

Package leaflet: Information for the user

OLFEN-50 LACTAB OLFEN-100 SR DEPOCAPS Diclofenac sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Olfen is and what it is used for
2. What you need to know before you take Olfen
3. How to take Olfen
4. Possible side effects
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1. What Olfen is and what it is used for

Diclofenac sodium, the active ingredient in Olfen, belongs to a group of medicines called NSAIDs (non-steroidal anti-inflammatory drugs) which work by reducing pain, inflammation and fever.

Olfen is used for inflammatory and degenerative rheumatic disorders of muscles, joints, joint capsules, synovial bursae, synovial sheaths and the spine.

These include:

- Chronic polyarthritis, arthritis, arthroses, ankylosing spondylitis (Bechterew's disease), soft tissue rheumatism, lumbago, sciatica, bursitis, tendovaginitis, tendinitis.
- Acute gouty arthritis.
- Painful conditions of inflammation and swelling after injuries and surgery.
- 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.

Olfen should not be used just to reduce fever.

2. What you need to know before you take Olfen

Do NOT take Olfen:

- if you are allergic to diclofenac sodium or any of the other ingredients of this medicine (listed in section 6)
- if you are suffering from an ulcer or bleeding in the stomach or small intestine (duodenum) or if you have had two or more of these episodes in the past
- if you have suffered from an ulcer or bleeding in the stomach or small intestine (duodenum) related to previous use of drugs for pain and inflammation (NSAIDs)
- if you are in the last trimester of pregnancy
- if you suffer from severe liver, kidney or heart problems (heart failure or heart disease)
- if you have ever had an allergic reaction (asthma attack, itchy rash, runny or blocked nose and sneezing) after you have taken medicines containing acetylsalicylic acid (aspirin) or other drugs for pain and inflammation (NSAIDs)
- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking Olfen:

- if you smoke
- if you have diabetes
- if you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- if you suffer from allergies, hay fever, asthma, swelling of nasal mucosa or chronic obstructive affections of the respiratory tract
- if you have liver, kidney or heart disease
- if you have inflammation of the colon with ulcers (ulcerative colitis), inflammation affecting the digestive tract (Crohn's disease) or other stomach or intestinal diseases (or a history suggestive of these diseases)
- if you suffer from hepatic porphyria
- if you are about to have or have just had major surgery
- if you are elderly
- if you have an intolerance to some sugars
- if you are in the first six months of pregnancy
- if you are breast-feeding.

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Elderly

If you are elderly you will be more prone to side effects, especially bleeding and perforation in the digestive tract, which may be fatal.

Ulcers, perforation and bleeding in the stomach or intestines

Bleeding, ulceration or perforation in the stomach or intestines which can be fatal may occur at any time without any warning signs even in patients who have never had such problems before, if this happens treatment should to be stopped immediately.

The risk generally increases with higher doses of Olfen. The risk also increases if certain other medicines are taken at the same time as Olfen (see “Other medicines and Olfen” below).

Skin reactions

You should stop taking Olfen with the first sign of skin rash, lesions of the mucous membranes or other signs of allergy since this can be the first sign of serious skin reactions (exfoliative dermatitis, Steven-Johnson’s syndrome, Lyell’s syndrome), sometimes with fatal outcome. The highest risk of these reactions is in the first month of treatment.

Effects on the heart and brain

Medicines such as Olfen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Other medicines and Olfen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you take any of the following:

- lithium (a medicine to treat depression)
- digoxin (a medicine to treat heart conditions)
- diuretics (medicines for increasing the excretion of urine)
- antihypertensive agents (medicines to treat high blood pressure)
- other NSAIDs (such as acetylsalicylic acid (aspirin) and ibuprofen)
- corticosteroids (medicines to treat inflammation)
- anticoagulants & anti-platelet agents (medicines that prevent blood clotting)
- SSRIs (selective serotonin-reuptake inhibitors; medicines to treat depression and anxiety disorder)
- antidiabetic agents (medicines to treat diabetes)
- methotrexate (to treat cancer and autoimmune diseases)
- ciclosporin (an immunosuppressant)
- quinolone antibiotics (certain medicines to treat infections)
- phenytoin (a medicine to treat epilepsy)
- colestipol and cholestyramine (medicine to lower blood cholesterol level)
- potent CYP2C9 inhibitors (such as sulfinpyrazone and voriconazole)

Pregnancy, breast-feeding and fertility

Olfen must **not** be taken in the last 3 months of pregnancy since it may cause major heart, lung and kidney disorders in the unborn child. If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Treatment during the first 6 months of pregnancy will only be prescribed by your doctor if clearly necessary.

It is not recommended to breast-feed your baby while taking Olfen as it passes into the breast milk.

Olfen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

If you experience dizziness, visual disturbances, vertigo, drowsiness or other disturbances of the central nervous system, you should avoid driving or operating machinery and consult your doctor immediately.

Olfen Depocaps contains lactose

Olfen *Depocaps* contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Olfen

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended initial daily dose for adults is 100 mg-150 mg.

