

**Patient Information**

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Keep this leaflet. You may need to read it again.

## Olfen™-100 SR, prolonged-release capsules

**What is Olfen™-100 SR and when is it used?**

Olfen™-100 SR is a non-steroidal anti-inflammatory drug with an inflammation-reducing and pain-relieving effect.

Taking Olfen™-100 SR 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™-100 SR is particularly suitable for adult patients for whose condition the daily dose of 100 mg is appropriate. The option of a single daily administration simplifies prolonged treatment in particular.

Olfen™-100 SR is used on a doctor's prescription for the treatment of rheumatic diseases such as osteoarthritis, soft-tissue rheumatism, painful inflammatory states, swelling in the back and in the region of joints, inflammation and pain after injuries and surgical procedures, painful inflammatory gynaecological conditions.

Olfen™-100 SR retard 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.

**When must Olfen™-100 SR not be used?**

Olfen™-100 SR must not be used:

- 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;
- if 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;
- if you have inflammatory bowel disease (Crohn's disease, ulcerative colitis);
- if your liver or kidney function is severely impaired;
- if 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)
- in children below 14 years.

If any of these situations applies to you, tell your doctor and do not take Olfen™-100 SR. Your doctor will decide whether this medicine is suitable for you.

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

**When is caution needed while taking Olfen™-100 SR?**

During treatment with Olfen™-100 SR, 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™-100 SR. 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™-100 SR. Always let your doctor know about this.

Taking Olfen™-100 SR 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.

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.

Furthermore, particular caution is required if you are taking Olfen™-100 SR 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 Olfen™-100 SR.

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 (e.g. metformin) 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), rifampicin (an antibiotic used to treat bacterial infections).

Olfen™-100 SR 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, severe allergic reactions (e.g. rash) may occur in patients treated with Olfen™-100 SR, as with other anti-inflammatory medicines. For this reason, tell your doctor immediately if you experience such a reaction.

If you take Olfen™-100 SR 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, especially when frail or those with a low body weight. They may be more sensitive to the effect of Olfen™-100 SR. Consequently, they should use the lowest effective dose as a precaution.

**May Olfen™-100 SR be taken during pregnancy or breast-feeding?****Pregnancy**

If you are pregnant or planning a pregnancy, you should take diclofenac only after consultation with your doctor. Olfen™-100 SR must not be taken in the last trimester of pregnancy.

**Breast-feeding**

Olfen™-100 SR should not be taken during breast-feeding, unless specifically permitted by your doctor.

**How is Olfen™-100 SR taken?**

Dosage and administration are determined individually by the doctor, depending on the indication for use and the 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.

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, i.e. one 75 mg prolonged-release tablet, available under the commercial name of Olfen™-75 SR, or one 100 mg prolonged-release capsule, is usually sufficient.

Olfen™-100 SR is taken in the evening to prevent night-time pain and/or morning stiffness.

If necessary, the daily dose can be increased to 150 mg (one 100 mg prolonged-release capsule in combination with 25 or 50 mg gastro-resistant tablets or 2 prolonged-release tablets available under the commercial name of Olfen™-75 SR, prolonged-release tablets), preferably distributed throughout the day. Olfen™-100 SR should be taken unchewed with some liquid, preferably with meals. For easier dosing, the prolonged-release capsules can be opened and the contents taken without the shell. The capsule contents must not be chewed or crushed.

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.

**What are the possible side effects of Olfen™-100 SR?**

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

Common: 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).

Uncommon, 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: 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, jaundice (very rarely liver failure), hepatitis, impaired liver function, hives.

Very rare: 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, 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.

\*Impaired vision: If symptoms of poor eyesight should develop during treatment with Olfen™-100 SR, contact your doctor. An eye examination may be considered to rule out other causes. 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.

**What else should you be aware of?**

This medicine may only be used until the date marked with "EXP" on the pack.

Store in the original package. Do not store above 30°C. Keep out of the reach and sight of children.

Further information may be obtained from your doctor or pharmacist. These persons have the detailed prescribing information at their disposal.

**What does Olfen™-100 SR contain?**

Active substance: 1 prolonged-release capsule contains 100 mg diclofenac sodium.

Other ingredients: lactose monohydrate, microcrystalline cellulose, microcrystalline cellulose and carmellose sodium, glyceryl trimyristate, ammonio methacrylate copolymer (type B) dispersion, triethyl citrate, colloidal anhydrous silica, gelatin, colouring agents: titanium dioxide, iron oxide red, iron oxide black, erythrosine (E127).

**Where can you obtain Olfen™-100 SR? What packs are available?**

At pharmacies, on medical prescription only. Olfen™-100 SR: packs of 10, 30 and 100 prolonged-release capsules.

Not all dosages and packs sizes may be marketed.

**Date of information**

September 2016.

**Marketing Authorization Holder and Manufacturer**

Acino Pharma AG, Birsweg 2, 4253 Liesberg, Switzerland.

To report a safety issue or for queries in relation to drug safety – please send an e-mail to: [pv@acino.swiss](mailto:pv@acino.swiss).

<b>Kunde:</b> Client: Acino Pharma AG <b>Lohnhersteller:</b> <b>Auftr.-Nr.:</b> Order No.: 43380-1320 <b>Produkt:</b> Product: Olfen-100 SR/retardcap Acino en/fr <b>Format:</b> Size: 160,0 x 590,0 mm <b>Leutescode:</b> Code: 32H <b>Code 128:</b>	<b>Datum/Zch.:</b> Date/Ref. - Date/Sig. 27.03.2020 FM 25.05.2020 KS <b>Geprüft:</b> Audited / Vérifié:	<b>Freigabevermerk:</b> Release note / Déblocage note <input type="checkbox"/> <b>Druckreif</b> / Released for printing / BAT approuvé <input type="checkbox"/> <b>Nach Korrektur druckreif</b> / Released for printing after correction / Approuvé sous réserve <input type="checkbox"/> <b>Neue Korrekturvorbereitung</b> / New proof / Refusé <b>Datum/Unterschrift:</b> Date / Signature:	<b>Korrekturbazug-Nr.:</b> Proof sheet No. / Bon à tirer No.  <b>1 2</b>
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