of asthma),
- glucocorticoids (e.g. cortisone),
- benzodiazepines (tranquilizers, such as diazepam, lorazepam),
- lamotrigine (a drug used for the treatment of epilepsy),
- clofibrate (a drug for lowering the blood fat),
- paracetamol (acetaminophen, a drug to relieve pain and fever),
- morphine (a narcotic pain killer).

Please, also follow the patient information leaflets of the other prescribed products.

If you are diabetic (if you have sugar diabetes) your required dose of blood-sugar lowering medicine (e.g. insulin) can change.

### **2.3.4 Laboratory tests**

Use of the 'Pill' may influence the results of certain laboratory tests, including the results of liver, thyroid, adrenal gland and kidney function testing, as well as certain blood protein levels, e.g., proteins, which affect blood fat usage, carbohydrate usage, and clotting.

### **2.4. Pregnancy and breast-feeding.**

Zinnia P should not be used during pregnancy. You should not be pregnant when starting Zinnia P . If pregnancy occurs during treatment with Zinnia P, further intake should be stopped, and you should see your doctor.

Do not use Zinnia P during the first 6 months of breast-feeding, since milk production may be reduced and small quantities of the active substance can pass into breast milk.. You should use a non-hormonal method of contraception, if you are breastfeeding.

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

### **2.5 Driving and using machines**

No special precautionary measures are necessary.

### **2.6 Zinnia P contains lactose and sucrose.**

Each tablet of this medicinal product contains lactose and sucrose (sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE ZINNIA P**

Always take Zinnia P exactly as your doctor or health care provider told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The usual dose is: One tablet of Zinnia P daily.

### **3.1 How to take Zinnia P**

Each blister card contains 21 active tablets (white) and 7 placebo tablets (yellow). Take one tablet daily until the blister card is empty. Start with the next blister pack on the following day without any pause.

You should take the 'Pill' whole (do not chew) with some liquid, if necessary.

You must take the 'Pill' each day at about the same time in the sequence indicated on the blister pack for 28 consecutive days.

After you have taken all the 21 active tablets (white), take the placebo tablets (yellow) the next seven days. Generally the withdrawal bleeding will start during these 7 days. This usually begins 2 to 3 days after taking the last active tablet and can persist until you start taking tablets from the next blister pack.

### **3.2 When to start taking Zinnia P**

If you did not take a contraceptive 'Pill' last month:

Start with the white active tablets in your blister card. You may start taking Zinnia P on day 1 of your natural cycle, i.e. the first day of your menstrual bleeding. If you begin taking the tablets on any other day, an additional barrier contraceptive should be used during the first seven days of taking the 'Pill'.

If you are switching to Zinnia P from another 'Pill' (with two hormonal active substances), or from a vaginal ring or a patch:

- if you have been taking a 'Pill' with a tablet-free interval once a month following your last 'Pill' containing an active substance, start taking Zinnia P on the day following your tablet-free interval.
- if you have been taking a 'Pill' that comes in a calendar pack containing placebo tablets along with the 'Pills' containing active substances, start taking Zinnia P on the day following your last placebo.
- if you have been using a vaginal ring or a patch, start taking Zinnia P on the day following the usual ring-free, or patch-free interval.

If you are switching to Zinnia P from a 'Pill', that contains only one hormone (progestogen), a so-called mini pill:

You can discontinue the 'mini pill' on any day. Start taking Zinnia P on the following day. During the first seven days, you should use an additional barrier contraceptive (e.g. condom).

If you are switching to Zinnia P from an injectable product (so-called 'three-month injection'), from an implant or an intrauterine device:

Start taking Zinnia P at the time you would normally get the next injection or on the day the implant or intrauterine device is removed. Use an additional barrier contraceptive during the first seven days.

If you have just had a baby and are not breastfeeding:

Do not start taking the product any earlier than 21 days after delivery. A longer period of up to 42 days should be allowed in any woman having risk factors for blood clots (See section 2.2.3, The "Pill" and blood vessel disease).

If you begin to take the tablets later, you should use an additional barrier contraceptive during the first seven days. If you have already had sexual intercourse, pregnancy must be ruled out, or you must wait for your first menstrual bleed before starting to take Zinnia P. See also section 2.4 'Pregnancy and breastfeeding'.

If you have just had a miscarriage or an abortion:

You may take Zinnia P immediately.

### **3.3 Duration of use**

Zinnia P can be taken for as long as a hormonal method of contraception is desired and there are no significant health risks (see 2.1 'Do not take Zinnia P' and 2.2.1 'Stop taking Zinnia P immediately'). Regarding check-ups see 2.2.7 'Medical consultation / examination.'

### **3.4 If you take more Zinnia P than you should**

Possible signs of an overdose are nausea, vomiting (usually after 12 to 24 hours, sometimes continuing for several days), chest tightness, giddiness, abdominal pain, sleepiness / tiredness, vaginal bleeding. If you have taken large quantities, consult a doctor so that the symptoms can be treated.

