PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

JARINA® PLUS
Film-coated tablets

Read all of this leaflet carefully before you start taking JARINA PLUS.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- JARINA PLUS 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 PLUS CONTAINS:

Active substances: 21 hormone-containing orange film-coated tablets each with 3 mg drospirenone, 0,030 mg ethinylestradiol (as betadex clathrate) and 0,451 mg levomefolate calcium, plus 7 hormone-free light orange film-coated tablets each with 0,451 mg levomefolate calcium.
The other ingredients are: Croscarmellose sodium, hydroxypropylcellulose 5 cP, hypromellose 5 cP, ferric oxide red (E172), ferric oxide yellow (E172), lactose monohydrate, macrogol 6000, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide (E171).

WHAT JARINA PLUS IS USED FOR:

JARINA PLUS is a contraceptive pill and it is used to prevent pregnancy and to improve the folate status in women who decide to use oral contraception.

Each of the 21 orange film-coated tablets contains a small amount of the female hormones ethinylestradiol and drospirenone and levomefolate calcium (which is also contained in the 7 light orange hormone-free film-coated tablets).

Contraceptive pills that contain two hormones are called “combined pills” or “combined oral contraceptives”.

BEFORE YOU TAKE JARINA PLUS:

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

Do not take JARINA PLUS:

- If you are **allergic** (hypersensitive) to ethinylestradiol, drospirenone, levomefolate calcium or any of the other ingredients in JARINA PLUS. This may cause, for example, itching, rash or swelling.
- If you have (or have ever had) a **blood clot** in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other parts of the body.
- If you have (or have ever 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 **disease that can be an indicator (i) of a future heart attack** (for example, angina pectoris which causes severe chest pain which may spread to the left arm) **or (ii) of a stroke** (for example, a minor stroke with no residual effects, a so-called transient ischaemic attack).

- If you have a severe or multiple risk factor(s) for blood clots (see “The Pill and blood clots” and consult your doctor who will decide whether you may use JARINA PLUS).
- If you have (or have ever had) a certain kind of **migraine** (with so-called focal neurological symptoms such as visual symptoms, speech disability, or weakness or numbness in any part of your body).
- If you have diabetes mellitus with damaged blood vessels.
- If you have (or have ever had) **liver disease** (symptoms of which may be yellowing of the skin or itching over the whole body) and your liver is still not working normally.
- If you have (or have ever 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 acute kidney failure.
- If you have (or have ever had) a benign or malignant **tumour of the liver.**
- If you have any **unexplained bleeding from the vagina.**
- If you are pregnant or think you might be pregnant;

General notes:

In this leaflet, several situations are described where you should stop using JARINA PLUS, or where the reliability of JARINA PLUS may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because JARINA PLUS alters the monthly changes of body temperature and cervical mucus.

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

Take special care with JARINA PLUS:

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

- 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 ever 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 have epilepsy (see “Using other medicines”);
- 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're not sure);
- if you or someone in your immediate family has ever had high blood levels of cholesterol or triglycerides (fatty substances);
- if a close relative has or has ever had breast cancer;
- if you have a disease of the liver or gall bladder;
- if you have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (or SLE, a disease of the immune system);
- if you have haemolytic uremic syndrome (or HUS, a disorder of blood coagulation causing failure of the kidneys);
- if you have sickle-cell disease;
- 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, or a neurological disease called Sydenham's chorea);
- if you have or have ever had golden brown pigment patches so-called “pregnancy patches” especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet

light;
- if you suffer from vitamin B12 deficiency (for example due to a reduced B12 diet such as a strict vegetarian diet, due to a history of gastrointestinal surgery or certain types of gastritis) tell your doctor that you use JARINA PLUS because folates may hide vitamin B12 deficiency;
- 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 oestrogens may induce or worsen symptoms of angioedema.

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

JARINA PLUS and blood clots (thrombosis):

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). If a blood clot breaks away from the vein where it has 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 oestrogen 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.

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

- with 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 specialist before deciding about using JARINA PLUS. 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 PLUS (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 PLUS, 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 PLUS.

JARINA PLUS and cancer:

Breast cancer has been observed slightly more often in women using combined pills. The risk of breast tumours becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

Benign liver tumours, and **malignant liver tumours** have been reported in contraceptive pill users. These tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

The most important risk factor for cervical cancer is persistent Human Papilloma Virus (HPV) infection. Some studies suggest that long-term use of the Pill increases a woman's risk of developing **cervical cancer**.

The afore mentioned tumours may be life-threatening or may have a fatal outcome.

Bleeding between periods:

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 PLUS (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 PLUS 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.

Pregnancy and breastfeeding:

Do not take JARINA PLUS if you are pregnant, or, if you think you may be pregnant. If you become pregnant while taking JARINA PLUS, stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking JARINA PLUS at any time (see also “If you want to stop taking JARINA PLUS”). If you stop JARINA PLUS in order to become pregnant you should consider to continue to take folate supplements.

JARINA PLUS should not be used during breastfeeding or before the breastfeeding mother has completely weaned her child.

