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PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S3

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

JARINA®
Film-coated tablets

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING JARINA.
- Keep this leaflet. You may need to read it again.
- This leaflet will provide information about the benefits and risks of using combined oral contraceptives such as JARINA. It will also advise you on how to take JARINA properly and when to tell your doctor about health related conditions. If you have further questions, please ask your doctor, professional healthcare provider, or your pharmacist.
- JARINA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT JARINA CONTAINS:

Active substances: The active substances are ethinyloestradiol (0,03 mg) and drospirenone (3 mg).
The other ingredients are: Ferric oxide pigment yellow (E172), hydroxylpropylmethyl cellulose, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, povidone K25, pregelatinised starch, talc, titanium dioxide (E171).

WHAT JARINA IS USED FOR:

JARINA is a combined oral contraceptive ("the combined Pill") consisting of 21 light yellow tablets with active ingredients and 7 white inactive tablets (bottom row of the blister pack). Each active tablet contains a small amount of two different female hormones. These are drospirenone (a progestogen) and ethinyloestradiol (an oestrogen). Contraceptive pills that contain two hormones are called "combined oral contraceptives".

JARINA is used to prevent pregnancy.

BEFORE YOU USE JARINA:

Do not use JARINA, if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use JARINA. Your doctor may advise you to use a different type of contraceptive pill or an entirely different (non-hormonal) method of birth control.

Do not use JARINA:

- If you have, or have ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), or other parts of the body. (See also the section later in this leaflet called *"The Pill and blood clots"*).
- If you have or have had a heart attack or stroke (caused by a blood clot or a rupture of a blood vessel in the brain).
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body.
- If you have diabetes mellitus with blood vessel damage.
- If you have jaundice (yellowing of the skin) or severe liver disease.

- If you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- If you have a severe kidney insufficiency or an acute failure of your kidney.
- If you have or have had a benign or malignant liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are hypersensitive (allergic) to ethinyloestradiol or drospirenone or any of the other ingredients of JARINA tablets. This may cause, for example, itching, rash or swelling.

If any of these conditions appear for the first time while using the pill, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also *"General notes"* in the next section.

- **General notes:**

In this leaflet, several situations are described where you should stop taking JARINA, or where the reliability of JARINA may be decreased. In such situations you should not have sexual intercourse or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use the rhythm or temperature methods. These methods can be unreliable because JARINA alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases (STDs). Women should be advised that additional barrier contraceptive measures are needed to prevent transmission of STDs and HIV infection.

Before you start to use JARINA:

If a combined contraceptive pill is used in the presence of any of the conditions listed below, you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use JARINA.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you have an increased potassium blood level (e.g. due to problems with your kidneys) and also use diuretics that may increase the potassium in your blood (ask your doctor);
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE, a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease (for example, *sickle cell anaemia,* or other sickle cell conditions);
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea);
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation;
- you have hereditary angioedema: exogenous oestrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema

such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

If any of the above conditions appear for the first time, recur or worsen while using the pill, you should contact your doctor.

The contraceptive pill and blood clots:

A thrombosis is the formation of a blood clot, which may block a blood vessel.
A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). Venous thromboembolism (VTE) can develop whether or not you are taking the pill. It can also happen if you become pregnant. If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". The risk for venous thromboembolism is highest during the first year a woman ever uses the Pill.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities, may be life-threatening or may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke.

When using the pill you should stop smoking, especially if you are older than 35 years of age.

If you develop high blood pressure while using the pill, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use the pill the risk may be yet higher. Tell your doctor you are using the pill well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking the pill several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking the pill again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking JARINA and consult your doctor immediately.

The contraceptive pill and cancer:

Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the pill.

Benign liver tumours, and malignant liver tumors have been reported in users of the pill. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the pill may further contribute to this increased risk but there continues to be controversy about the extent to which this finding is attributable to other factors, e.g. cervical screening and sexual behaviour, including use of barrier contraceptives.
The aforementioned tumours may be life-threatening or may have a fatal outcome.

Take special care with JARINA:

Regular check-ups:

When you are using the Pill, your doctor will tell you to return for regular check-ups.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also: *"Do not use JARINA"* and *"Before you use JARINA"*; do not forget about the items related to your immediate family);
- you feel a lump in your breast;
- you are going to use other medications (see also *"The contraceptive pill and other medicines"*);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhoea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke:

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or have speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

Pregnancy and breastfeeding:

JARINA must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using JARINA, you should consult your doctor as soon as possible.

