この説明書は製品についての参考情報です。正しくは製品に記載されている説明をご確認ください。

This document serves as reference information. Please ensure to read the information provided with the product.

Underlined parts: Revisions made in October 2024

[Keep this information leaflet with this medication and be sure to read it before taking the medication.]

EVE THREE SHOT PREMIUM

Class² OTC drug

[Antipyretic-Analgesic Medication]

 EVE THREE SHOT PREMIUM is a drug product designed to work effectively on headaches, menstrual pain, and shoulder stiffness pain.

<< Product Features>>

- This medication contains the two analgesic agents of ibuprofen and acetaminophen as double active ingredients.
- The quick-action tablet formulation with the original technology that has realized rapid dissolution of ibuprofen was adopted for this medication.
- This medication contains magnesium oxide (a gastric mucosal protective agent) that protects the stomach but does not contain any ingredient that causes drowsiness.

rianglePrecautions for Use

Con

Contraindications

If you do not follow the precautions exactly as listed below, your current symptoms may worsen and you may be placed at increased risk of side effects or the risk of having some accidents.

- The following persons must not take this medication:
 - (1) Persons who have had an allergic reaction to any of the ingredients of EVE THREE SHOT PREMIUM.
 - (2) Persons who have experienced asthma after taking this medication or after taking other antipyretic-analgesics or common cold medications.
 - (3) Children under 15 years of age.
 - (4) Pregnant women whose due date is within 12 weeks ahead.
- Do not take any of the following medications during the period of taking EVE THREE SHOT PREMIUM:

Other antipyretic-analgesics, common cold medications, and sedatives

- This medication must not be taken soon before or soon after alcohol intake.
- Do not use this medication for a long and continuing period.



Consultation

- The following persons should consult a physician, dentist, pharmacist, or registered salesperson before taking this medication:
 - (1) Persons who are receiving any treatment from a physician or dentist.
 - (2) Women who are or may be pregnant.(3) Breast-feeding women.
 - (4) Elderly persons.(5) Persons who have had any allergic reactions to drugs or other substances.
 - (6) Persons who have received a diagnosis of any of the following diseases: Heart diseases, kidney diseases, liver diseases, systemic lupus erythematosus, mixed connective tissue disease
 - (7) Persons who have had any of the following diseases: Gastroduodenal ulcers, ulcerative colitis, Crohn's disease

If any of the symptoms listed below develop after taking EVE THREE SHOT PREMIUM, they
might be side effects of the medication. Stop taking this medication immediately and consult a
physician, dentist, pharmacist, or registered salesperson, presenting this leaflet.

| Affected area | Symptoms | |
|------------------|---|--|
| Skin | Rash/redness, itching, bruise | |
| Gastrointestinal | Nausea/vomiting, inappetence, stomach discomfort, stomachache, stomatitis, heartburn, heavy | |
| | feeling in the stomach, gastrointestinal hemorrhage, abdominal pain, diarrhea, bloody stools | |
| Neuropsychiatric | Dizziness | |
| Cardiovascular | Palpitations | |
| Respiratory | Shortness of breath | |
| Other | Blurred vision, tinnitus, swelling, nasal bleeding, gingival bleeding, difficulty in stopping bleeding, | |
| | bleeding, back pain, excessively decreased body temperature, general malaise | |

In rare cases, any of the serious symptoms listed below may occur. In such cases, immediately consult a physician.

| Name of symptoms | Symptoms |
|---------------------------|---|
| Shock (anaphylaxis) | Itchy skin, urticaria, hoarse voice, sneezing, itchy throat, respiratory distress, palpitations, clouding of consciousness or such occurring immediately after taking this medication. |
| syndrome (Stevens-Johnson | Symptoms, such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, rashes and redness over an extensive area of the skin, small rashes (small pustules) on the reddened skin, general malaise, and inappetence, persisting or suddenly worsening. |
| <u> </u> | Redness involving an extensive area of the skin, generalized rash, fever, malaise, swelling of |
| hypersensitivity syndrome | the lymph nodes or such occur. |

(Continued on the reverse side)

