SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Olfen-50 *Lactab*
Olfen-100 SR *Depocaps*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Olfen-50 Lactab contains:
Diclofenac sodium: 50 mg

Each Olfen-100 SR Depocaps contains:
Diclofenac sodium: 100 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lactab: film-coated, gastro-resistant tablet.

Depocaps: gelatin capsules containing the active substance in pellets with controlled release.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Initial treatment of the following conditions:

- exacerbation of inflammatory or degenerative forms of rheumatism (rheumatoid arthritis, ankylosing spondylitis, arthrosis, spondylarthrosis, painful vertebral syndromes, extraarticular rheumatism);
- acute attack of gout;
- renal and biliary colic;
- pain, inflammations and swelling after injuries and surgical interventions;
- painful and/or inflammatory conditions in gynaecology;
- as an adjuvant in cases of acute painful inflammatory infections of the throat, the nose or the ears.

4.2 Posology and method of administration

Posology

Adverse reactions may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).

Adults
The initial daily dose is usually 100 – 150 mg. In less severe cases and for long-term therapy, 75 – 100 mg per day are in most cases sufficient.
In general, the daily dose is divided into 2 - 3 individual administrations, in the case of long-term treatment, for example, 2 × per day 1 Olfen-50 *Lactab* or 1 × per day 1 Olfen-100 SR *Depocaps*.

For primary dysmenorrhoea, the daily dose, adapted individually, is generally 50 - 150 mg; the initial dose should be selected to be 50 - 100 mg and is, if required, to be increased over a number of menstruation cycles to a maximum of 200 mg/day. Therapy should be initiated when the first symptoms occur and should continue for a number of days, depending on the symptoms.

Paediatric population
Because of the high content of active ingredient Olfen *Lactab* 50 mg and Olfen *Depocaps* 100 mg are not recommended for use in children.

Method of administration

To be taken before a meal, without chewing and with a glass of water.

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Active gastric or intestinal ulcer, bleeding or perforation.
- History of gastrointestinal bleeding or perforation, related to previous non-steroidal anti-inflammatory drugs (NSAIDs) therapy. Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- Last trimester of pregnancy (see section 4.6).
- Severe hepatic, renal or cardiac failure (see section 4.4).
- Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Like other NSAIDs, Olfen is contraindicated in patients in whom asthma attacks, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.

4.4 Special warnings and precautions for use

General

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.2 and GI and cardiovascular risks below).

The concomitant use of diclofenac with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects.

Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose is used in frail elderly patients or those with a low body weight.

As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rare cases with diclofenac without earlier exposure to the drug.

Like other NSAIDs, diclofenac may mask the signs and symptoms of infection due to its pharmacodynamic properties.

Gastrointestinal effects:

Gastrointestinal bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs, including diclofenac, and may occur at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving diclofenac, the medicinal product should be withdrawn.

As with all NSAIDs, including diclofenac, close medical surveillance is imperative and particular caution should be exercised when prescribing diclofenac in patients with symptoms indicative of gastrointestinal (GI) disorders or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation (see section 4.8). The risk of GI bleeding is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation. The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose.

Combination therapy with protective agents (e.g. proton pump inhibitors or misoprostol) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low-dose acetylsalicylic acid (ASA) or other medicinal products likely to increase gastrointestinal risk.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding). Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, anti-platelet agents or selective serotonin-reuptake inhibitors (see section 4.5).

Close medical surveillance and caution should also be exercised in patients with ulcerative colitis or Crohn's disease, as their condition may be exacerbated (see 4.8).

Hepatic effects:

Close medical surveillance is required when prescribing diclofenac to patients with impaired hepatic function, as their condition may be exacerbated.

As with other NSAIDs, including diclofenac, values of one or more liver enzymes may increase. During prolonged treatment with diclofenac, regular monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if

clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash), diclofenac should be discontinued. Hepatitis may occur with use of diclofenac without prodromal symptoms.

Caution is called for when using diclofenac in patients with hepatic porphyria, since it may trigger an attack.

Renal effects:

As fluid retention and oedema have been reported in association with NSAID therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion from any cause, e.g. before or after major surgery (see section 4.3). Monitoring of renal function is recommended as a precautionary measure when using diclofenac in such cases. Discontinuation of therapy is usually followed by recovery to the pre-treatment state.