In less severe cases and for long-term therapy, 75 mg-100 mg per day is sufficient in most cases. In general, the daily dose is divided into 2-3 individual administrations (in case of long-term treatment, for example, 2 x per day 1 Olfen-50 Lactab or 1 x per day 1 Olfen-100 SR Depocaps).

For painful menstruation, the daily dose is generally 50 mg-150 mg.

The initial dose should be 50 mg-100 mg and the dose can be increased over the course of several menstruation cycles to a maximum of 200 mg/day (if required).

Therapy should be initiated when the first symptoms occur and should continue for some days, depending on the symptoms.

Olfen should be taken orally, without chewing, before a meal and with a glass of water.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Olfen Lactabs are coated with a protective coating, which is not destroyed by gastric juice.

The Depocaps are suitable for patients for whom the daily dose of 100 mg is appropriate for their illness. The active ingredient is released over a relatively long period of time from the Depocaps, ensuring sustained effect. Once daily administration simplifies long-term treatment with Olfen.

Use in children

Not recommended for use in children.

If you take more Olfen than you should

If you take more Olfen than you should, contact your doctor or go to the nearest hospital **immediately**. Take your box of Olfen with you.

If you forget to take Olfen

Refer to the directions above on how to take the medicine. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Medicines such as Olfen may be associated with a small increased risk of heart attack or stroke.

STOP taking Olfen and inform your doctor IMMEDIATELY if you experience any of the following side effects:

- a sudden allergic reaction such as swelling of the face, tongue or throat (larynx), difficulty in breathing or swallowing, rash, itching, hives, dizziness, severe fall in blood pressure which may include life threatening shock
- severe pain in the upper abdomen, black, tarry stools or blood-stained vomit
- stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis)
- chest pain
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever
- mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Olfen and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).

Other possible side effects are:

Common (may affect more than 1 person in 100):

- headache
- dizziness, vertigo
- nausea (feeling sick), vomiting (being sick), diarrhoea
- indigestion, abdominal pain, flatulence, loss of appetite
- abnormal liver function test results (e.g. elevated transaminases)
- skin rash.

Rare (may affect less than 1 person in 1000):

- a sudden allergic reaction such as swelling of the face, tongue or throat (larynx), difficulty in breathing or swallowing, rash, itching, hives, dizziness, severe fall in blood pressure which may include life threatening shock
- drowsiness
- asthma, shortness of breath
- stomach pain, intestinal bleeding, vomiting blood, bloody diarrhea, black tarry stools, gastrointestinal ulcers (potentially with bleeding and perforation)
- yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure)

- itchy rash
- generalised swelling (signs of oedema)

Very rare (may affect less than 1 person in 10,000):

- reduction in blood platelets, which increases risk of bleeding or bruising
- reduction in number of white blood cells which makes infections more likely
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- serious allergic reaction which causes swelling of the face or throat
- disorientation, depression, sleeplessness, nightmares, irritability, psychotic disorder
- tingling or numbness in the hands or feet
- memory impairment, convulsion, anxiety, tremor
- stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis)
- taste disturbances
- stroke
- visual disturbances (for example blurred vision, double vision)
- impaired hearing, ringing in the ears (tinnitus)
- unpleasant awareness of heart beat, chest pain, heart failure, heart attack
- high blood pressure, inflammation of blood vessels often with skin rash
- inflammation of the lungs which causes breathlessness, cough and raised temperature
- inflammation of the large intestine which causes abdominal pain or diarrhoea, worsening of Crohn's disease or ulcerative colitis (chronic inflammatory disease of the large intestine)
- constipation, inflammation of mouth and lips, tongue, pancreas (causing severe pain in abdomen and back)
- disorder of the food pipe, diaphragm-like intestinal strictures
- liver failure
- abnormal redness and inflammation of the skin (erythema), blisters, eczema, skin rash with flaking or peeling (sign of dermatitis exfoliative), hair loss, increased skin sensitivity to light, purple skin patches, itching
- serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- serious illness with blistering of the skin (Lyell's syndrome)
- blood in urine, excess protein in urine, inflammation of the kidneys and kidney failure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5.How to store Olfen

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date stated «EXP» on the outer box.

Store in a dry place and below 25° C.

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

6. Contents of the pack and other information

What Olfen contains

Olfen-50 Lactab

The active substance is diclofenac sodium. Each tablet contains 50 mg of diclofenac sodium.

The other ingredients are: 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

The active substance is diclofenac sodium. Each tablet contains 100 mg of diclofenac sodium.

The other ingredients are: 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.

Contents of the pack

Olfen-50 Lactab: packs of 20 Lactab

Olfen-100 SR Depocaps: packs of 10 and 20 Depocaps

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Mepha, Lda.

Lagoas Park,

Edificio 5 A, Piso 2

2740 - 298 Porto Salvo

Portugal

Manufacturer

Vivian Corporation Ltd

29 Sanitas Building

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Msida

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This leaflet was last revised in August 2016.