(Continued from the front side)

| Name of symptoms | Symptoms | | |
|------------------------|--|--|--|
| Hepatic impairment | Fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, general malaise, inappetence or such occurring. | | |
| Renal disorders | Fever, rashes, decreased urine output, generalized swelling, general malaise, arthralgia (pain in joints), diarrhea or such occurring. | | |
| Aseptic meningitis | Symptoms such as severe headache with neck stiffness, fever, and nausea/vomiting occurring. (Frequent occurrences of such symptoms have been reported particularly among patients who are undergoing treatment for systemic lupus erythematosus or mixed connective tissue disease.) | | |
| Myocardial infarction | Pain with chest tightness, respiratory distress, and cold sweat occurring. | | |
| Cerebrovascular | The following symptoms suddenly occurring: Decreased or loss of consciousness, | | |
| <u>disorders</u> | difficulty in moving hand and foot unilaterally, headache, vomiting, dizziness, difficulty speaking, and speech impairment. | | |
| Interstitial pneumonia | The following symptoms suddenly occurring or persisting: Shortness of breath or respiratory distress when climbing stairs or slightly overworking, dry cough, and fever. | | |
| Asthma | Breathing sounds, such as wheezing and whistling, respiratory distress and such occurring. | | |
| Aplastic anemia | The following symptoms occurring: Bruising, nasal bleeding, gingival bleeding, fever, pallor of the skin or mucous membranes, fatigue, palpitations, shortness of breath, feeling sick and fainting, and hematuria. | | |
| Agranulocytosis | Sudden high fever, chills, sore throat or such occurring. | | |

The condition mentioned below may occur after taking EVE THREE SHOT PREMIUM. If such symptoms
persist or worsen, stop taking this medication and consult a physician, pharmacist, or registered
salesperson, presenting this leaflet.

Constipation

If there is no alleviation of the symptoms for which this medication is being taken, after 3 or 4
doses, stop taking this medication and consult a physician, dentist, pharmacist, or registered
salesperson, presenting this leaflet.

Indications

- Relief of the following pains: Headache, painful menses (menstrual pain), shoulder stiffness pain, toothache, sore throat, arthralgia (joint pain), myalgia (muscle pain), neuralgia (nerve pain), lower back pain, pain after tooth extraction, contusion pain, ear pain, fracture pain, pain associated with sprain (sprain pain), and traumatic pain
- Relief of chills (chilliness due to fever) and fever

Dosage and Administration

Take a dose of EVE THREE SHOT PREMIUM, according to the table below, with cold or lukewarm water, up to 2 times daily. Each dose should not be taken on an empty stomach whenever possible. There must be an interval of at least 6 hours between doses.

| Age | Adults (aged 15 years or older) | Children under 15 years of age |
|------|---------------------------------|-------------------------------------|
| Dose | 3 tablets | XThis medication must not be taken. |

<Pre><Pre>cautions concerning Dosage and Administration>

- (1) EVE THREE SHOT PREMIUM must be used strictly in accordance with the specified dosage and administration.
- (2) How to remove the tablet: As shown in the illustration on the right, firmly press the raised portion of the press-through package (PTP) with a fingertip to push the tablet through the aluminum foil on the reverse side. (If the PTP sheet is mistakenly swallowed, its sharp edges may perforate the esophageal mucosa or lead to incidental events.)



Ingredients

Ibuprofen195 mgAcetaminophen195 mgMagnesium oxide70 mgAnhydrous caffeine65 mg

in a total of 3 tablets

Excipients: Anhydrous silicic acid, cellulose, hydroxypropylcellulose, hypromellose, crospovidone, macrogol, magnesium stearate, talc, titanium oxide

Precautions for Storage and Handling

- (1) Store in a dry, cool place away from direct sunlight.
- (2) Keep out of the reach of children.
- (3) Do not transfer the contents to another container (which may lead to drug misuse or changes in the quality of this product).
- 4) Do not take this medication after the expiration date.

| Contact Information | Inquiries should be made to the drugstore where you purchased the product or to the |
|---------------------|---|
| | customer service office. |
| | Customer Service Office, SSP Co., Ltd. Phone: 0120-028-193 |
| | Opening hours: 9:00 to 17:30 (closed on Saturdays, Sundays, and Japanese public holidays) |

Manufactured and Distributed by:



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