PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

JARINA® 0,03 mg/3 mg film-coated tablets
Ethinylestradiol/Drospirenone
Contains sugar (lactose)

Read all of this leaflet carefully before you start taking JARINA.

- Keep this leaflet. You may need to read it again.
- 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 is in this leaflet

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

1. What JARINA is and what it is used for

JARINA is a combined oral contraceptive ("the combined Pill") consisting of 21 light yellow hormone-containing tablets and 7 white hormone-free tablets (bottom row of the blister pack). Each hormone-containing tablet contains a small amount of two different female hormones. These are drospirenone (a progestogen) and ethinylestradiol (an estrogen). Contraceptive pills that contain two hormones are called "combined oral contraceptives".

JARINA is used to prevent pregnancy.

2. What you need to know before you take JARINA

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.

JARINA does not protect against HIV infections (AIDS) and other sexually transmitted diseases (STDs). Additional barrier contraceptive measures are needed to prevent transmission of STDs and HIV infection.

Do not take 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.

- If you are hypersensitive (allergic) to ethinylestradiol or drospirenone or any of the other ingredients of JARINA (listed in section 6). This may cause, for example, itching, rash or swelling.
- 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 *"JARINA and blood clots"*).
- If you have a high risk of venous or arterial blood clots (see "*JARINA and blood clots*" and consult your doctor who will decide whether you may use JARINA).
- 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 are taking any antiviral medicines which contain ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).
- 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 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"*.

Warnings and precautions

In some situations you need to take special care while taking JARINA and your doctor may need to examine you regularly. Consult your doctor before starting to use JARINA if any of the following conditions apply to you or if any of them develop or worsen while you are taking JARINA:

- If you smoke
- If you have diabetes
- If you are overweight
- If you have high blood pressure
- If you have a heart valve disorder or a certain heart rhythm disorder
- If you have an inflammation of your veins (superficial phlebitis)
- If you have varicose veins
- If anyone in your immediate family has had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age
- If you suffer from migraine
- If you suffer from epilepsy (see "*Other medicines and JARINA*")
- If 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 if you are not sure)

- If you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- If anyone in your immediate family has ever had breast cancer
- If you have a disease of the liver or gallbladder
- If you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- If you have systemic lupus erythematosus (SLE, a disease of the immune system affecting the skin all over the body)
- If you have haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys)
- If you have sickle cell disease (for example, *sickle cell anaemia,* or other sickle cell conditions)
- If 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)
- If you have or have ever 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
- If you have hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing estrogens may induce or worsen symptoms of angioedema.

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

JARINA and depression

Some women using hormonal contraceptives including JARINA 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.

JARINA 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". Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack). Blood clots or a ruptured blood vessel in the brain may cause a stroke.

The risk of venous thromboembolism is highest during the first year of use. This increased risk is present after initially starting the combined Pill or restarting (following a 4 week or greater pill-free interval) the same or a different combined Pill. Data from a large study suggest that this increased risk is mainly present during the first 3 months.

Overall the risk for venous thromboembolism in users of low estrogen dose pills is two to threefold higher than for non-users of combined oral contraceptives who are not pregnant. Venous or arterial thromboembolic events may cause serious permanent disabilities or may even be fatal. Blood clots can occur in other parts of the body including the liver, gut, kidney, brain or eye.

Very occasionally venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening or may even be fatal.

Stop taking the pill and contact a doctor immediately if you notice signs of:

Deep venous thrombosis, such as: swelling of one leg or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discoloured skin on the leg.

Pulmonary embolism, such as: sudden onset of unexplained shortness of breath or rapid breathing; sudden coughing which may bring up blood; sharp chest pain which may increase with deep breathing; sense of anxiety; severe light-headedness or dizziness; rapid or irregular heartbeat. Some of these symptoms (e.g. "shortness of breath", "coughing") are non-specific and might be misinterpreted as more common or less severe events (e.g. respiratory tract infection).

