

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

External

Revised: 09/2022

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

Brand name:Nasanyl Nasal Spray 0.2%

Active ingredient:Nafarelin acetate hydrate

Dosage form:limpid and colorless nasal solution, (octagonal container) pink

Imprint or print on wrapping:Gn-RH 誘導體製剤, ナサニール点鼻液 0.2%



Effects of this medicine

This medicine suppresses ovarian function by decreasing the GnRH receptors of pituitary.

It is usually used to treat endometriosis, to improve menorrhagia/lower abdominal pain/low back pain/anemia based on shrinking uterine fibroids and uterine fibroids and to prevent premature ovulation in assisted reproductive technology. However, in the case of uterine fibroids, it does not cure the cause of the symptoms themselves.

The following patients may need to be careful when 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 or foods.
If you have abnormal genital bleeding which cannot be diagnosed or submucous uterine myoma.
- If you are pregnant, possibly 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 endometriosis and improving menorrhagia, lower abdominal pain, low back pain and anemia based on shrinking uterine fibroids and uterine fibroids: In general, for adults, apply 1 spray (200 μg of nafarelin) to the nasal cavity of one side at a time twice a day from first to second day of menstrual cycle.
 - For preventing premature ovulation in assisted reproductive technology: In general, for adults, apply 1 spray (200 μg of nafarelin) to the nasal cavity of one side at a time twice a day.
- In any case, strictly follow the instructions.
- For stable absorption, clear the nasal passages by blowing your nose before spraying.
 - When this medicine is used to prevent premature ovulation in assisted reproductive technology, the patient and partner are examined before starting this medicine. If the results show diseases such as hypothyroidism, adrenal insufficiency, hyperprolactinemia and pituitary or hypothalamic tumor, treatment of them is given priority.
 - When this medicine is used to treat endometriosis and to improve menorrhagia, lower abdominal pain, low back pain and anemia based on shrinking uterine fibroids and uterine fibroids, it should be determined whether the patient is pregnant or not before starting this medicine.
 - If you miss a dose, skip the missed dose and follow your regular dosing schedule. You should never apply two doses at one time.
 - If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
 - Do not stop applying this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- When this medicine is used to improve menorrhagia, lower abdominal pain, low back pain and anemia based on shrinking uterine fibroids and uterine fibroids, it may not be effective for lower abdominal pain and back pain in the early stages of use, and other appropriate treatment may be administered until the effect is seen.
 - When this medicine is used to treat endometriosis and to improve menorrhagia, lower abdominal pain, low back pain and anemia based on shrinking uterine fibroids and uterine fibroids, non-hormonal contraception should be used while this medicine is being used.
- This medicine is discontinued if the mass increases in size or if symptoms do not improve while using this medicine. Long-term use of this medicine may cause a decrease in bone mass. As a rule, continued use for more than 6 months is not recommended. If this medicine is used again, it should be carefully used with attention to the possibility of bone loss, such as by performing tests related to bone mass.
- When this medicine is used to prevent premature ovulation in assisted reproductive technology, ovarian hyperstimulation syndrome may occur. If any of the following abnormalities are observed, consult with your doctor or other health care professional immediately; abdominal tightness, nausea, decreased urine output, pain/tightness in lower abdomen, back pain or rapid weight gain.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hot flash, stiff shoulder and headache. 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 reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- depressed feeling, general malaise, loss of appetite [depressed state]
- nose bleeding, gum bleeding, subcutaneous bleeding [decreased platelets]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatic dysfunction, jaundice]
- menostaxis (excessively long menses), hypermenorrhea (excessive menstrual bleeding), frequent menstruation [atypical genital bleeding]
- abdominal bloating, lower abdominal pain, loss of appetite [ovarian cyst rupture]

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 reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.