JARINA is not recommended for use during breastfeeding. If you wish to take the pill while breastfeeding, please seek the advice of your doctor.

Driving and using machinery:

No effects have been observed that would show that taking this contraceptive pill would influence your ability to drive.

Using other medicines with JARINA:

Some medicines can make JARINA less effective in preventing pregnancy. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampicin, rifabutin) and HIV infections (e.g. ritonavir, nevirapine); antibiotics (e.g. penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's Wort (primarily used for the treatment of depressive moods). Some medicines (e.g. ketoconazole, erythromycin, cyclosporin) may inhibit the metabolism of JARINA. The pill may also interfere with the working of other medicines, e.g. medicines containing cyclosporine, or the anti-epileptic lamotrigine.

There is a theoretical potential for an increase in serum potassium if you are taking JARINA tablets with other drugs that may increase serum potassium levels. Such drugs include certain blood pressure medication or some water tablets such as angiotensin-II-receptor antagonists, diuretics that may increase the potassium in your blood, and aldosterone antagonists. However, in studies in women taking drospirenone (combined with oestradiol) together with an ACE inhibitor or indomethacin, no significant difference in the potassium blood level could be observed.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use JARINA. They can tell you if you need to take additional contraceptive precautions, and if so, for how long.

HOW TO USE JARINA:

When and how to take the tablets:

The JARINA pack contains 28 tablets (21 active tablets and 7 inactive tablets). The first course of JARINA is started on the first day of the menstrual period (day 1 of the cycle) from the white section of the pack by selecting the appropriate tablet for that day of the week (e.g. "MO" for Monday). The tablet is swallowed whole with some liquid. Thereafter one tablet must be taken daily for 28 days following the direction shown by the arrows. It does not matter at what time of the day the tablet is taken, but once you have selected a particular time, the tablet should be taken as near as possible at the same time each day. Withdrawal bleeding usually starts on day 2 or 3 after starting the inactive tablets and may not have finished before the next pack is started. Each subsequent pack is started in the white section the day after the last tablet of the current pack. If you start JARINA during the latter part of the week, the very first cycle may be slightly shortened.

Starting your first pack of JARINA:

When no hormonal contraceptive has been used in the past month:

Start taking JARINA on the first day of your cycle, i.e. the first day of menstrual bleeding. Take the tablet marked with that day of the week from the white section of the pack. For example, if your period starts on a Friday, take the tablet marked "FR". Then take 1 tablet every day following the directions shown by the arrows. During the first cycle an additional barrier method is recommended for the first 7 days of tablet-taking.

When changing from another combined pill, vaginal ring or transdermal (contraceptive) patch:

You should start with JARINA preferably on the day after the last active tablets of your previous combined oral contraceptive, but at the latest on the day following the usual tablet-free or inactive tablet interval of your previous combined oral contraceptive. In case you have used a vaginal ring or transdermal patch, you should start using JARINA preferably on the day of removal, but at the latest when the next application would have been due. If you follow these instructions, it is not necessary to use an additional contraceptive method.

When changing from a progestogen-only method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS):

You may switch any day from the minipill, from an implant or the IUS on the day of its removal, and from an injectable when the next injection would be due, but in all these cases you are advised to use an additional barrier method for the first 7 days of tablet-taking.

After having a baby:

If you are breastfeeding and want to take JARINA, you should discuss this first with your doctor, who will advise you.

After a miscarriage or an abortion:

Your doctor will advise you.

If too many JARINA tablets are taken (overdose):

There has not yet been any clinical experience of overdose with JARINA. There have been no reports of serious harmful effects from overdose in preclinical studies. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken JARINA, ask

your doctor for advice. Taking the white tablets from the bottom row of the blister is harmless because they do not contain active ingredients.

If you forget to take JARINA:

- If you are **less than 12 hours** late in taking an active tablet, the reliability of the pill is maintained. Take the tablet as soon as you remember and take the next tablet at the usual time.
- If you are **more than 12 hours late** in taking any active tablet, the reliability of the pill may be reduced. The more consecutive active tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is a particularly high risk of becoming pregnant if you miss tablets in the week before or in the week after the inactive tablets. Therefore, you should follow the rules given below.