Arterial thromboembolism (arterial blood vessels blocked by blood clots and such blood clots which have broken away)

- **Stroke** such as: sudden numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure.
- **Blood clots blocking other arterial blood vessels**, such as: sudden pain, swelling and slight blue discolouration of an extremity; "acute" abdomen.
- **Heart attack** such as: pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats.

Your doctor will check, e.g. whether you have a higher risk of getting a thrombosis due to a combination of risk factors or perhaps one very strong risk factor. In the case of a combination of factors the risk may be higher than simply adding two individual risks. If the risk is too high, your doctor will not prescribe the Pill. (see also '*Do not take JARINA*')

The risk of venous or arterial blood clots (e.g. deep venous thrombosis, pulmonary embolism, heart attack) or stroke increases:

- with older age
- if you are overweight
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age, or if you or any of your relatives are known or suspected of having a hereditary blood clotting disorder increasing your risk for developing blood clots. In this case you should see a healthcare professional before deciding about using JARINA. Certain blood factors that may suggest you have tendency for venous or arterial thrombosis include Activated Protein C (APC) resistance, hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).
- with prolonged immobilisation (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs, or major trauma. In these situations, it is better to stop taking JARINA (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again
- if you smoke (the risk increases the more you smoke and the older you get, especially in women over 35 years of age). When using the pill you should stop smoking, especially if you are older than about 35 years of age.
- if you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if you have high blood pressure. If you develop high blood pressure while using JARINA, you may be told to stop using it.
- if you suffer from migraine
- if you have a heart valve disorder or a certain heart rhythm disorder

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking JARINA.

JARINA 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 tumours have been reported in users of the pill. These tumours 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 (HPV) 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 afore mentioned tumours may be life-threatening or may have a fatal outcome.

Bleeding between periods

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 JARINA (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

What to do if no bleeding occurs

If you have taken all the tablets correctly, have not had any vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take JARINA as usual.

If you have taken the tablets incorrectly, or, if you have taken the tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack until you are sure that you are not pregnant.

Other medicines and JARINA

Always tell your health care provider if you are taking any other medicines. This includes complementary or traditional medicines.
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.

Some medicines:

- can have an influence on the blood levels of JARINA
- can make it less effective in preventing pregnancy
- can cause unexpected bleeding

These include:

- medicines used for the treatment of:
    - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
    - tuberculosis (e.g. rifampicin)

  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole, ketoconazole).
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
  - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St. John's wort
- grapefruit juice

JARINA may influence the effect of other medicines, e.g.:
- ciclosporin
- lamotrigine
- melatonin
- midazolam
- theophylline
- tizanidine

In theory your potassium levels may increase if you are taking JARINA with other medicines that can also increase potassium levels. Such medicines 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 estradiol) together with an ACE inhibitor or indomethacin, no significant difference in the potassium blood level could be observed.

Laboratory tests

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

JARINA with food and drink

JARINA may be taken with or without food, if necessary, with a small amount of water.

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 machines

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

JARINA contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take JARINA

Do not share medicines prescribed for you with any other person.

Always take JARINA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The JARINA pack contains 28 tablets (21 light yellow hormone-containing tablets and 7 white hormone-free 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 hormone-free 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 hormone-containing tablets of your previous combined oral contraceptive, but at the latest on the day following the usual tablet-free or hormone-free 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 of the last ring or patch of a cycle, 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 you take more JARINA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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. Even girls who have not yet started to menstruate but have accidentally this medicine may experience such 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 hormone ingredients.