Skin effects:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see section 4.8). Patients appear to be at highest risk for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Diclofenac should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity.

Cardiovascular and cerebrovascular effects

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data consistently point towards an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) associated with the use of diclofenac, particularly at high dose (150 mg daily) and in long term treatment (see section 4.3 and section 4.8).

Patients with uncontrolled hypertension, congestive heart failure, established ischemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with diclofenac after careful consideration. The same consideration should be made before initiating treatment of patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).

As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Haematological effects:

Use of diclofenac tablets/capsules is recommended only for short term treatment. During prolonged treatment with diclofenac, as with other NSAIDs, monitoring of the blood count is recommended.

Like other NSAIDs, diclofenac may temporarily inhibit platelet aggregation. Patients with defects of haemostasis should be carefully monitored

Pre-existing asthma:

In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

Excipients:
Olfen-100 SR *Depocaps* contain lactose and therefore are not recommended for patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

4.5 Interaction with other medicinal products and other forms of interaction

The following interactions include those observed with Olfen gastro-resistant tablets and/or other pharmaceutical forms of diclofenac.

Lithium: If used concomitantly, diclofenac may raise plasma concentrations of lithium. Monitoring of the serum lithium level is recommended.

Digoxin: If used concomitantly, diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive agents
Like other NSAIDs, concomitant use of diclofenac with diuretics or antihypertensive agents (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors) may cause a decrease in their antihypertensive effect. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity. Concomitant treatment with potassium-sparing drugs may be associated with increased serum potassium levels, which should therefore be monitored frequently (see section 4.4).

Other non-steroidal anti-inflammatory drug (NSAIDs) and corticosteroids
Concomitant administration of diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal undesirable effects (see section 4.4).

Anticoagulants and anti-platelet agents
Caution is recommended since concomitant administration could increase the risk of bleeding (see section 4.4). Although clinical investigations do not appear to indicate that diclofenac affects the action of anticoagulants, there are reports of an increased risk of haemorrhage in patients receiving diclofenac and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.

Selective serotonin reuptake inhibitors (SSRIs)
Concomitant administration of systemic NSAIDs, including diclofenac, and SSRIs may increase the risk of gastrointestinal bleeding (see section 4.4).

Antidiabetic agents
Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of the antidiabetic agents during treatment with diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

Methotrexate
Diclofenac can inhibit the tubular renal clearance of methotrexate hereby increasing methotrexate levels. Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.

Ciclosporin
Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving ciclosporin.

Quinolone antibacterials
There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

Phenytoin
When using phenytoin concomitantly with diclofenac, monitoring of phenytoin plasma concentrations is recommended due to an expected increase in exposure to phenytoin.

Colestipol and cholestyramine
These agents can induce a delay or decrease in absorption of diclofenac. Therefore, it is recommended to administer diclofenac at least one hour before or 4 to 6 hours after administration of colestipol/ cholestyramine.

Potent CYP2C9 inhibitors
Caution is recommended when co-prescribing diclofenac with potent CYP2C9 inhibitors (such as sulfinpyrazone and voriconazole), which could result in a significant increase in peak plasma concentration and exposure to diclofenac due to inhibition of diclofenac metabolism.

4.6 Fertility, pregnancy and lactation

Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%.

The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality.

In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

the mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses;
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Breast-feeding
Like other NSAIDs, diclofenac passes into the breast milk in small amounts. Therefore, diclofenac should not be administered during breastfeeding in order to avoid undesirable effects in the infant.

Fertility
As with other NSAIDs, the use of diclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of diclofenac should be considered.

4.7 Effects on ability to drive and use machines

Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac, should refrain from driving or using machines.

4.8 Undesirable effects

Adverse reactions (see table below) are ranked under heading of frequency, the most frequent first, using the following convention: very common: (>1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000); very rare (<1/10,000); Not known: cannot be estimated from the available data.

The following undesirable effects include those reported with either short-term or long-term use.

Table 1

Frequency	Adverse reactions
Blood and lymphatic system disorders	
Very rare	Thrombocytopenia, leukopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis.
Immune system disorders	
Rare	Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock).
Very rare	Angioneurotic oedema (including face oedema).
Psychiatric disorders	
Very rare	Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.
Nervous system disorders	
Common	Headache, dizziness.
Rare	Somnolence.
Very rare	Paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident.
Eye disorders	
Very rare	Visual disturbance, blurred vision, diplopia.
Ear and labyrinth disorders	
Common	Vertigo.
Very rare	Tinnitus, hearing impaired.
Cardiac disorders	
Very rare	Palpitations, chest pain, cardiac failure, myocardial infarction.
Vascular disorders	
Very rare	Hypertension, vasculitis.
Respiratory, thoracic and mediastinal disorders	
Rare	Asthma (including dyspnoea).
Very rare	Pneumonitis.
Gastrointestinal disorders	
Common	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia.

Rare	Gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer (with or without bleeding or perforation).
Very rare	Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis (including ulcerative stomatitis), glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis.
Not known	Ischaemic colitis
Hepato-biliary disorders	
Common	Transaminases increased.
Rare	Hepatitis, jaundice, liver disorder.
Very rare	Fulminant hepatitis, hepatic necrosis, hepatic failure.
Skin and subcutaneous tissue disorders	
Common	Rash.
Rare	Urticaria.
Very rare	Bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus.
Renal and urinary disorders	
Very rare	Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.
General disorders and administration site conditions	
Rare	Oedema.

Clinical trial and epidemiological data consistently point towards an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) associated with the use of diclofenac, particularly at high dose (150 mg daily) and in long term treatment (see section 4.3 “Contraindications” and section 4.4 “Special warnings and precautions for use”).

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

Symptoms
There is no typical clinical picture resulting from diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal haemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

Therapeutic measures
Management of acute poisoning with NSAIDs, including diclofenac, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

Special measures such as forced diuresis, dialysis or haemo-perfusion are probably of no help in eliminating NSAIDs, including diclofenac, due to the high protein binding and extensive metabolism.

Activated charcoal may be considered after ingestion of a potentially toxic overdose, and gastric decontamination (e.g. vomiting, gastric lavage) after ingestion of a potentially life threatening overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic product, non-steroid
ATC-Code: M01A B05

Olfen contains the sodium salt of diclofenac, a nonsteroidal active substance having pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic properties. Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is thought to be important for the mechanism of action. Prostaglandins play an essential role in the development of inflammation, pain and fever.

The anti-inflammatory and analgesic properties become clinically evident in the case of rheumatic disorders in that the symptoms, such as pain at rest, pain on motion, morning stiffness, swelling of the joints, are significantly improved and functional ability increases. In post-traumatic/post-operative inflammations, Olfen causes a rapid reduction in spontaneous pain and pain on motion and reduces inflammatory swelling and wound oedema.

Also for moderate and severe pain of non-rheumatic type the pronounced analgesic effect was demonstrated in clinical trials. In cases of primary dysmenorrhoea, Olfen can alleviate pain and reduce the extent of bleeding.

Olfen *Lactab* are coated with an enteric protective coating.

The *Depocaps* are suitable for patients for whom the daily dose of 100 mg is appropriate to treat the symptoms. From the *Depocaps*, the active ingredient is released over a relatively

long period of time, ensuring sustained action. The administration once per day makes particularly long-term treatment with Olfen simpler.

5.2 Pharmacokinetic properties

Absorption
After having passed the stomach, diclofenac is absorbed rapidly and completely from the *Lactab*, which is resistant to gastric juices.

On average, the mean plasma concentration of 0.92 mg/l (Cmax) is reached 2.6 hours (tmax) after a 50 mg *Lactab* has been taken. The relation of the plasma concentration to the dose is linear.

When a *Lactab* is taken during or after a meal, passage through the stomach is slower than in the case of administration on an empty stomach, and may take from 2.5 to 12 hours. However, this does not negatively affect the amount of active ingredient absorbed.

From *Depocaps* diclofenac is absorbed completely. As a consequence of the delayed release of active ingredient, the maximum plasma concentrations reached are lower than those after administration of conventional administration forms. On the other hand, measurable concentrations can be detected even after several hours. When a *Depocaps* is taken during or after a meal, absorption sets in later than when the *Depocaps* is administered on an empty stomach. However, this does not negatively affect the amount of active ingredient absorbed. After a 100 mg *Depocaps* has been taken, the mean maximum plasma concentration of 0.43 µg/ml (1.35 µmol/l) is reached on average after about 3.5 hours.

