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## Patient Information Leaflet

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### Olfen™ - 25 / 50 Lactab™ Diclofenac sodium

#### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

#### In this leaflet

1. Serious side effects
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#### 1. Serious side effects

##### Cardiovascular risk:

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction and stroke, which can be fatal. This risk may increase with the duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (FDA, 2005);
- Diclofenac is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery (FDA, 2005);
- Gastrointestinal risk:
  - NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding ulceration and perforation of the stomach and intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (FDA, 2005).

#### 2. What Olfen is and what it is used for

Olfen is a non-steroidal anti-inflammatory drug with an inflammation-reducing and pain-relieving effect.

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Taking Olfen can relieve the symptoms of inflammation such as pain and swelling by blocking the synthesis of molecules (prostaglandins) responsible for inflammation, pain and fever. However, it cannot cure the causes.

Olfen is used on a doctor's prescription for the treatment of rheumatic diseases such as osteoarthritis, inflammation and pain in gout attacks, painful conditions of the back and neck vertebrae, soft-tissue rheumatism, inflammation and pain after injuries (e.g. sprains, strains) and surgical procedures (e.g. dental and orthopaedic), pain and inflammation in gynaecological conditions, as supplementary treatment in various painful acute infectious diseases, especially in the ear, nose and throat area.

Olfen should not be used exclusively for the reduction of fever.

If you have heart disease or significant risks for heart disease, your doctor will review the continuation of treatment with Olfen at regular intervals, particularly if the treatment lasts longer than 4 weeks.

### **3. Before you take Olfen**

#### **a. Do not take Olfen if:**

- you are allergic to any of the ingredients or if you have ever had shortness of breath or allergy-like skin reactions after taking acetylsalicylic acid or other painkillers or antirheumatic agents known as non-steroidal anti-inflammatory drugs; during the last trimester of pregnancy;
- you have active ulcers of the stomach and/or small intestine (duodenal ulcers) or gastrointestinal bleeding or perforation, or if you have symptoms such as blood in your stools or black stools;
- you have inflammatory bowel disease (Crohn's disease, ulcerative colitis);
- your liver or kidney function is severely impaired;
- you have severe heart failure;
- for the treatment of pain after coronary artery bypass surgery on the heart (or use of a heart-lung machine).

If any of these situations applies to you, tell your doctor and do not use Olfen. Your doctor will decide whether this medicine is suitable for you.

Due to their high active substance content, 50 mg film-coated tablets are not recommended for use in children under 14 years of age.

If you think you may be allergic, ask your doctor for advice.

#### **b. Take special care with Olfen**

During treatment with Olfen, mucous-membrane ulcers, rarely bleeding or, in isolated cases, perforations (of the stomach or bowel) may occur in the gastrointestinal tract. These complications can occur at any time during treatment, even without warning symptoms. To reduce this risk, your doctor will prescribe you the lowest effective dose for the shortest possible duration of treatment. Consult your doctor if you have stomach pain and suspect a connection with taking/using this medicine.

Caution is required if you have cardiovascular disease (including uncontrolled high blood pressure, heart failure, existing ischaemic heart disease or peripheral arterial disease), because treatment with Olfen is not usually recommended.

If you have cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high blood fat levels (cholesterol, triglycerides) or diabetes, or if you smoke, and your doctor decides to prescribe Olfen for you, you must not increase the dose to more than 100 mg per day if you are being treated for longer than 4 weeks.

Generally speaking, it is important to use the lowest Olfen dose which alleviates your pain and/or swelling for the shortest possible duration in order to minimise the risks of cardiovascular side effects.

For certain painkillers known as COX-2 inhibitors, an increased risk of heart attack and stroke has been found at high dosages and/or on long-term treatment. It is not yet known whether this increased risk also applies to Olfen. If you have already had a heart attack, stroke or venous thrombosis, or if you have risk factors such as high blood pressure, diabetes, high blood fats or smoking, your doctor will decide whether you can still use Olfen. Always let your doctor know about this.

Taking Olfen can affect the function of your kidneys, and this can lead to an increase in blood pressure and/or fluid accumulation (oedema). Tell your doctor if you have heart or kidney disease, if you are taking medicines for high blood pressure (e.g. water tablets, ACE inhibitors) or have increased fluid loss, e.g. through heavy sweating.