If you forget to take JARINA

- If you are **less than 12 hours** late in taking a light yellow hormone-containing 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 light yellow hormone-containing tablet, the reliability of the pill may be reduced. The more consecutive hormone-containing 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 white hormone-free 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 hormone-containing 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 hormone-containing 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 hormone-containing tablet-taking (Day 15 to 21)

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

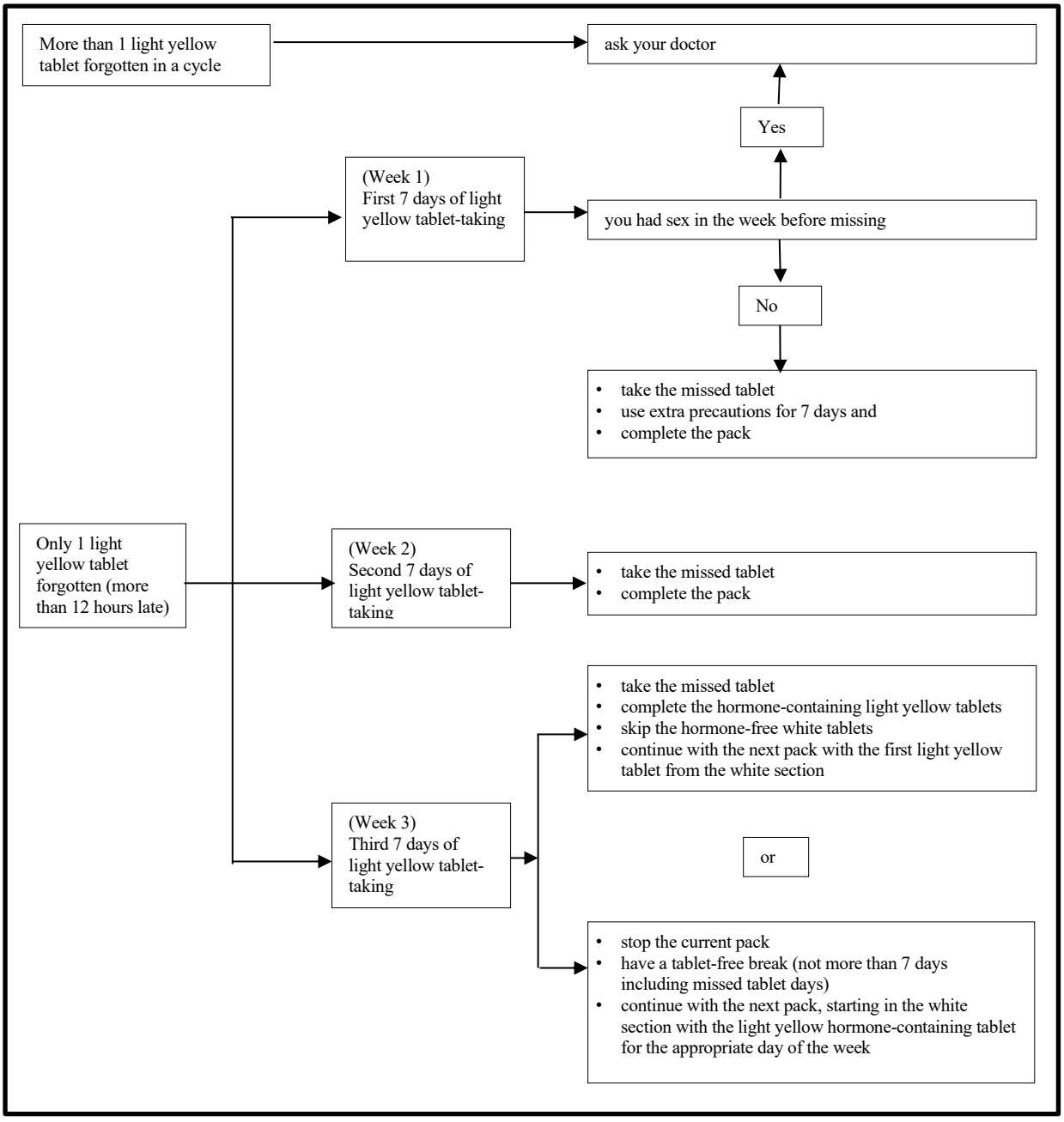
1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until the hormone-containing tablets are used up. The 7 hormone-free tablets must be discarded, (i.e. discard the current pack after taking the last light 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 hormone-containing tablets in the second pack, but you may have spotting or breakthrough bleeding on hormone-containing 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 hormone-containing 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.

