

Non-pyrine antipyretic analgesic

Aspirin tablet in Japanese Pharmacopoeia

Bayer Aspirin®

Aspirin

®: Registered mark of Bayer AG in German

**CAUTIONS FOR USE****To be avoided**

[Failure to observe the following may result in adverse drug reactions and accidents occurring.]

1. This medication should not be used by the following persons.

- (1) Persons who experienced allergic symptoms (rash/redness, itch, edema, etc.) by this medicine or any other aspirin (acetylsalicylic acid) preparation
- (2) Person who suffered from asthma after using this product, any other antipyretic analgesics or cold medications
- (3) Children under 15 years old
- (4) Patients with gastroduodenal ulcer
- (5) Persons with bleeding tendency (those who easily develop petechiae and purpura in the hands and feet, etc.)
- (6) Pregnant women who are planned to deliver within 12 weeks

2. The persons who are taking this drug must not take all of the following pharmaceutical products.

Other antipyretic analgesics, cold medications and analgesic agents.

3. Do not consume alcohol when using this medication.**4. Do not use this medication for a prolonged period of time.****Consult a physician for the following****1. The following persons should consult a physician, dentist or pharmacist before using this medication.**

- (1) Persons undergoing medical treatment from a physician or dentist
- (2) Pregnant women or women suspected of being pregnant
- (3) Elderly people
- (4) Persons or their family have allergic predisposition
- (5) Persons with a medical history of being allergic to medicines
- (6) Persons diagnosed as having the following:
Cardiac disease, renal disease, hepatic disease
- (7) Persons with a medical history of the following:
Gastroduodenal ulcer

**2. In the following cases, discontinue use immediately and consult a physician, dentist or pharmacist, taking the instruction leaflet with you.**

- (1) When the following symptoms appear after use:

Affected site	Symptoms
Skin	rash/redness and itching
Digestive organs	Nausea/vomiting, anorexia, heartburn, stomach pain, gastrointestinal haemorrhage
Neuropsychiatric system	Dizziness
Others	Oedema, anaemia, tinnitus, deafness

Characteristics

Bayer Aspirin is a non-pyrine antipyretic analgesic developed by Bayer AG in German. The active ingredient aspirin (acetylsalicylic acid) suppresses generation of causative substances of pain and fever. For aspirin contained in Bayer Aspirin, minute and homogeneous crystals are used. As aspirin dissolves quickly and is rapidly absorbed in the stomach and intestines, it has a beneficial effect on pain and fever.

Rarely, the following serious symptoms may appear. In such case, immediately consult a physician.

Diagnosis	Symptoms
Shock (anaphylaxis)	Turning pale with cold hands and feet, cold sweats, breathing difficulties, combined with hives, edema, and a heaviness in the chest soon after use.
Oculomucocutaneous syndrome (Stevens-Johnson syndrome) Toxic epidermal necrosis (Lyell syndrome)	Violent symptoms, such as a rash, redness and burn-like blisters appearing all over the body and in the mucosa of the mouth and eyes accompanied by a high fever.
Hepatic dysfunction	The whole body feels fatigued, the appearance of jaundice (the skin and whites of the eyes turn yellow), etc.
Asthma	

- (2) When the symptoms do not improve after having used this medicine 5 to 6 times.

INDICATIONS

- Relief of headache, toothache, tooth extraction pain, menstrual pain (menstrual cramps), sore throats, earache, arthralgia, neuralgia, lumbar pain, myalgia, stiff shoulder, bruise pain, bone fracture pain, sprain pain and traumatic pain
- Antipyretic action when you feel chills and have a fever

DOSAGE AND ADMINISTRATION

The following dosages should not be taken on an empty stomach if possible. Maintain at least a 4-hour interval between dosages.

Age	One dosage	Daily dosing frequency
Adults (15 years and over)	1 tablet	Do not use. Up to 3 times
Children under 15 years	Do not use.	

- ★ This medicine should be taken with a cup of water.

<Precautions>

- (1) Please follow the defined dosage and administration.

(2) How to remove a tablet

As shown in the diagram, firmly push the bulging portion of the sheet containing the tablet with the tip of one finger and break the aluminum film on the rear side. Remove the tablet. (Be careful to avoid swallowing the packaging sheet by mistake, doing so may injure the esophageal mucosa.)

**Ingredients and activity**

Bayer Aspirin is a white tablet that contains the following ingredient.

Ingredient	Content (per tablet)	Activity
Aspirin (acetylsalicylic acid)	500mg	The ingredient relieves the symptoms of fever and pain.

- Additives: Cellulose, corn starch

CAUTIONS ON STORAGE AND HANDLING

- (1) Store this medicine in a cool place free from direct sunlight and moisture.
- (2) Keep all medications out of reach of children.
- (3) Do not transfer this medicine to a different container (It may be misused or the quality may deteriorate.)
- (4) Do not use the product after its validity date has expired.

Packaging

- * Bayer Aspirin (500 mg) 10 tablets, 30 tablets

- * Further information available from

* The store you bought it from

* Sato Pharmaceutical Co., Ltd.

Drug Information Center: Phone:

03-5412-7393

Office hours: 9 am - 6 pm

(except Sat., Sun. and holidays)

Contact for adverse drug reactions
Pharmaceuticals and Medical Devices
Agency (PMDA)

<http://www.pmda.go.jp/kenkohigai.html>

Phone: 0120-149-931 (toll free)

03-3506-9111 (available from cellular phones and public phones)

