



Apernyl mit Acetylsalicylsäure

32 mg/dental stick (Apernyl with acetylsalicylic acid) · Acetylsalicylic acid

Read all of this leaflet carefully before this medicine is administered to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your dentist or pharmacist if you need more information or advice.
- If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a dentist if you do not feel better or if you feel worse.

What is in this leaflet

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1. What Apernyl with acetylsalicylic acid is and what it is used for

Apernyl with acetylsalicylic acid is a pain-relieving drug (analgesic) for external (topical) use in dentistry.

Apernyl with acetylsalicylic acid is used for the treatment of mild to moderate pain after pulling a tooth (tooth extraction) or orthodontic surgery.

2. What you need to know before Apernyl with acetylsalicylic acid is administered to you

Do not use Apernyl with acetylsalicylic acid:

- if you are allergic to acetylsalicylic acid, other salicylates or any of the other ingredients of this medicine (listed in section 6);
- in the last three months of pregnancy;
- in children and adolescents with feverish diseases because of a potential risk of the occurrence of Reye's syndrome (a very rare, but life-threatening condition);
- in case of abnormally increased bleeding tendency;
- to prevent pain after tooth extractions (pulling a tooth);
- in case of gastric or intestinal ulcers;
- to prevent infection of the coagulum after extractions (prevent infection by blood clot after pulling a tooth);
- in case of an intended tight suture closure of the extraction wound (wound which results from pulling a tooth).

Warnings and precautions

Talk to your dentist or pharmacist before Apernyl with acetylsalicylic acid is administered to you, especially:

- if you are allergic to other anti-inflammatory drugs for the treatment of rheumatism or to other substances causing hypersensitivity reactions;
- in the first six months of pregnancy;
- in case of a concomitant therapy with anticoagulant drugs (e.g. cumarin derivatives, heparin, exception: low-dose heparin treatment);
- in cases of bronchial asthma;
- in cases of chronic and recurrent gastric or duodenal ulcers;
- in cases of impaired kidney function;
- in cases of severe liver dysfunction.

Contact of Apernyl with acetylsalicylic acid with mucous membranes produces symptoms of etching ("aspirin burn").

Patients suffering from asthma, hay fever, swelling of the nasal mucous membrane (nasal polyps), or chronic infections of the respiratory tract (in particular in combination with symptoms resembling those of hay fever), and patients with hypersensitivity to all kinds of pain relievers and antirheumatic agents are at risk for asthmatic seizure when using Apernyl with acetylsalicylic acid (so-called analgesic intolerance/analgesic asthma). The same applies to patients who are allergic to other substances, e.g. by responding with skin reactions, pruritus, or urticaria.

Children

The safety of Apernyl with acetylsalicylic acid in children under 12 years of age has not yet been established. Apernyl with acetylsalicylic acid should therefore be used with caution in children under 12 years of age.

Other medicines and Apernyl with acetylsalicylic acid

Tell your dentist or pharmacist if you are using, have recently used or might use any other medicines.

Acetylsalicylic acid potentiates:

- the effects of agents against blood clots (anticoagulants), for example, cumarin derivatives and heparin;
- the risk of gastrointestinal bleeding under simultaneous treatment with corticosteroids or in case of concomitant consumption of alcohol;
- the effects of oral antidiabetic agents (sulphonyl carbamides);
- the efficacy and adverse effects of methotrexate;
- the concentration of digoxin or barbiturates and lithium in the blood plasma;
- the efficacy and adverse effects of all non-steroidal anti-rheumatic agents;
- the desired and adverse effects of chemotherapeutically effective sulphonamides, including cotrimoxazole;
- the effect of triiodothyronine.

Acetylsalicylic acid reduces the efficacy of:

- spironolactone and canrenoate;
- loop diuretics (e.g. furosemide);
- drugs against high blood pressure (anti-hypertension drugs);

- uricosuric drugs (e.g. probenecid, sulphapyrazone).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist or pharmacist for advice before using this medicine.

Apernyl with acetylsalicylic acid must not be used in the last three months of pregnancy.

Apernyl with acetylsalicylic acid should only be used with particular caution in the first six months of pregnancy.

Driving and using machines

Apernyl with acetylsalicylic acid has no known effects on the ability to drive and use machines.

3. How to use Apernyl with acetylsalicylic acid

This medicine is exclusively administered by your dentist.

Depending on the size of the extraction wound your dentist will insert up to 3 dental sticks into the wound.

Apernyl with acetylsalicylic acid is normally applied once.

However, if you suffer from persisting pain, repeated applications are possible. The duration of use should not exceed a few days.

If you suffer from persisting pain, your dentist will clarify the cause and will initiate an appropriate treatment.

If you have any further questions on the use of this medicine, ask your dentist or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare (may affect up to 1 in 1,000 people)

Hypersensitivity reactions (respiratory distress, skin reactions), particularly in asthma patients.

Other possible side effects

Upon administration of acetylsalicylic acid in the dosage forms for oral use various other side-effects have been reported, which have been observed to occur frequently, occasionally, seldom, or in individual cases (stomach and intestinal complaints such as gastric pains, micro-bleedings, nausea, vomiting, diarrhoea, as well as secondary effects due to increased bleeding tendency etc.).

Reporting of side effects

If you get any side effects, talk to your dentist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Germany, website: www.bfarn.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Apernyl with acetylsalicylic acid

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the container after "Verwendbar bis". The expiry date refers to the last day of that month.

Do not store above 30 °C.

6. Contents of the pack and other information

What Apernyl with acetylsalicylic acid contains

- The active substance is: acetylsalicylic acid. One dental stick contains 32 mg acetylsalicylic acid.

- The other ingredients are: Carbopol, sodium dodecyl sulphate, maize starch.

What Apernyl with acetylsalicylic acid looks like and contents of the pack

Apernyl with acetylsalicylic acid are white, wedge-shaped dental sticks with a length of approx. 8 mm, a width of 4 mm and a thickness of 2–2.4 mm.

Apernyl with acetylsalicylic acid is available in clear glass containers with white screw caps with 5 and approx. 100 dental sticks.

Not all pack sizes may be marketed.