### **3.5 If you forget to take Zinnia P**

- If you are less than 12 hours late in taking one tablet, the contraceptive effect of Zinnia P is not reduced. You should take the missed tablet as soon as possible, and then take the subsequent 'Pills' at your usual time.
- If you are more than 12 hours late in taking one of the tablets, the contraceptive effect is no longer fully ensured. If no bleeding appears during the seven day placebo period (yellow tablets) after having taken the 21 white active tablets, you could be pregnant. In this case, you must see your doctor before starting a new blister pack.

There are generally two things to bear in mind:

1. You must never stop taking the 'Pill' for more than seven days..

2. In order to build up sufficient contraceptive protection, you should take the 'Pill' without interruption for seven days.

You missed one 'Pill' in week 1:

Take the missed 'Pill' as soon as possible, even if this means taking two 'Pills' at the same time. Then continue taking the tablets as usual. However, an additional barrier contraceptive (e.g. condom) should be used for the next seven days. If you had sexual intercourse in the week prior to the missed 'Pill', you are at risk of being pregnant. The likelihood of becoming pregnant is greater, the closer the missed 'Pill' is to the period when the yellow placebo tablets were taken

You missed one 'Pill' in week 2:

Take the missed 'Pill' as soon as possible, even if this means taking two 'Pills' at the same time. Then, take the subsequent 'Pills' again at your usual time. Provided you took Zinnia P regularly on the seven days preceding the missed 'Pill', then the contraceptive effect of the 'Pill' is ensured, and you do not have to use any additional contraceptive measures. If this was not the case or if you missed more than one 'Pill', then you are advised to use an additional barrier contraceptive (e.g. condom) for seven days.

You missed one 'Pill' in week 3:

Due to the upcoming seven-day placebo tablet interval, contraceptive protection is no longer fully assured. You can, however, sustain the contraceptive effect by adjusting your tablet-taking schedule. By following one of the two procedures described below, it is not necessary to use additional contraceptive measures, although this is only true if you took the tablets correctly on the seven days preceding the first missed 'Pill.' (If this is not the case, you should proceed as described above, "You Missed one 'Pill' in week 1." You should also use an additional barrier contraceptive (e.g. condom) for the next seven days.)

You can choose between two options:

1. Take the missed 'Pill' as soon as possible, even if this means taking two 'Pills' at the same time. Then, take the subsequent 'Pills' again at your usual time. Skip the seven yellow placebo tablets and start taking the "Pills"(white tablets) from the next blister pack right away. Withdrawal bleeding will probably not occur until you have used up the second blister pack, but there may be spotting and breakthrough bleeding while you are taking the second pack.

Or

2. You can immediately , start the yellow placebo tablets (you also have to count the day you missed the 'Pill' as if it were a placebo pill day). Start taking the tablets from the next blister pack right away. If you wish to start taking the next blister pack on your accustomed day of the week, you can take fewer yellow placebo tablets accordingly. Please bear in mind that the maximum time between your last white tablet from the previous blister and the first white tablet of the current blister should not exceed 7 days.

If you have missed more than one 'Pill' from the current blister pack:

If you miss more than one "Pill" of Zinnia P from the current blister pack, contraceptive protection is no longer certain.

The likelihood of becoming pregnant is all the greater, the more 'Pills' you missed and the closer this is to the period when the yellow placebo tablets were taken. It is advisable for you to use an additional barrier contraceptive (e.g. condom) until your next regular withdrawal bleed. If no bleeding occurs during the placebo period (yellow tablets), you could be pregnant. In this event, you must see your doctor before starting a new blister pack.

**What has to be considered if you suffer from vomiting or diarrhoea**

If you have digestive problems, such as vomiting or diarrhoea, occurring within the first four hours after taking the white active tablets, the active substances might not have been completely absorbed. In

such cases, follow the instructions that apply to when you miss a ‘Pill’, and you notice it within 12 hours. If you do not wish to deviate from your tablet-taking rhythm, you will have to take the replacement tablet from another blister pack. If your gastrointestinal complaints continue for several days or recur, you or your partner should use an additional barrier contraceptive (e.g. diaphragm, condom), and you should inform your doctor.

### What has to be considered if you wish to change the timing of the withdrawal bleed

To postpone withdrawal bleeding, you should continue taking the ‘Pills’ from the next pack of Zinnia P right away, skipping the yellow placebo tablets. Withdrawal bleeding can be delayed for as long as desired by taking the tablets continuously, though evidence for this is limited beyond 2 years. If you do this, you may experience increased breakthrough bleeding or spotting. Following a subsequent regular seven-day use of the yellow placebo tablets, you can continue to take the white active tablets as usual.

### 3.6 If you stop taking Zinnia P

If you wish to stop taking Zinnia P, ask your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor, health care provider or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Zinnia P can cause side effects, although not everybody gets them.

The most common side effects, which may affect more than 1 in 10 people associated with taking the ‘Pill’ containing the active substances, ethinylestradiol and levonorgestrel, are headaches (including migraine), spotting and intermenstrual bleeding.