Driving and using machinery:

No studies on the effects of the ability to drive and use machines have been performed.

Important information about some of the ingredients of JARINA PLUS:

Each orange film-coated tablet of JARINA PLUS contains 45 mg lactose per tablet and each light orange film-coated tablet contains 48 mg lactose per tablet. If you are intolerant to some types of sugar contact your doctor before taking JARINA PLUS.

Using other medicines with JARINA PLUS:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of JARINA PLUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Some medicines can make JARINA PLUS **less effective in preventing pregnancy**, or 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 infections (e.g. ritonavir, nevirapine), other infections (antibiotics such as penicillins, tetracyclines, griseofulvin).
- the herbal remedy St. John's wort (primarily used for the treatment of depressive moods).

The efficacy of levomefolate calcium in JARINA PLUS **can be diminished** by:

- medicines containing methotrexate, trimethoprim, sulphasalazine, triamterene, cholestyramine, or by antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone or valproic acid.

JARINA PLUS may **influence the effect** of other medicines, e.g.

- anti-epileptics such as lamotrigine and phenytoin;
- cyclosporin;
- methotrexate or pyrimethamine.

In theory your potassium levels may increase if you are taking JARINA PLUS with other medicines that can also increase potassium levels.

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.

HOW TO TAKE JARINA PLUS:

Do not share medicines prescribed for you with others.

The JARINA PLUS pack contains 28 tablets (21 hormone-containing orange tablets and 7 hormone-free light orange tablets). Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 28 tablets have been taken.

The first course of JARINA PLUS is started on the first day of the menstrual period (day 1 of the cycle) from the silver section of the pack by selecting the appropriate tablet for that day of the week (e.g. “MO” for Monday). 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 silver section the day after the last tablet of the current pack.

When taken correctly, combined oral contraceptives have a failure rate of approximately 1 % per year. The failure rate may increase when pills are missed or taken incorrectly.

Starting your first pack of JARINA PLUS:

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

Start taking JARINA PLUS on the first day of the cycle (that is, the first day of your period). For example, if your period starts on a Friday, start with the tablet marked “FR”. Then follow the days in order. It is not necessary to use an additional contraceptive method, if iniated and taken as directed above.

If you take more JARINA PLUS than you should:

There are no reports of serious harmful effects of taking too many JARINA PLUS tablets.

If you take several hormone-containing tablets at once, you may feel sick or vomit. Young girls may have bleeding from the vagina.

If you have taken too many JARINA PLUS tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

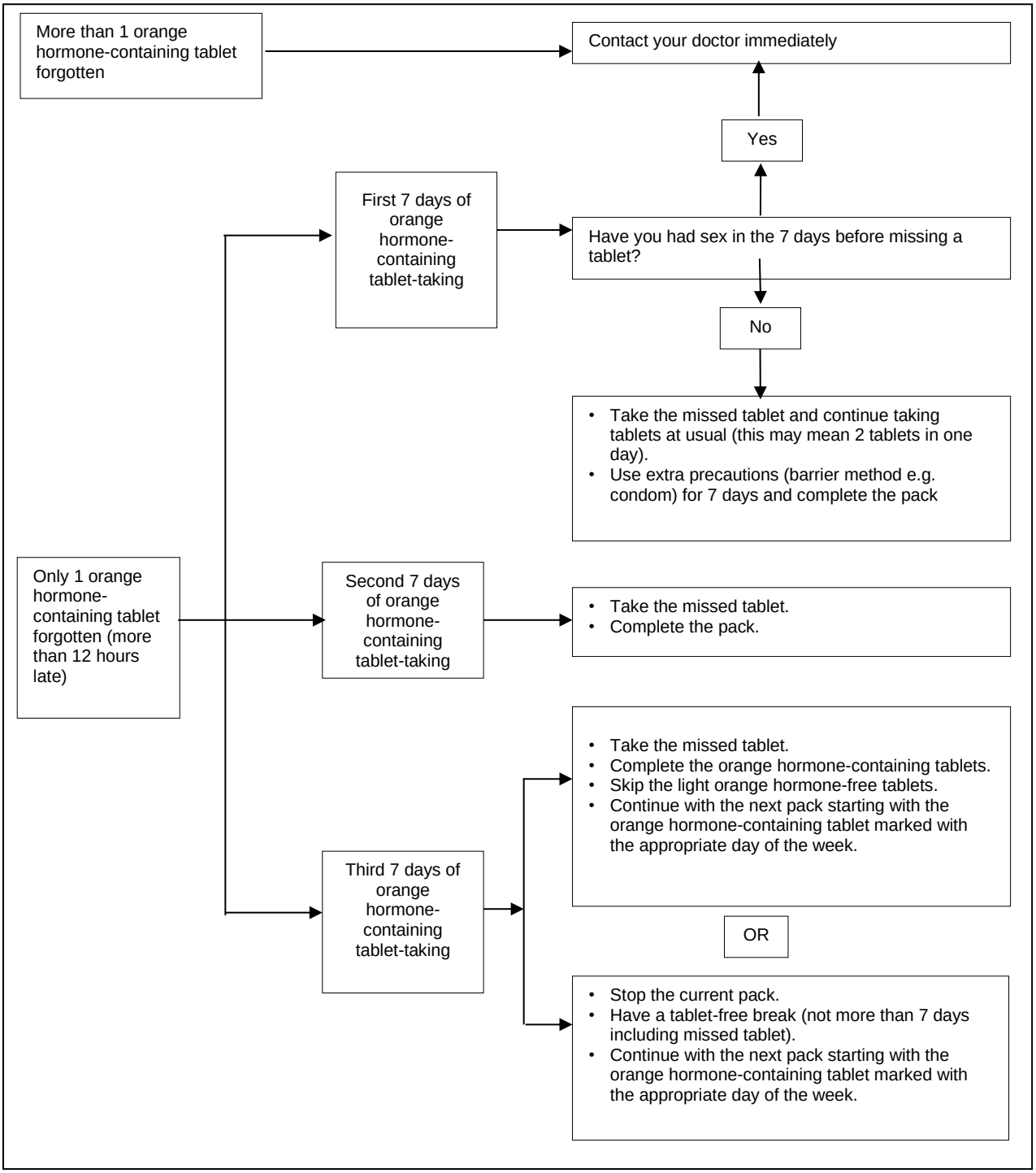
If you forget to take JARINA PLUS:

If you forgot to take any of the 7 hormone-free light orange film-coated tablets **(the last 7 tablets in the blister)**, you are still protected against pregnancy because they do not contain any hormones.

The following advice refers to the orange tablets (those containing hormones) **(tablets 1 to 21 of your blister)**:

- If you are **less than 12 hours** late when taking any hormone-containing tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 12 hours** late in taking any of the orange tablets your protection against pregnancy may be reduced. The more orange tablets you have forgotten, the greater the risk that the protection from pregnancy is reduced. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning of the pack or at the end (the last of the 21 orange tablets). Therefore, you should follow the rules given below (see also the diagram below).
- **More than one tablet forgotten in a pack:** Ask your doctor for advice.

What to do if you forget to take JARINA PLUS orange hormone-containing tablets:



What to do if you vomit or have severe diarrhoea:

If you vomit or have severe diarrhoea after taking any of the orange tablets, the active ingredients in that 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 forget to take JARINA PLUS". If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the 7 hormone-free light orange film-coated tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you want to stop taking JARINA PLUS:

You can stop taking JARINA PLUS at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking JARINA PLUS and wait for a menstrual period before starting to try to become pregnant.

POSSIBLE SIDE EFFECTS:

Not all side effects reported for JARINA PLUS are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

JARINA PLUS can cause side effects.

Serious side effects:

See also section "Take special care with JARINA PLUS", "JARINA PLUS and blood clots" and "JARINA PLUS and cancer" for side effects, including serious reactions, associated with the use of JARINA PLUS. Please read these sections carefully and consult your doctor at once where appropriate.

The following side effects were reported in studies with Yasmin and are also regarded as being representative for JARINA PLUS:

Frequent side effects:

Depressive mood, headache, migraine, nausea, breast pain including breast tenderness, leukorrhoea (vaginal discharge), vaginal moniliasis (fungal infection), menstrual disorder, intermenstrual bleeding (bleeding irregularities usually subside during continued treatment).

Less frequent side effects:

Body weight changes, fluid retention, changes in interest in sex, high blood pressure, low blood pressure, vomiting, acne, eczema, itching, vaginitis (vaginal inflammation).

Rare side effects:

Hypacusia~~s~~ (hearing impairment), thromboembolism (blood clots including embolism), asthma, breast discharge.

Other side effects that have been reported are: allergic reactions (hypersensitivity), altered mood, contact lens intolerance, abdominal pain, diarrhoea, rash, urticaria (hives), skin disorders such as erythema nodosum or multiforme, breast enlargement.

If you have hereditary angioedema (swelling which involve lips, eyes or tongue) medicines containing certain female sex hormones (estrogens) may induce or worsen the symptoms of angioedema (see section "Take special care with JARINA PLUS").

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

STORING AND DISPOSING OF JARINA PLUS:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Store at or below 30 °C.
Keep the blister strip in the pouch, in the original carton until required for use.
Do not use after the expiry date stated on the carton and the blister strip.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF JARINA PLUS:

JARINA PLUS is packed in colourless transparent high barrier foil (HBF) PVC/PE.EVOH.PE/PCTFE/ aluminium blisters containing 21 orange film-coated hormonal tablets, plus 7 light orange hormone-free film-coated tablets per blister strip packed in a hermetic pouch (PET/Al/PE). The pouch is packed into an outer cardboard carton. Pack sizes: 1 x 28 tablets, 3 x 28 tablets, 6 x 28 tablets.

IDENTIFICATION OF JARINA PLUS:

21 orange, round, biconvex film-coated tablets, with one side embossed with “Y+” in a regular hexagon, while the other side is blank, plus 7 light orange, round, biconvex film-coated tablets, with one side embossed with “M+” in a regular hexagon, while the other side is blank.

REGISTRATION NUMBER:

55/18.8/0462

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