Missed pill chart



Hormone-free tablet-taking

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

What to do if you vomit or have severe diarrhoea

If you vomit, or have severe diarrhoea after taking any light yellow hormone-containing 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 under "*If you forgot to take JARINA"*. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the hormone-free white tablets does not have an influence on the contraceptive reliability.

Delaying your period: what you need to know

You can delay your period if you start with your next pack of JARINA tablets immediately after finishing the hormone-containing light yellow tablets of your current pack (do not take the hormone-free 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 hormone-containing tablet-taking days.

If you 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.

4. Possible side effects

JARINA can have side effects.

Not all side effects reported for JARINA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking JARINA, please consult your health care provider for advice.

Serious side effects

Serious reactions associated with the use of the pill, as well as the related symptoms, are described in the following sections: *"JARINA and blood clots/JARINA 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

- nausea
- breast pain, unscheduled uterine bleeding (bleeding between periods), genital tract bleeding (vaginal bleeding) not further specified

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

Description of selected adverse reactions

Adverse reactions with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives are listed below (see also sections '*Do not take JARINA*', and '*Warnings and precautions*'):

Tumours

- The frequency of diagnosis of breast cancer is very slightly increased among users of oral contraceptives. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. It is not known whether there is a direct link to users of combined oral contraceptives.
- liver tumours (benign and malignant)

Other conditions

- erythema nodosum (a skin condition characterised by tender red nodules)
- women with hypertriglyceridemia (increased blood fats resulting in an increased risk of pancreatitis when using combined oral contraceptives)
- high blood pressure
- occurrence or worsening of conditions for which a link to combined oral contraceptives is not definite: jaundice and/or itching related to cholestasis (blocked bile flow); gallstone formation; a metabolic condition called porphyria; systemic lupus erythematosus (a chronic autoimmune disease); haemolytic uremic syndrome (a blood clotting disease); a neurological condition called Sydenham's chorea; herpes gestationis (a type of skin condition that occurs during pregnancy); otosclerosis-related hearing loss
- In women with hereditary angioedema (characterised by sudden swelling of e.g. the eyes, mouth, throat etc.) external estrogens may induce or worsen symptoms of angioedema.
- disturbed liver function
- changes in glucose tolerance or effect on peripheral insulin resistance
- Crohn's disease, ulcerative colitis
- chloasma
- hypersensitivity (including symptoms such as rash, urticaria)

Interactions

Unexpected bleeding and/or contraceptive failure may result from interactions of other medicines with oral contraceptives (e.g. the herbal remedy St. John's wort, or medicines for epilepsy, tuberculosis, HIV and Hepatitis C Virus infections). See section '*Other medicines and JARINA*'.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's

publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of JARINA.

5. How to store JARINA

Store all medicines out of reach and sight of children.
Store at or below 30 ºC.
Keep the blister strip in the original carton until required for use.
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).

6. Contents of the pack and other information

What JARINA contains

The active substances are ethinylestradiol (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, modified starch (pregelatinised starch), povidone K25, talc, titanium dioxide (E171).

What JARINA looks like and contents of the pack

Each blister of JARINA contains 21 film-coated tablets containing hormones and 7 hormone-free film-coated tablets.

JARINA tablets are contained in blister packs consisting of transparent film of either PVC-Aluminium or PVC/PE.EVOH.PE/PCTFE-Aluminium.

The film-coated tablet containing hormones is light yellow, round with convex faces, one side marked with the letters "DO" in a regular hexagon.
The hormone-free tablet is white, round, with convex faces, one side marked with the letters "DP" in a regular hexagon.

Holder of certificate of registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
Isando
1609

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