

Patient Information Leaflet (PIL)
Olfen™ 75 mg IM, solution for injection IM
Diclofenac Sodium & Lidocaine

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.

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1. Serious side effects.

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.
- Olfen 75 mg IM, solution for injection is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

2. What Olfen 75 mg IM is, and what they are used for

Diclofenac sodium, the active ingredient in Olfen 75 mg IM, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation. Olfen 75 mg IM also contains lidocaine 20 mg to reduce pain at the injection site.

The intramuscular injection is used to treat a number of painful conditions including:

- 'Flare-ups' of joint or back pain
- Attacks of gout
- Pain caused by kidney stones
- Pain, inflammation and swelling following injuries and surgery
- Severe migraine attacks.

Olfen 75 mg IM can be given as an injection into the muscle.

Olfen 75 mg IM is not suitable for children.

3. Before you take Olfen 75 mg IM

a. Don't take Olfen 75 mg IM if:

- you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Olfen 75 mg IM. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, runny nose, skin rash or any other allergic type reaction
- you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- you have had stomach or bowel problems after you have taken other NSAIDs
- you have moderate or severe heart, kidney or liver failure
- 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 bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- you are more than six months pregnant

b. Take special care with Olfen 75 mg IM if you:

- suffer from any bowel disorders including ulcerative colitis or Crohn's disease
- have kidney or liver problems, or are you elderly
- suffer from any blood or bleeding disorder
- have a condition called porphyria
- ever had asthma
- breastfeeding
- have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- have heart problems, or have you had a stroke, or do you think you might be at risk of these conditions (for example, if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- have diabetes
- smoke
- have Lupus (SLE) or any similar condition
- be suffering from dehydration
- suffered any heavy loss of blood recently

c. Other special warnings

- You should take the lowest dose of Olfen 75 IM for the shortest possible time, particularly if you are underweight or elderly.
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Olfen 75 IM. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms.
- Because it is an anti-inflammatory medicine, Olfen 75 IM may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Olfen 75 IM.
- Olfen 75 mg IM should not be used in children.

d. Taking other medicines with Olfen 75 mg IM

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Medicines to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin)
- Diuretics (water tablets)
- Lithium (used to treat some mental problems)
- Methotrexate (for some inflammatory diseases and some cancers)
- Ciclosporin and tacrolimus (used to treat some inflammatory diseases and after transplants)
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID or COX-2 (cyclo-oxygenase-2) inhibitor, for example aspirin or ibuprofen
- Mifepristone (a medicine used to terminate pregnancy)
- Cardiac glycosides (for example digoxin), used to treat heart problems
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)
- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors.
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol/cholestyramine (used to lower cholesterol)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

e. Pregnancy, breast-feeding

- Are you pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not have a Olfen injection during the last 3 months of pregnancy as it may affect the baby's circulation.
- Are you trying for a baby? Having Olfen injections may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant.

f. Driving and using machines

Very occasionally people have reported that Olfen 75 mg IM have made them feel dizzy, tired or sleepy. Problems with eyesight have also been reported. If you are affected in this way, you should not drive or operate machinery.

4. How to take Olfen 75 mg IM

Your doctor will decide when and how to treat you with Olfen 75 mg IM. The intramuscular injection is usually injected into the buttocks.

The usual dose is:

Adults

One or two ampoules (75 to 150 mg) each day for one or two days.

Elderly

Your doctor may give you a dose that is lower than the usual adult dose if you are elderly.

Children

Not suitable for children.

A doctor, nurse or pharmacist will prepare the injection for you.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

a. If you take more Olfen 75 mg IM than you should

If you think you have been given too much Olfen 75 mg IM tell your doctor or nurse straight away.

5. Possible side effects

Olfen 75 mg IM are suitable for most people, but, like all medicines, they can sometimes cause side effects. Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Some side effects can be serious

Tell the doctor straight away if you notice:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
Any sign of bleeding in the stomach or intestine, for example, when emptying your
- bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm) Swollen, face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Olfen 75 mg IM and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain.

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

The side effects listed below have also been reported.

Common side effects (*These may affect between 1 and 10 in every 100 patients*):

Stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
Headache, dizziness, vertigo
Skin rash or spots
Raised levels of liver enzymes in the blood
Injection site reactions, symptoms include redness, swelling, change in the skin colour, inflammation, pain, and hypersensitivity

Rare side effects (*These may affect between 1 in every 1000 to 1 in every 10,000 patients*):

Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
Gastritis (inflammation, irritation or swelling of the stomach lining)
Vomiting blood
Diarrhoea with blood in it or bleeding from the back passage
Black, tarry faeces or stools
Drowsiness, tiredness
Hypotension (low blood pressure, symptoms of which may include faintness, giddiness or light headedness)
Skin rash and itching
Fluid retention, symptoms of which include swollen ankles
Liver function disorders, including hepatitis and jaundice
Injection site necrosis (dead skin and tissue around the injection site)

Very rare side effects (*These may affect less than 1 in every 10,000 patients*):

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental disorders, disorientation and loss of memory, fits, headaches together with a dislike of bright lights, fever and a stiff neck, disturbances in sensation.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, taste changes, lower gut disorders (including inflammation of the colon, or worsening of colitis or Crohn's disease).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), chest pain, hypertension (high blood pressure), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), heart disorders, including congestive heart failure or heart attack, blood disorders (including anaemia).