More than one tablet forgotten in a pack:

Ask your doctor for advice.

1 tablet missed in the first 7 days of active tablet-taking (Day 1 to 7):

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days.

If you have had sexual intercourse in the week before missing the tablet, there is a possibility of becoming pregnant, so tell your doctor immediately.

1 tablet missed in the second 7 days of active tablet-taking (Day 8 to 14):

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Provided that you have taken all your tablets correctly in the 7 days before the missed tablet, the reliability of the pill is maintained and you need not use extra contraceptive precautions. If this is not the case use extra precautions for 7 days.

1 tablet missed in the third 7 days of active tablet-taking (Day 15 to 21):

You may choose either of the following options, without the need for extra contraceptive precautions:

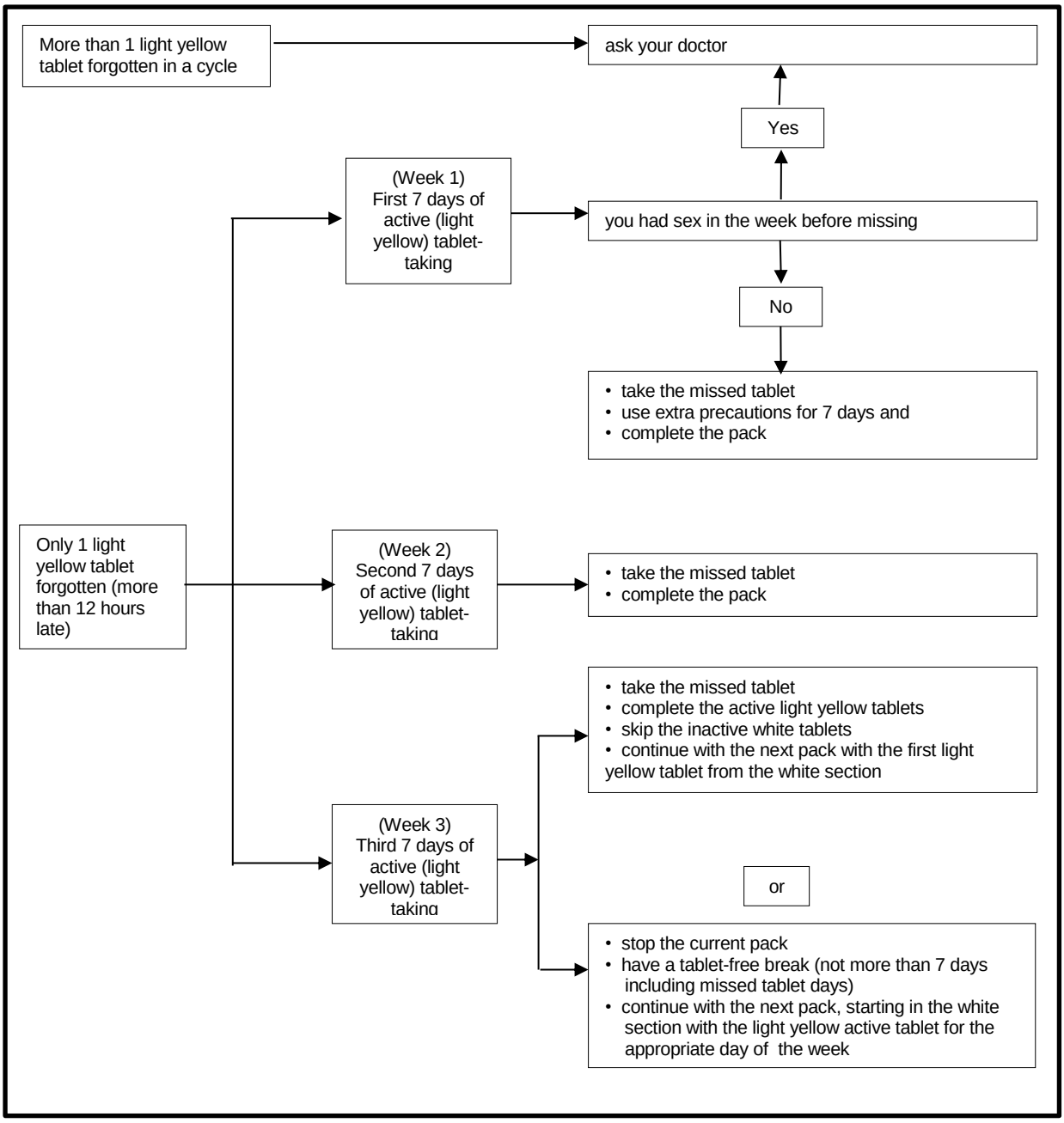
1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until the active tablets are used up. The 7 inactive tablets must be discarded (i.e. discard the current pack after taking the last light yellow tablet). Start the next pack right away, with the first light yellow tablet from the white section. You may not have a withdrawal bleed until the end of the active tablets in the second pack, but you may have spotting or breakthrough bleeding on active tablet-taking days.

