SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DYMOL®, Diclofenac sodium and Paracetamol Tablets 50 mg / 500 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diclofenac sodium ..... 50 mg
Paracetamol ……...500mg
For one tablet.

Excipient:
Excipient with notorious effects are Methyl and Propyl Hydroxybenzoate.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Due to its anti-inflammatory and analgesic effects, DYMOL is indicated for the treatment of:

- Rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylosis, intervertebral disc syndrome, and sciatica.
- Non-articular rheumatic conditions such as fibrositis, myositis, bursitis, low back pain etc.
- Soft tissue injuries such as sprains, strains, and sports injuries.
- Painful inflammatory conditions in gynaecology.
- Post-operative and post-traumatic inflammation and swelling.
- Pain and inflammation following surgery.
- Acute attacks of gout.

4.2. Posology and method of administration

Method of administration
Oral use.
The tablet should be taken with or after meals.

Posology
The initial daily dose for adults is 1 tablet two or three times a day. For long-term therapy, one tablet twice a day should be sufficient (see section 4.4).

4.3. Contraindications

- Hypersensitivity to diclofenac sodium or paracetamol.
- Peptic ulceration or history of peptic ulcers.
- In asthmatic patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetyl salicylic acid or by other drugs with prostaglandin synthetase inhibiting activity.

4.4. Special warnings and precautions for use

DYMOL contains diclofenac sodium and paracetamol. The precautions to be taken with both these drugs individually should also apply to this combination, such as:

- Close medical surveillance is required in patients with symptoms indicative of Gastrointestinal disease, a history of dyspepsia, Crohn's disease, active colitis, etc. and in patients with blood coagulation disorders, and those with severe cardiac, hepatic or renal disease.
- Caution should be exercised in elderly patients, who are generally more likely to experience side-effects.
- In patients receiving long term treatment, it is advisable to check blood counts at intervals and monitor hepatic and renal function.
- When given along with oral anti-coagulants or oral antidiabetics, as a precaution, the dosage of these drugs should be carefully adjusted in accordance with prothrombin time and blood glucose levels respectively.

4.5. Interaction with other medicinal products and other forms of interaction

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. As with other NSAIDs, caution should be exercised in patients receiving oral anticoagulants, heparin via parenteral route and ticlopidine, thiazide diuretics, moclobemide, lithium, sulphonamide hypoglycemiant, methotrexate, pentoxifylline, zidovudine and baclofen. Take into account interactions with antihypertensives (beta-blockers, conversion enzyme inhibitors, and diuretics), digoxin, and thrombrolytics.

4.6. Pregnancy and lactation

Paracetamol crosses the placental barrier and is excreted in breast milk.
Diclofenac appears in the breast milk in very low concentrations and is likely to affect the breast-fed infant adversely. Whilst, human and animal studies have not identified any risk to pregnancy or embryofoetal development, the use of DYMOL during pregnancy should, if possible, be avoided.
Human studies have not identified any risk to lactation or the breast-fed offspring.

4.7. Effects on ability to drive and use machines

No significant effect.

4.8. Undesirable effects

At recommended doses DYMOL is generally well tolerated. At the start of treatment, however, patients may sometimes complain of epigastric pain, nausea, diarrhoea, dizziness or headache. These unwanted effects are normally of a mild nature. Peripheral oedema and skin reactions such as drug rash, urticaria, and eczema, have also been reported.
The following side-effects have seldom been reported with DYMOL, although there are reported cases:

- CNS side-effects, such as tiredness, insomnia, and irritability.
- Gastrointestinal effects such as ulceration and haemorrhage, hypersensitivity reactions such as bronchospasm, elevated transaminase levels, hepatitis, renal failure and nephrotic syndrome; isolated cases of leucopenia, and thrombocytopenia have also been observed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Diclofenac is a potent anti-inflammatory with analgesic and antipyretic action. Its analgesic and antipyretic effects are further reinforced by paracetamol. The mode of action can best be understood by looking at each active constituent of DYMOL separately.
Diclofenac sodium: It is an NSAID which has been demonstrated to inhibit prostaglandin biosynthesis, thus exerting a pronounced anti-inflammatory, analgesic and antipyretic action.

Paracetamol: The analgesic and antipyretic actions of paracetamol are similar to those of the salicylates. Analgesia is mediated peripherally and also centrally whereas antipyresis is produced by a central action on the hypothalamic regulatory centre.

5.2. Pharmacokinetic properties

Absorption

Diclofenac sodium is well absorbed after oral administration, and peak concentrations are usually attained after 1-4 hours. Absorption occurs more rapidly when ingested on an empty stomach than when administered after a meal.
Paracetamol is rapidly and almost completely absorbed from the Gastrointestinal tract.
Both diclofenac sodium and paracetamol in DYMOL tablets are well absorbed from the Gastrointestinal tract.

Distribution
Plasma concentrations show a linear relationship with the size of the dose. Doses are maintained at higher levels in the synovial fluid rather than in plasma.
However, paracetamol achieves peak plasma concentration much faster than diclofenac sodium, as the latter is enteric coated. This ensures rapid action and at the same time minimises the chances of gastric irritation.

Metabolism
A large proportion of diclofenac sodium is metabolised in the liver and about 30% of the ingested dose undergoes first pass metabolism.
The complete ingested dose is extensively metabolised in the liver and excreted in the urine as inactive metabolites.
DYMOL is metabolised in the liver and excreted mainly in the urine.

Excretion
Approximately 60% of the dose is excreted through the kidney and the remainder in the faeces, in the form of metabolites. Less than 1% is excreted via the kidneys in an unchanged form.
The plasma half-life to the terminal elimination phase is about 1-2 hours. More than 99% is protein bound.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize Starch, Anhydrous Calcium hydrogen Phosphate, Microcrystalline Cellulose, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Povidone (K-30), Cellulose Acetate Phthalate (Cellacefate), Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica, Sodium Starch Glycolate, Croscarmellose Sodium, Opadry Orange OY-5628.

- Excipient with notorious effects are Methyl and Propyl Hydroxybenzoate.
May cause allergic reactions (possibly delayed).

6.2. Shelf Life

36 months.

6.3. Special precautions for storage

Store in a dry place below 30°C.

6.4. Nature and contents of container

Primary packing:

10 Tablets are packed in blisters using printed Aluminium foil and PVC transparent clear film.

Secondary packing:

One such blister is placed in a carton along with a leaflet.

Pack size: 10 tablets (1x10s)

7. NAME AND ADDRESS OF MANUFACTURER

M/S. MEDREICH LIMITED

Survey No: 4/3, Avalahalli, Anjanapura Post,
Off Kanakapura Road, Bangalore - 560 062, INDIA.
For Sanofi

9. CONDITIONS FOR PRESCRIPTION AND RELEASE

List II

Sale on medical prescription ☒ Sale without medical prescription ☐

10. DATE OF REVISION OF THE TEXT

August 2018