Effects on the liver or kidneys:

Kidney or severe liver disorders including liver failure, presence of blood or protein in the urine.

Effects on skin or hair:

Serious skin rashes including Stevens-Johnson syndrome, Lyell's syndrome and other skin rashes which may be made worse by exposure to sunlight.
Hair loss.

Other side effects that have also been reported include:

Inflammation of the pancreas, impotence. Facial swelling, inflammation of the lining of the brain (meningitis), stroke, throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, tissue damage at the injection site.

Do not be alarmed by this list - most people have an injection of Olfen 75mg IM without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

6. How to store Olfen 75 mg IM

Do not store above 30°C.

Store the Olfen 75 mg IM in the original package in a dry place.

Keep out of the reach and sight of children.

Do not use Olfen 75 mg IM after the expiry date which is stated on the pack.

7. Further information

a. What Olfen 75 mg IM contains

Active substances: diclofenac sodium, lidocaine hydrochloride. Each 2 ml ampoule contains diclofenac sodium 75 mg, lidocaine hydrochloride 20 mg.

Excipients: N-acetylcysteine, disodium edetate, macrogol 400, propylene glycol, sodium hydroxide, water for injections.

b. What 75 mg IM looks like and contents of the pack

The product is filled into 2 ml amber (brown) glass ampoules (hydrolytic class I), with white OPC (One Point Cut) point.

Packs of 3 and 5 ampoules of 2 ml; hospital packs.

Not all pack sizes may be marketed.

c. Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

Acino Pharma AG, Liesberg, Switzerland

Manufacturer

Manufactured by Haupt Pharma Wulfing GmbH, Gronau/Leine, Germany

Batch releaser: Acino Pharma AG, Aesch, Switzerland

d. This package leaflet was last revised in July 2018

e. To report any side effects:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sFDA.gov.sa
- Website: www.sFDA.gov.sa/npc

By reporting side effects, you can help provide more information on the safety of this medicine.

f. Council of Arab Health Ministers

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- 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

The following information is intended for healthcare professionals only:

Dosage and Administration

Adults:

Olfen 75 mg IM should not be given for more than two days; if necessary, treatment can be continued with Olfen Tablets or Suppositories.

Intramuscular injection: The following directions for intramuscular injection must be adhered to in order to avoid damage to a nerve or other tissue at the injection site.

One ampoule once (or in severe cases twice) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required it is advised that the alternative buttock be used for the second injection. Alternatively, one ampoule of 75 mg can be combined with other dosage forms of Olfen (tablets or suppositories) up to the maximum daily dosage of 150 mg.

Renal colic: One 75 mg ampoule intramuscularly. A further ampoule may be administered after 30 minutes if necessary. The recommended maximum daily dose of Olfen is 150 mg.

Recommended injection procedure

1. The patient may lie down or stand (holding a stable piece of furniture for support) whichever is most comfortable.
2. The buttocks should be exposed and inspected to find the most suitable injection site. Avoid scars and lumps and choose the buttock which is free from any problems. If more than one injection needs to be given the other buttock should be used.
3. The injection site should be thoroughly disinfected e.g. with isopropyl alcohol and allowed to dry before injecting the solution.
4. Give the deep intramuscular injection high into upper outer quadrant of the buttock taking particular care to avoid the sciatic nerve and blood vessels. Avoid injecting into an area where resistance is felt.

N.B. In obese patients avoid deposition of the drug into the subcutaneous fatty tissue.

In small thin patients with little muscle bulk, be especially aware of the sciatic nerve which may be quite superficial.

5. Before injection and after needle insertion, pull back the syringe plunger to check the needle has not entered a vessel. If blood is drawn, withdraw the needle to another site and check again.
6. The injection should be given slowly to minimise local tissue damage.
7. If the patient complains of severe pain or pronounced discomfort stop the injection immediately. Retry at another site. A dull aching pain may be experienced after normal injection.
8. Advise the patient to remain reasonably mobile for one to two hours after the injection, whenever possible.

Children:

Olfen 75 mg IM are not recommended for use in children.

Elderly: Although the pharmacokinetics of Olfen 75 mg IM are not impaired to any clinically relevant extent in elderly patients, non-steroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also Precautions) and the patient should be monitored for GI bleeding for 4 weeks following initiation of NSAID therapy.

The recommended maximum daily dose of Olfen 75 mg IM is 150 mg.

Incompatibilities

The ampoules used as an infusion should not be mixed with other injection solutions.