**Drug Information Sheet ("Kusuri-no-Shiori")**

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse effects (risks) as well as efficacies (benefits). It is important to minimize adverse effects and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

<table>
<thead>
<tr>
<th>Brand name: PLANOVAR COMBINATION TABLETS</th>
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<tbody>
<tr>
<td>Active ingredient: Norgestrel Ethinylestradiol</td>
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<td>Dosage form: white tablet, diameter: 5.6 mm, thickness: 3.8 mm</td>
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<td>Print on wrapping: (face) プラノバール配合錠, AK376 (back) PLANOVAR, プラノバール</td>
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**Effects of this medicine**

This medicine replaces progesterone and estrogen to control hormone balance, and consequently improves abnormality in menstrual cycles and amount of menstrual bleeding and menstrual symptoms. It is usually used in the treatment of dysfunctional uterine bleeding, dysmenorrhea, menstrual cycle disorder (oligomenorrhea and polymenorrhea), menorrhagia, endometriosis and ovarian failure.

**Before using this medicine, be sure to tell your doctor and pharmacist**

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you have: thrombophlebitis, pulmonary embolism or a history of it, a suspect of breast cancer or endometrial cancer, hepatic disorder, sickle cell anemia, Dubin–Johnson syndrome, Rotor’s syndrome, dyslipidemia or abnormal genital bleeding which is not diagnosed.
- If you have breast cancer or reproductive organ cancer, you are suspected to have these diseases.
- If you have previously experienced jaundice, persistent pruritus, exacerbation of otosclerosis or herpes gestationis while you were pregnant.
- If you are pregnant, possible pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

**Dosing schedule (How to take this medicine)**

- Your dosing schedule prescribed by your doctor is << to be written by a healthcare professional >>
- For dysfunctional uterine bleeding: In general, take 1 tablet daily, for 7 to 10 consecutive days.
- For dysmenorrhea, menstrual cycle disorder (oligomenorrhea and polymenorrhea), menorrhagia, endometriosis and ovarian failure: In general, start with taking 1 tablet daily on the fifth day of menstrual cycle, and continue to take for 3 weeks consecutively.
- Strictly follow the instructions in any case.
- If you miss a dose, take a dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

- You are prone to develop side effects (thrombosis etc.) due to smoking. Refrain from smoking.
- This medicine may cause freckles. Avoid being exposed to sunlight over a long time.
- If you wear contact lenses, you may feel difficult in correcting visual acuity.
- The foods containing Hypericum perforatum may diminish therapeutic effects of this medicine. Refrain from taking those foods.

**Possible adverse effects of this medicine**

The most commonly reported adverse reactions include nausea, vomiting, loss of appetite, headache, breast pain, edema, weight gain and rash. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse effects indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- swelling and pain in legs, severe headache, shortness of breath, sudden focus disorder, [thrombosis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.
**Storage conditions and other information**

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only**

For further information, talk to your doctor or pharmacist.