Distribution
The mean distribution volume of diclofenac is 0.12 - 0.17 l/kg. Plasma protein binding is more than 99%.

The therapeutic plasma concentration is 0.7 - 2 µg/ml.

After administration of equivalent doses (mg/kg body weight), the plasma concentrations in children are similar to those of adults.

Repeated administration does not change the kinetics. There is no accumulation if the recommended dosage intervals are adhered to.

Diclofenac passes into the synovial fluid, where maximum concentrations are measured 2 – 4 hours after peak plasma values have been obtained. The apparent elimination half-life from the synovial fluid is 3 – 6 hours. As a consequence, even 4 – 6 hours after administration, the concentrations of active ingredient are higher than in the plasma, and they remain higher for up to 12 hours.

Metabolism
About half of the active ingredient is subject to first-pass metabolism. As a result, the areas under the concentration curves (AUC) are, after oral administration, about half of those after parenteral administration of a dose of the same amount.

After oral administration, only 60% of the substance reaches the circulation in unmodified form. Biotransformation is partly by glucuronidation of the intact molecule, but mainly by hydroxylation and methoxylation. Two of the phenolic metabolites formed are pharmacologically active, but less so than diclofenac.

Elimination
Diclofenac is eliminated from the plasma with a systemic clearance of 263 ± 56 ml/min (mean ± SD). The terminal half-life is 1 – 2 hours. Approximately 60% of the administered dose is eliminated via the kidneys in the form of metabolites, and less than 1% in unchanged form. The remainder of the dose is eliminated via the bile in metabolised form.

Kinetics in special clinical situations
Relevant differences in absorption, metabolism and elimination owing to the age of the patients have not been observed.

In the case of patients suffering from impaired kidney function, an increase of the unmodified active substance was not observed when a normal individual dose was administered. If creatinine clearance is less than 10 ml/min, the theoretical steady-state plasma level of the metabolites is approximately four times higher than in healthy people. In spite of this, the metabolites are ultimately eliminated via the bile.

In case of impaired liver function (chronic hepatitis, compensated cirrhosis of the liver), kinetics and metabolism are as in patients with normal hepatic function. The maximum plasma concentration after administration of Depocaps is within the range of an individual dose of 25 mg, but is more sustained, corresponding to the higher content of active ingredient of the Depocaps.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Olfen®-50 *Lactab*®

Core:
Sodium starch glycolate
Microcrystalline cellulose
Sodium stearyl fumarate
Colloidal anhydrous silica
Talc
Hypromellose

Gastric-resistant coating:
Eudragit L 30 D-55

Triethyl citrate
Talc

Colour coating:
Hypromellose
Titanium dioxide E171
Talc
Quinoline yellow E104
Iron oxide yellow E172
Macrogol 6000

Olfen®-100 SR *Depocaps*®

Core:
Lactose monohydrate
Microcrystalline cellulose
Microcrystalline cellulose and carmellose sodium
Glycerin trimyristate
Titanium dioxide E171
Eudragit RS 30 D
Triethyl citrate
Silica colloidal hydrated

Capsule shell:
Gelatin
Titanium dioxide E171
Iron oxide black E 172
Iron oxide red E 172
Erythrosine E127

6.2 Incompatibilities

Not applicable

6.3 Shelf life

- Olfen®-50 *Lactab*®
5 years

- Olfen®-100 SR *Depocaps*®
5 years

6.4 Special precautions for storage

Store dry below 25°C.

6.5 Nature and contents of container

- Olfen®-50 *Lactab*®

The *Lactab* are packed into blister strips of PVDC/Aluminium foils.
Packings of 20 *Lactab*
Hospital packings

- Olfen®-100 SR *Depocaps*®

The *Depocaps* are packed into blister strips of PVDC/Aluminium foils.
Packings of 10 and 20 *Depocaps*
Hospital packings

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MEPHA Lda
Lagoas Park
2740-298 Porto Salvo
Portugal

8. MARKETING AUTHORISATION NUMBER(S)

MA092/00103 Olfen-50 Coated Tablets
MA092/00107 Olfen-100 SR Depocaps Capsule

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th August 2006

10. DATE OF REVISION OF THE TEXT

3rd August 2016