In very rare cases, anti-inflammatory drugs (including Olfen) may trigger serious skin reactions (e.g. skin rash). At the first signs of a skin reaction, treatment with Olfen must be discontinued and a doctor informed.

### **c. Taking other medicines, herbal or dietary supplements**

Furthermore, particular caution is required if you are taking Olfen together with other anti-inflammatory medicines (such as acetylsalicylic acid/aspirin, corticosteroids), "blood thinners" or selective serotonin re-uptake inhibitors (SSRIs, antidepressants), if you have asthma, hay fever (seasonal allergic rhinitis), liver or kidney problems, blood clotting disorders or other problems with your blood, including a rare liver problem known as porphyria.

If any of these situations applies to you, tell your doctor before taking/using Olfen.

If you notice any signs or symptoms of difficulties with your heart or blood vessels, such as chest pain, shortness of breath, weakness or slurred speech, while you are using Olfen, contact your doctor without delay.

Tell your doctor or pharmacist if you suffer from other illnesses, have any allergies or are taking or externally using any other medicines (including those purchased without a prescription), especially if you are taking the following medicines: lithium or serotonin reuptake inhibitors (SSRIs) (used to treat depression), digoxin (for heart problems), diuretics (to increase urine output), ACE inhibitors or beta-blockers (for high blood pressure and heart problems), other anti-inflammatory agents such as acetylsalicylic acid or ibuprofen, corticosteroids, medicines to prevent blood clotting (anticoagulants), medicines used to treat diabetes (except insulin), methotrexate (for arthritis and cancer), ciclosporin or tacrolimus (in organ transplants), trimethoprim (for urinary tract infections), quinolone antibiotics (medicines used for infections), voriconazole (a medicine used to treat fungal infections) or phenytoin (a medicine used to treat epileptic seizures).

Olfen may reduce the signs of infection (e.g. headache, high body temperature) and thus make it difficult to detect and appropriately treat the infection.

In very rare cases, Olfen, like other anti-inflammatory medicines, may cause severe allergic reactions (e.g. skin rash). For this reason, tell your doctor immediately if you experience such a reaction.

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If you take Olfen for a prolonged time (more than 2-3 weeks), you should not miss the regular check-ups arranged by your doctor.

Caution is advised in elderly patients. They may be more sensitive to the effect of Olfen. Consequently, they should use the lowest effective dose as a precaution.

#### **d. Pregnancy, breast-feeding & fertility**

##### *Pregnancy*

If you are pregnant or planning a pregnancy, you should take diclofenac only after consultation with your doctor. Olfen must not be taken in the last trimester of pregnancy.

##### *Breast-feeding*

Olfen should not be taken during breast-feeding, unless specifically permitted by your doctor.

#### **e. Driving and using machines**

This medicine may affect your reactions and your ability to drive or to use tools or machines. In particular, if dizziness, visual disturbances or other central nervous system disorders occur, you should refrain from driving motor vehicles or using machines and consult your doctor immediately.

#### **4. How to take Olfen**

Dosage and administration are determined individually by the doctor, depending on the indication for use, age and severity of the symptoms; these instructions must be followed carefully. Do not exceed the recommended daily dose and treatment duration prescribed by your doctor.

If you use Olfen for longer than a few weeks, you should visit your doctor for regular check-ups to make sure that you do not have any unnoticed side effects.

*Adults:* At the start of treatment, the daily dose is generally 100-150 mg. In relatively mild cases and for long-term treatment, 75-100 mg per day is usually sufficient. Normally, the daily dose is spread over 2-3 divided doses. Do not take more than the maximum daily dose of 150 mg.

In order to avoid night pain and/or morning stiffness, one 100 mg Olfen Rectocap can be administered at night and two 25 mg Olfen 25 Lactab film-coated tablets or one 50 mg Olfen 50 Lactab film-coated tablet during the day.

For *period pains*, start treatment with a single dose of 50-100 mg as soon as the first symptoms occur. If required, continue the treatment for a few days at 50 mg up to three times daily. The film-coated tablets should be taken with plenty of liquid, preferably before a meal. The film-coated tablets must not be chewed or divided.

