Summary of Product Characteristics (SPC)

1. Name of the medicinal product

Olfen™ 140 mg Patch

2. Qualitative and quantitative composition

1 patch contains 140 mg diclofenac sodium per 14 g

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Transdermal Patch

Tissue with gel 14 g.

4. Clinical particulars:

4.1 Therapeutic Indications:

For topical treatment of traumatically-induced inflammation of the tendons, ligaments, muscles and joints as a result of sprains, dislocations, contusions and strains.

4.2 Posology/Administration

Adults

1 self-adhesive patch is applied to the area to be treated twice daily, morning and evening.

Before use, remove the transparent film that protects the gelatinous surface.

The duration of treatment depends on the severity of the symptoms, but must not be longer than 14 days. Olfen™ Patch may be used as adjunctive therapy together with an oral non-steroidal anti-inflammatory drug.

Children

The use and safety of Olfen™ Patch in children have not yet been systematically tested.

4.3 Contraindicationolfen

Individual, confirmed hypersensitivity to diclofenac, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (see under “Undesirable effects”), or to any of the component excipients

4.4 Special Warnings and precautions for use

Olfen™ Patch must not be used on open wounds (abrasions, lacerations, burns) or on pathologically altered skin surfaces (e.g. on eczematous, erythematous skin, etc.). Olfen™ Patch must not come into contact with the eyes and mucous membranes.

4.5 Interactions with other medicinal products and other forms of interaction

None known to date.

4.6 Fertility, Pregnancy and lactation

Pregnancy

1st and 2nd trimesters: Reproduction studies in animals have not shown any risks to the foetus, but no controlled studies are available in pregnant women.
Caution is advised with use in the 1st and 2nd trimesters.
3rd trimester: Olfen™ Patch should not be used due to possible premature closure of the ductus arteriosus and possible tocolysis.

Lactation

Since non-steroidal anti-inflammatory drugs are excreted in breast milk, Olfen™ Patch, as a precaution, should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

No specific study has been carried out with Olfen™ Patch on the ability to drive and use machines. A negative effect is unlikely.

4.8 Undesirable effects

Topical reactions

Uncommon: itching, redness, burning skin, rashes and, rarely, photosensitisation reactions occur.

Systemic reactions
Hypersensitivity reactions (e.g. asthma, angioedema, urticaria) in patients with intolerance to acetylsalicylic acid or additives. Particularly prone are patients with (intrinsic) asthma or chronic urticaria.

If Olfen™ Patch is used to treat larger areas over prolonged periods, the onset of adverse systemic effects cannot be completely excluded.

-To reports any side effect(s):

- ***Saudi Arabia:***

- The National Pharmacovigilance and Drug Safety Centre (NPC)
o Fax: +966-11-205-7662
o Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
o Toll free phone: 8002490000
o E-mail: npc.drug@sfda.gov.sa
o Website: www.sfda.gov.sa/npc

4.9 Overdose

To date, when properly used, there have been no known cases of overdose.
If significant systemic adverse effects should occur through improper use or accidental overdose of Olfen™ Patch (e.g. children), precautions as for intoxication with non-steroidal anti-inflammatory drugs should be taken.

5.0 Pharmacological properties:

5.1 Pharmacodynamic properties

ATC code: M02AA15
Pharmacotherapeutic group: Antiinflammatory preparations, non-steroids for topical use.

Mechanism of action

Olfen™ Patch contains diclofenac as the active substance, a derivative of phenylacetic acid with anti-inflammatory and analgesic properties, belonging to the class of non-steroidal anti-inflammatory drugs.

The inhibition of prostaglandin biosynthesis, demonstrated experimentally, is regarded as significant in terms of the mechanism of action. Prostaglandins play a considerable role in the development of inflammation, pain and fever.

Pharmacodynamics

Studies have shown that upon topical application, diclofenac passes through the skin into the underlying tissues and attenuates acute and chronic inflammatory reactions.

Clinical efficacy

The efficacy of Olfen™ Patch has been demonstrated in a blinded, placebo-controlled study in patients with acute sports injuries.

Olfen™ Patch was significantly superior to placebo with regard to the regression of pain.

5.2 Pharmacokinetic properties

Absorption

After topical application of Olfen™ Patch, the active substance is absorbed through the skin. The plasma concentrations of diclofenac at steady state are characterised by continuous uptake of diclofenac from the patch, irrespective of whether the patch is applied in the morning or evening. Mean plateau concentrations are approximately 3 ng/mL.

Metabolism/Elimination

The mechanism of metabolism and elimination kinetics of diclofenac after topical use correlate with those observed after oral administration.

5.3 Preclinical safety data

There are no available preclinical data of relevance to the application.

6.0 Pharmaceutical particulars

6.1 List of excipients

propylene glycol, antioxidants: sodium sulphite (E221), butylated hydroxytoluene (E321), aromatic agents, Macrogol lauryl ether, diisopropyl adipate, glycerol, sorbitol, sodium polyacrylate, carmellose sodium, basic butylated methacrylate copolymer, silica, colloidal anhydrous, natural light kaolin, disodium edetate, dried aluminium potassium sulphate and tartaric acid.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

After the pouch is first opened, the patches are to be used within 3 months.

6.4 Special precautions for storage

- Keep out of the sight and reach of children.
- Do not store above 30°C.
-Do not refrigerate or freeze.

6.5 Nature and contents of container

Olfen™ 140 mg Transdermal Patch

Packs of 2, 5 and 10 patches.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

Acino Pharma AG, Liesberg (Switzerland)

8.0 Marketing authorisation number

62770 (Swissmedic)

9. Date of first Authorisation/ renewal of the authorisation

26 July 2012

10. Date of revision of the text

June 2016