Contraindications

When must aspirin protect 100 mg not be used?
Aspirin protect 100 mg must not be used by patients who:
- Are known to be hypersensitive to the active ingre-
dient acetylsalicylic acid or to salicylates (a group
of substances related to acetylsalicylic acid) or any
of the other constituents
- Have gastric or duodenal ulcers
- Have a pathologically increased tendency to blood
(haemorrhagic diathesis)

When should you consult a doctor before taking
aspirin protect 100 mg?
Described below are cases in which you should only
take aspirin protect 100 mg under certain circum-
stances and with particular caution. Please consult
your doctor in these cases.

Particularly careful medical supervision is required if
- Are hypersensitive to other analgesic anti-inflam-
matory or antiemetic medicines or if you have
other allergies.
- Are taking anticoagulant medicines (e.g coumarin
derivatives, heparin (except low-dose heparin)
- Suffer from bronchial asthma
- Have chronic or recurrent gastric or duodenal com-
plaints
- Have pre-existing kidney damage
- Have severely impaired liver function.

What should you be aware of when pregnant or
breast feeding?
If pregnancy should occur during a period of treat-
ment with aspirin protect 100 mg, a doctor must
be informed. Aspirin protect 100 mg should not be
taken in the first and second trimesters of pregnancy
without consulting a doctor. Aspirin protect 100 mg
should not be taken in the last three months of preg-
nancy owing to an increased risk of complications for mother and child during delivery.
Small quantities of the active ingredient acetylsalicylic acid and its metabolites pass into the breast milk, since no detrimental effects on infants have been reported to date, it will generally not be necessary to stop breast feeding if the daily dose does not exceed 150 mg, if higher doses are taken (more than 150 mg daily), the patient should stop breast feeding.

What precautions should be taken for children?
Aspirin protect 100 mg should not be taken by children or adolescents with feverish illnesses unless they have been instructed to do so by a doctor or other therapeutic measures have failed. Prolonged vomiting in conjunction with such illnesses could be a sign of Reye’s syndrome, a very rare but life-threatening disease which requires immediate medical attention.

Precautions and warnings
What precautions should be taken?
Patients who suffer from asthma, have fever, nasal polyps or chronic respiratory tract infections (particularly if they are accompanied by high fever like symptoms) or who are hypersensitive to any type of analgesic or antirheumatic drugs are at risk of asthma attacks (analgesic intolerance / analgesic-induced asthma) if they take aspirin protect 100 mg. They should consult a doctor before taking aspirin protect 100 mg the same applies to patients who react hypersensitivity (allergically) to other substances in the form of skin reactions, pruritus or nettle rash.

A doctor/dentist must be consulted or informed about any use of aspirin protect 100 mg before operations.

Drugs containing acetylsalicylic acid should not be taken for prolonged periods or at high doses without consulting a doctor.

What precautions should be taken when driving, operating machinery or working without a secure foothold?
No special precautions are necessary.

Interactions with other drugs
What other medicines affect the way aspirin protect 100 mg works, and how does aspirin protect 100 mg affect the action of other medicines?
Aspirin protect 100 mg increases
- The effect of anticoagulant drugs (e.g coumarin derivatives and heparin)
- The risk of gastrointestinal bleeding if taken concomitantly with alcohol or medicines that contain cortisone or cortisone-like substances)
- The effect of certain blood glucose-lowering medicines (sulphonylureas)
- The effects and unwanted effects of methotrexate
- Blood levels of digoxin, barbiturates and lithium
- The desirable and unwanted effects of a particular group of analgesic, anti inflammatory and antirheumatic medicines (nonsteroidal anti-inflammatory drugs) and of antirheumatic medicines in general
- The effect of certain antibiotics (sulphonamides and sulphonamide combinations (e.g sulphamethoxazole/trimethoprim)
- The effect of triiodothyronine, a medicine for treating hypothyroidism;
- The effect of valproic acid, a medicine for treating convulsions (epilepsy)

Aspirin protect 100 mg weakness the action of
- Certain medicines that increase the excretion of urine (aldosterone antagonists e.g spironolactone and canrenoate and loop diuretics, e.g furosemide)
- Blood pressure lowering medicines;
- Gout remedies that promote the excretion of uric acid (e.g probenecid sulphinpyrazone)

Accordingly patients should not take aspirin protect 100 mg in conjunction with any of the above-mentioned substances unless expressly instructed to do so by a doctor.

Please note that this information may also apply to medicines used recently.

What foods and drinks should you avoid?
Please note that medicines should not be taken with alcohol.

Dosage and administration
Unless otherwise prescribed by your doctor you should use aspirin protect 100 mg as described
The most favorable time for starting treatment with aspirin protect 100 mg after an aortocoronary venous bypass (ACVB) would appear to be 24 hours after the operation.

For how long should you use aspirin protect 100 mg?
Aspirin protect 100 mg is intended for long term use. The attending doctor must decide on the length of the treatment.

Incorrect use and over dosage
What should you do if you take too much aspirin protect 100 mg (either intentionally or by accident)?
Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning.
Please notify your doctor if you suspect an overdose of aspirin protect 100 mg. He will decide on the necessary measures to be taken depending on the severity of overdose/intoxication.

What should you do if you have taken too little aspirin protect 100 mg or have forgotten to take a dose?
Do not take a double dose the next time you take aspirin protect 100 mg. Simply continue taking the tablets as shown in the instructions as prescribed by your doctor.

What should you do if you want to interrupt the treatment or stop using aspirin protect 100 mg before the end of the course?
Please do not interrupt or discontinue this treatment without first consulting your doctor.

Side effects
What side effects can occur when taking aspirin protect 100 mg?
Gastrointestinal complaints such as stomach pain and mind gastrointestinal blood loss (microhaemorrhages) are frequent side effects. Occasionally nausea, vomiting and diarrhea occur. Rarely gastric haemorrhaging and gastric ulcers and in particular in asthmatics, hypersensitivity reactions
(attacks of difficult breathing skin reactions) may occur.

Isolated cases of impaired hepatic and renal function, a reduction in blood glucose levels (hypoglycemia) and particularly severe skin rashes (including erythema exsudativum multiforme) have been reported.

At low doses acetylsalicylic acid reduces the excretion of uric acid, this may cause a gout attack in predisposed patients.

In rare cases long-term use of aspirin protect 100 mg can result in anemia due to occult blood loss from the gastrointestinal tract, if you pass black stools (tarry stools, a sign of serious bleeding in the stomach) you should inform your doctor immediately (see also “what action should be taken if any of these side effects occur?”)

Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning (see also incorrect use and over dosage)

Note: if you experience side effects that are not mentioned in this information leaflet, please inform your doctor or pharmacist.

**What action should be taken if any of these side effects occur?**

If you experience any of the above mentioned side effects, do not take any more aspirin protect 100 mg. Notify your doctor so that he can determine the severity of the side effect(s) and decide on any necessary further action.

Use of aspirin protect 100 mg should be stopped at the first signs of hypersensitivity, if you pass black stools (tarry stools, a sign of serious bleeding in the stomach) you must inform your doctor immediately.

**Information on the shelf-life of the product**

The expiry date of this product is printed on the cardboard box. Do not use the product after this date.

Do not store above 25°C!

Date of preparation: March 2004 (D7)

Keep medicines out of the reach of children.