Do not change the prescribed dosage yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

#### **5. Possible side effects**

The following side effects can occur when taking/using Olfen:

Common (> 1/100 and < 1/10): headache, light-headedness, dizziness, nausea, vomiting, diarrhoea, stomach discomfort, abdominal pain, bloating, decreased appetite, skin rash, fluid accumulation, swelling, increased blood pressure; change in liver function (e.g. increased liver enzyme levels in the blood).

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Uncommon (> 1/1000 and < 1/100 ), especially if a high daily dose (150 mg) is taken for a prolonged period of time: sudden vice-like chest pain (signs of heart muscle infarction and heart attack); shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure).

Rare (> 1/10,000 and < 1/1000): hypersensitivity reaction with swelling of the face, mouth, limbs (as far as a drop in blood pressure and shock), asthma, drowsiness, inflammation and ulcers of the gastrointestinal tract, vomiting of blood, bloody diarrhoea, impaired liver function, hepatitis, jaundice (very rarely liver failure), hives.

Very rare (< 1/10,000): changes in blood count, unusual bleeding, bruising, psychiatric problems (including insomnia, irritability), abnormal skin sensations, memory impairment, convulsions, anxiety, tremor, impaired taste, impaired vision, lazy eye, ringing in the ears, impaired hearing, stiff neck, heart problems, raised blood pressure, inflammation of the blood vessels, lung or colon, constipation, inflammation of the pancreas, mouth lining or tongue, eczema, itching, inflammatory reddening of the skin, hair loss, skin bleeding, acute kidney problems, blood in urine.

Tell your doctor if you experience any of these side effects.

If you notice any side effects not described here, you should tell your doctor or pharmacist.

## 6. How to store Olfen

Store in the original package.

Keep out of the sight and reach of children.

Do not store Olfen above 30° C.

Do not use Olfen after the expiry date which is stated on the blister and carton after "EXP".

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 7. Further information

### a. What Olfen contains

**Olfen - 25 / 50 Lactab**

*The active substance:*

One tablet contains 25 mg, 50 mg diclofenac sodium.

*The other ingredients are:* Sodium starch glycolate, Microcrystalline cellulose, Sodium stearyl fumarate, Colloidal anhydrous silica, Talc, Hypromellose, Methacrylic acid/ethyl acrylate copolymer, Triethyl citrate, Titanium dioxide, Quinoline yellow, Iron oxide yellow and Macrogol 6000.

### b. What Olfen looks like and the contents of the pack

**Olfen - 25 Lactab**

Ochre yellow, biconvex, film coated tablet, embossed "mp" on the one side and "O 25" on the other.

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Packs: 10 and 30 tablets; hospital packs.  
The tablets are packed in PVC/PVDC - Aluminium blisters.  
Not all pack sizes may be marketed.

**Olfen - 50 Lactab**

Ochre yellow, biconvex, film coated tablet, embossed “mp” on the one side and “O 50” on the other.

Packs: 10 and 20 tablets; hospital packs.  
The tablets are packed in PVC/PVDC - Aluminium blisters.  
Not all pack sizes may be marketed.

**c. Marketing Authorisation Holder and Manufacturer**

Manufactured by Acino Pharma AG, Aesch, Switzerland for Acino Pharma AG, Liesberg, Switzerland.

**d. This leaflet was last approved in October 2014.**

**e. To report any side effects:**

The National Pharmacovigilance and Drug Safety Centre (NPC) <ul style="list-style-type: none"> <li>• Fax: +966-11-205-7662</li> <li>• Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.</li> <li>• Toll free phone: 8002490000</li> <li>• E-mail: npc.drug@sfga.gov.sa</li> <li>• Website: www.sfga.gov.sa/npc</li> </ul>
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By reporting side effects you can help provide more information on the safety of this medicine.

**f. Council of Arab Health Ministers**

<p><b>This is a Medicament</b></p> <ul style="list-style-type: none"> <li>• Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.</li> <li>• Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.</li> <li>• The doctor and the pharmacist are the experts in medicines, their benefits and risks.</li> <li>• Do not by yourself interrupt the period of treatment prescribed.</li> </ul>
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- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists