

Ibuprofen Aspirin

Final SPC and PIL wording agreed by PhVWP June 2008

Summary of Product Characteristics

For ibuprofen

SPC 4.5

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 5.1).

SPC 5.1

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin dosing (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

PL

What should you avoid when you are taking this medicine?

Some medicines that are anti-coagulants (against clotting) (e.g. acetylsalicylic acid/aspirin, warfarin, ticlopidin), some medicines against high blood pressure (ACE-inhibitors e.g. captopril, betareceptor blocking medicines, angiotensin II antagonists), and even some other medicines may affect or be affected by the treatment of ibuprofen. Seek therefore always advice of a doctor before you use ibuprofen with other medicines.

For aspirin

SPC 4.5

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PL

What should you avoid when you are taking this medicine?

Effect of the treatment may be influenced if aspirin is concomitantly taken with some other medicines for:

- Blood clot (e.g. warfarin)
- Rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- pain and inflammation (e.g. steroids or anti-inflammatory medicines)
- gout (probenecid)
- cancer och reumatoid arthritis (methotrexate)
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Before using aspirin inform your doctor about the medicines you are taking. If you are using aspirin regularly seek advice of your doctor before taking any other medicine (including OTC medicines).