System Organ Class	Frequency of side effects			
	Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)	Rare (may affect up to 1 in 1,000 people)	Very rare (may affect up to 1 in 10,000 people)
Infections	vaginal inflammation, including mycosis (Candidiasis)			
Immune system disorders		hives	allergic reactions	painful swelling of the skin and mucous membrane (angioedema), very severe allergic reactions with breathing and circulatory symptoms

Metabolism and nutrition disorders		changes of appetite (increase or decrease)	decreased ability to metabolize glucose (glucose intolerance)	
Psychiatric disorders	mood swings including depression; changes of the sex drive (libido)			
Nervous system disorders	nervousness; giddiness, dizziness			
Eye disorders	visual disturbances		contact lens intolerance	
Gastrointestinal disorders	nausea, vomiting, abdominal pain	diarrhoea, abdominal cramps, flatulence		
Hepatobiliary disorders			jaundice caused by cholestasis	
System Organ Class	Frequency of side effects			
	Common (may affect up to 1 in 10 people)	Uncommon (may affect up to 1 in 100 people)	Rare (may affect up to 1 in 1,000 people)	Very rare (may affect up to 1 in 10,000 people)
Skin and subcutaneous tissue disorders	acne	rash, yellowish-brown skin spots (chloasma) possibly persisting, increased body and facial hair, hair loss	red nodules (Erythema nodosum) severe skin rash (Erythema multiforme)	
Reproductive system and breast disorders	breast pain, breast tenderness, breast hypertrophy, breast discharge, painful menstrual bleeding, changes in the strength of menstrual bleeding, increased vaginal discharge, missed menstrual bleeding			
General disorders	fluid retention in tissue			
Investigations	weight changes (increase or decrease)	blood pressure increase, changes in blood lipid	reduction of the folic acid levels in blood	

		levels		
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As regards other severe side effects, such as the formation of blood clots, see 2.2.3 ‘The “Pill” and vascular disease’, or with respect to hepatic tumors, breast and cervical cancer, see 2.2.4 ‘The “Pill” and cancer’.

Moreover, the following side effects have been reported in connection with using the ‘Pill’: The frequency of these reactions cannot be calculated from the reports.

- optic neuritis (can cause partial or complete loss of vision),
- worsening of varicose veins,
- pancreatitis with a currently existing, severe lipid (fat) metabolism disturbance,
- gall bladder disorder, including gall stones,
- a blood disorder resulting in kidney damage (haemolytic-uremic syndrome),
- herpes, which can occur during pregnancy (Herpes gestationis),
- a kind of deafness (otosclerosis),
- deterioration of lupus, an immune disorder,
- deterioration of a blood disorder called porphyria,
- deterioration of body movement diseases called “chorea”,
- deterioration of depression,
- deterioration of chronic inflammatory bowel disease (Crohn's disease and ulcerative colitis).

If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

## 5. HOW TO STORE ZINNIA P

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

Store below 30°C. Store in the original package. Protect from light.

Do not use this medicine after the expiry date which is stated on the label after {EXP}. The expiry date refers to the last day of that month.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What Zinnia P contains:

The active substances are 30 micrograms of ethinylestradiol and 150 micrograms of levonorgestrel.

The other ingredients are:

*White active tablets (21 per blister)*

Tablet core: Lactose monohydrate, magnesium stearate, maize starch, povidone, talc

Tablet coating: Calcium carbonate, carnauba wax, glycerol, macrogol, povidone, sucrose talc, titanium dioxide

*Yellow placebo tablets (7 per blister)*

Tablet core: Lactose, magnesium stearate, maize starch, povidone, talc

Tablet coating: Calcium carbonate, carnauba wax, glycerol, macrogol, povidone, sucrose, talc, titanium dioxide, yellow oxide of iron

### What Zinnia P looks like and contents of the pack:

Zinnia P tablets are 21 white active tablets and 7 yellow placebo tablets.

A blister strip of Zinnia P tablets contains 21 white, circular, biconvex, sugar coated tablets, and 7 yellow, circular, biconvex, sugar coated tablets.

Zinnia P tablets are provided in clear transparent PVC/PVdC-Alu blister cards in a carton, containing 1, 3, 6 or 100 blister cards of 28 tablets each.

### **Supplier and Manufacturer**

#### **Supplier**

Mylan Laboratories Limited  
Plot No.564/A/22, Road No.92,  
Jubilee Hills  
Hyderabad, Telangana – 500033,  
India

#### **Manufacturer**

Mylan Laboratories Limited  
Unit II  
1608/1609  
G.I.D.C, Sarigam  
396155 Valsad  
Gujarat, India

#### **Mylan Laboratories Limited**

Sarkhej- Bavla NH No- 8A, Plot No 20/21,  
Pharmaceutical Special Economic Zone, Near  
Village Matoda, Taluka: Sanand  
Ahmedabad, Gujarat – 382 213  
India

**For any information about this medicinal product, please contact the local representative of the supplier:**

Miatrayee Mukherji  
Mylan Laboratories Limited  
Plot No.564/A/22, Road No.92, Jubilee Hills  
Hyderabad, Telangana – 500033, India

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<http://www.who.int/prequal/>.