HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

3 January 2007

DICLOFENAC SODIUM MIKA PHARMA 4%, skin spray solution
7.5 g Vial (CIP: 362 261-8)
12.5 g Vial (CIP: 362 262-4)
25 g Vial (CIP: 362 263-0)

Applicant : SERB

Diclofenac sodium

List II

Date of Marketing Authorisation: July 28, 2003

Reason for request: Inclusion on the list of medicines reimbursed by National Insurance and approved for use by hospitals.

Health Technology Assessment Division

1 CHARACTERISTICS OF THE MEDICINAL PRODUCT

1.1. Active ingredient

diclofenac sodium

1.2. Indications

Symptomatic treatment of mild to moderate pain and inflammation following acute blunt trauma, without lesion, of small and medium-sized joints and periarticular structures.

1.3. Dosage

For cutaneous use only. Not to be administered orally.

Adults

A sufficient quantity of solution should be applied to the skin to ensure a covering of DICLOFENAC SODIUM MIKA PHARMA 4% skin spray solution over the affected area. Normally 4 to 5 pump strokes (0.8–1.0 g of spray containing 32-40 mg of diclofenac sodium) would be required. The treatment should be repeated 3 times a day at regular intervals. The maximum daily dose is 15 pump strokes (3.0 g of spray containing 120 mg of diclofenac sodium).

DICLOFENAC SODIUM MIKA PHARMA 4%, skin spray solution should be applied gently into the skin. Wash hands after application, unless this is the treatment area. After applying the gel some minutes for drying should be allowed before dressing or bandaging the treated area.

The treatment should be discontinued when the symptoms (pain and swelling) have subsided. Treatment should not be continued beyond 7-8 days without medical review. The patient is requested to consult his physician if improvement is not seen after 3 days of treatment.

Elderly patients

Dosage adjustment is not necessary.

Children

The use of the product in children under the age of 15 years is not assessed and therefore not recommended.

Renal or hepatic impairment

For the use of DICLOFENAC SODIUM MIKA PHARMA 4%, skin spray solution in patients with renal or hepatic impairment.

2 SIMILAR MEDICINAL PRODUCTS

2.1. ATC Classification

M:	Musculo-skeletal system
M02:	Topical products for joint and muscular pain
M02A:	Topical products for joint and muscular pain
M02AA:	Anti-inflammatory preparations, non-steroids for topical use
M02AA15:	diclofenac

2.2. Medicines in the same therapeutic category

Comparator medicines
Other topical NSAIDs with the same indications.

2.3. Medicines with a similar therapeutic aim

All analgesics/anti-inflammatory drugs with the same indications.

3 ANALYSIS OF AVAILABLE DATA

3.1. Efficacy

The file comprises a single clinical study:

Study LINK R (unpublished)
Randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of DICLOFENAC SODIUM MIKA PHARMA 4% in the treatment of post-traumatic ankle oedema (contusions, minor sprains, etc.) occurring mainly during physical activity.

Patients were administered 4 to 5 pump strokes of DICLOFENAC SODIUM MIKA PHARMA 4% spray, three times daily for two weeks, corresponding to a daily dose of 96 to 120 mg of diclofenac (n=97) or a placebo (n=94).

Primary study endpoint: response to treatment defined as a reduction by more than 50% in swelling following treatment shorter than 10 days.

Results:
A statistically significant difference in favour of DICLOFENAC SODIUM MIKA PHARMA 4% for the primary study endpoint was demonstrated.

In the DICLOFENAC SODIUM MIKA PHARMA 4% group, 87/97 (89.7%) of patients responded to treatment compared to 74/94 (78.7%) in the placebo group.

Level of pain was assessed as a secondary endpoint:

Table 1: Reduction in pain at rest (EVA 100 mm)

	Diclofenac (n=97)	Placebo (n=94)	p
At baseline	39.3 ± 19	36.9 ± 20.1	NS
D3-D4	12.4 ± 14.6	20.2 ± 18.2	0.0006
D7-D8	5.9 ± 9.9	10.5 ± 13.3	0.01
D10-D11	2.7± 6.7	5.5 ± 8.2	0.0009
D13-D15	1.2 ± 5.1	2.4± 4.3	0.0007

MIKA PHARMA DICLOFENAC 4% was superior to placebo in reducing pain at rest (secondary endpoint).

3.2. Adverse events

The total incidence of undesirable effects was similar in both groups: 6/120 patients of the DICLOFENAC SODIQUE MIKA PHARMA 4% group compared to 8/116 patients of the placebo group experienced adverse events.

3.3. Conclusion

In a clinical study, DICLOFENAC SODIUM MIKA PHARMA 4%, administered in 4 to 5 pump strokes 3 times daily, was shown to be superior to placebo for response to treatment, defined as a reduction by more than 50% in swelling following treatment shorter than 10 days. In the DICLOFENAC SODIUM MIKA PHARMA 4% group, 87/97 (89.7%) of patients responded to treatment compared to 74/94 (78.7%) of patients in the placebo group.

The safety profile for this medicinal product was satisfactory in the clinical study.

4 TRANSPARENCY COMMITTEE CONCLUSIONS

4.1. Actual benefit

Post-traumatic “oedema” is benign in the absence of a subjacent lesion, in particular tendinous or ligamentary or bone lesion. It subsides spontaneously within a few days.
This medicinal product is intended for symptomatic treatment.

Public health benefit:

In light of the results of the clinical studies and taking into account the available alternatives, it is not expected that the medicinal product DICLOFENAC SODIUM MIKA PHARMA 4% will benefit public health.

The efficacy/safety ratio is intermediate.
This medicinal product is intended for first-line therapy.
There are treatment alternatives.
The actual benefit of DICLOFENAC SODIUM MIKA PHARMA 4% is moderate.

4.2. Improvement in actual benefit

The medicinal product DICLOFENAC SODIUM MIKA PHARMA 4% does not provide an improvement in actual benefit (IAB V) compared to other topical NSAIDs.

4.3. Therapeutic use

Topical NSAIDs may be used to reduce oedema and pain. They constitute a possible complementary treatment to application of cold packs and an alternative to general medical treatments.

4.4. Target population

In the absence of French epidemiological data, it is not possible to determine the target population of DICLOFENAC SODIUM MIKA PHARMA 4% in the Marketing Authorisation indication.

4.5. Transparency Committee Recommendations

The Transparency Committee recommends inclusion on the list of medicines reimbursed by National Insurance and on the list of medicines approved for use by hospitals and various public services in the indications and dosages of the Marketing Authorisation.

4.5.1 Packaging: Appropriate for the prescription conditions

4.5.2 Reimbursement rate: 35%