

NON-SELECTIVE NSAIDS FOR SYSTEMIC ADMINISTRATION

OVER THE COUNTER (OTC) PRODUCTS

Final wording for SPC and package leaflet (PL)

As agreed by the PhVWP in December 2006

ALL OTC NON-SELECTIVE NSAIDS FOR SYSTEMIC ADMINISTRATION

Section 4.2

[No new wording necessary]

Section 4.3 Contraindications

Severe heart failure

Section 4.4 Special Warnings and precautions for use

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Section 4.8 Undesirable effects

Oedema, hypertension, and cardiac failure, have been reported in association with NSAID treatment.

ALL OTC NON-SELECTIVE NSAIDS EXCEPT NAPROXEN, IBUPROFEN, DICLOFENAC FOR SYSTEMIC ADMINISTRATION

Section 4.4 Special Warnings and Precautions for Use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long-term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for <substance> when given at a daily dose of <dose-range for OTC>.

Section 4.8 Undesirable effects

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long-term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Package leaflet:

Warnings

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [x days *OTC products only*].

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Side effects

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

OTC DICLOFENAC FOR SYSTEMIC ADMINISTRATION

Section 4.4 Special Warnings and Precautions for Use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of diclofenac, particularly at high doses (150mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Available data do not suggest an increased risk with use of low dose diclofenac *<dose range of OTC product>* up to *<refer to recommended duration for use of OTC product>*.

Section 4.8 Undesirable effects

Clinical trial and epidemiological data suggest that use of diclofenac (particularly at high doses 150mg daily and in long-term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Package leaflet:

Warnings

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [x days *OTC products only*].

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Side effects

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

OTC IBUPROFEN FOR SYSTEMIC ADMINISTRATION

Section 4.4 Special Warnings and Precautions for Use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. \leq 1200mg daily) is associated with an increased risk of myocardial infarction.

Section 4.8 Undesirable effects

Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Package leaflet:

Warnings

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [x days *OTC products only*].

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Side effects

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

OTC NAPROXEN FOR SYSTEMIC ADMINISTRATION

Section 4.4 Special Warnings and Precautions for Use

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).

Cardiovascular and cerebrovascular effects

Clinical trial and epidemiological data suggest that use of coxibs and some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Although data suggest that the use of naproxen (1000 mg daily) may be associated with a lower risk, some risk cannot be excluded. There are insufficient data regarding the effects of low dose naproxen *<dose range of OTC product>* to draw firm conclusions on possible thrombotic risks.

Section 4.8 Undesirable effects

Clinical trial and epidemiological data suggest that use of coxibs and some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see section 4.4).

Package leaflet:

Warnings

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment [x days *OTC products only*].

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Side effects

Medicines such as [product] may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.