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Javna agencija Republike Slovenije
za zdravila in medicinske pripomočke
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VSEM IMETNIKOM DOVOLJENJ ZA PROMET Z
ZDRAVILI, ki vsebujejo ibuprofen ali nizke
odmerke acetilsalicilne kisline

**Predložitev spremembe tipa II – dopolnitev povzetka glavnih značilnosti
zdravil (SmPC) in navodil za uporabo (PIL) za zdravila, ki vsebujejo
ibuprofen ali nizke odmerke acetilsalicilne kisline**

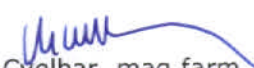
Spoštovani,

Delovna skupina za farmakovigilanco (PhVWP) je na podlagi ocene razpoložljivih podatkov glede tveganja za medsebojno delovanje med ibuprofenom in nizkimi odmerki acetilsalicilne kisline (ASA v odmerkih do 325 mg na tableto in odobrena indikacija <preprečevanje trombemboličnih zapletov>) priporočila dopolnitev povzetkov glavnih značilnosti in navodil za uporabo zadevnih zdravil. Prosimo imetnike dovoljenj za promet z zadevnimi zdravili, ki še niso predložili vloge za spremembo tipa II, naj le-to predložijo v čim krajšem času, oz najkasneje v 30 dneh. Dodatna strokovna podpora dokumentacija za odobritev spremembe ni potrebna.

V nadaljevanju vam podajamo odobreno originalno besedilo spremembe.

S spoštovanjem,




dr. Martina Cvelbar, mag.farm., spec.
direktorica

Final SPC and PIL wording agreed by PhVWP June 2008

**Ibuprofen
Summary of Product Characteristics**

SmPC 4.5

Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid 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).

SmPC 5.1

Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid 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 acetylsalicylic acid 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.

PIL

What should you avoid when you are taking this medicine?

Some medicines that are anti-coagulants (against clotting) (e.g. acetylsalicylic acid, 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.

Acetylsalicylic acid

Summary of Product Characteristics

SmPC 4.5

Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid 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).

SmPC 5.1

Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid 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 acetylsalicylic acid 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.

PIL

What should you avoid when you are taking this medicine?

Effect of the treatment may be influenced if acetylsalicylic acid 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 acetylsalicylic acid inform your doctor about the medicines you are taking. If you are using acetylsalicylic acid regularly seek advice of your doctor before taking any other medicine (including OTC medicines).

Besedilo spremembe je objavljeno na spletni strani vodij agencij za zdravila
<http://www.hma.eu/222.html>.