or

2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (**also count the day you missed your tablet)** and then continue with the next pack, starting in the white section with the light yellow active tablet for the appropriate day of the week.

If you have forgotten tablets in a pack and you do not have your period as expected, you may be pregnant. Consult your doctor before you start the next pack.

What to do if you forget tablets:



Inactive tablet-taking:

The white tablets are inactive tablets and missing these can be disregarded. However, the missed inactive tablets should be discarded to avoid unintentionally prolonging the inactive tablet phase.

What to do if:

You suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea):

If you vomit, or have severe diarrhoea after taking active tablets, the active ingredients of your JARINA tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice for missed tablets. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking tablets from the inactive white tablets does not have an influence on the contraceptive reliability.

You want to delay a period:

You can delay your period if you start with your next pack of JARINA tablets immediately after finishing the active light yellow tablets of your current pack (do not take the inactive white tablets). You can continue with this pack for as long as you wish, e.g. until this pack is empty, to get a period approximately 3 weeks later than usual. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days.

You have unexpected bleeding:

With all pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

You have missed a period:

If you've missed a period, consult your doctor.

When you want to stop taking JARINA:

You can stop taking JARINA at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

POSSIBLE SIDE EFFECTS:

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the pill.

Serious side effects:

Serious reactions associated with the use of the pill, as well as the related symptoms, are described in the following sections: *"The contraceptive pill and blood clots/The contraceptive pill and cancer".* Please read these sections for additional information and consult your doctor at once where appropriate.

Other possible side effects:

The following side effects have been reported by users of the pill, although they were not necessarily caused by the pill. These side effects may occur in the first few months that you are using the pill and usually lessen with time.

Frequent side effects:

- emotional lability (mood swings), depression/depressive mood
- decrease and loss of libido (reduced or loss of sex drive)
- migraine
- headache
- nausea
- abdominal pain
- breast pain, unscheduled uterine bleeding (bleeding between periods), genital tract bleeding (vaginal bleeding) not further specified
- increased weight

Less frequent side effects:

- any blockage or clot in a deep peripheral vein, clots which travel through the venous blood system (e.g. to the lung known as pulmonary embolism or as pulmonary infarction), heart attack caused by blood clots, stroke caused by blockage of the blood supply to or in the brain;
- Vomiting, diarrhoea, fluid retention, breast enlargement, rash, urticaria (hives), contact lens intolerance, allergic reactions (hypersensitivity), weight loss, increased interest in sex, vaginal discharge, breast discharge, erythema nodosum or multiforme (skin disorders).

If you have hereditary angioedema (a skin reaction involving the deep dermis), exogenous oestrogens may induce or exacerbate symptoms of angioedema (see also *"Before you use JARINA"*).

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF JARINA:

KEEP THE BLISTER STRIP IN THE ORIGINAL CARTON UNTIL REQUIRED FOR USE.
Keep all medicines out of the reach and sight of children.
Store at or below 30 ºC.
Do not use after expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF JARINA:

Cartons containing 1 or 3 transparent blister strips, with each transparent blister strip containing 28 tablets (21 light yellow film-coated active tablets plus 7 white film-coated inactive tablets).

IDENTIFICATION OF JARINA:

21 light yellow, active, round film-coated tablets with convex faces, one side embossed with the letters "DO" in a regular hexagon. 7 white, inactive, round film coated tablets with convex faces, one side embossed with the letter "DP" in a regular hexagon.

REGISTRATION NUMBER:

43/18.8/0782

NAME AND ADDRESS OF REGISTRATION HOLDER:

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DATE OF PUBLICATION:
06 June 2014