

Package leaflet: Information for the user

Olfen™ Gel *diclofenac sodium*

Read all of this leaflet carefully before you start using 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 Gel is and what it is used for
2. What you need to know before you use Olfen Gel
3. How to use Olfen Gel
4. Possible side effects
5. How to store Olfen Gel
5. Contents of the pack and other information

1. What Olfen Gel is and what it is used for

Olfen Gel contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin.

Olfen Gel is used to relieve pain and reduce inflammation and swelling.

- Olfen Gel is suitable for external treatment of rheumatic disorders localised in joints, tendons and muscles, for example, arthrosis, muscle rheumatism, pain or swelling near a joint (bursitis), painful shoulder stiffness or tendon inflammation (tendovaginitis).
- Olfen Gel is also used for the treatment of pain and swelling caused by sprains, dislocations, bruising (contusions) and strains.

2. What you need to know before you use Olfen Gel

Do NOT use Olfen Gel:

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction (asthma attack, itchy rash, runny or blocked nose and sneezing) to any non-steroidal anti-inflammatory medicines or acetylsalicylic acid (aspirin).
- if you are in the last 3 months of pregnancy.

Warnings and precautions

Contact your doctor if you need to use Olfen Gel over a large area of skin or for a prolonged time as this should be avoided because you are more likely to experience side effects (see section 4).

Do not apply to skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema.

Discontinue the treatment if a skin rash develops after applying the product.

Eyes and mucous membranes should NOT come into contact with the product.

Olfen Gel should NOT be ingested.

Olfen Gel cannot be used under air-and water-tight bandage.

Children and adolescents

The use and safety of Olfen Gel in children and adolescents under 14 years of age has not been fully established.

In adolescent aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen, the patient/parents of the adolescent is/are advised to consult a doctor.

Other medicines and Olfen Gel

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Olfen Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Olfen Gel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Breast-feeding

Olfen Gel should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Olfen Gel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

Driving and using machines

Olfen Gel has no influence on the ability to drive and use machines.

3. How to use Olfen Gel

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

Adults

- Depending on the size of the body area to be treated, 2-4 g (about 1-2 loaded fingertips) of Olfen Gel is applied 3-4 times daily and spread on the affected area of the skin (do not rub in).
- A daily dosage of 15 g of gel should not be exceeded.
- Inform your doctor, if after 2 weeks the affected area has not improved or has got worse.
- Take care that Olfen Gel does NOT come into contact with your eyes. If this happens, **rinse your eyes immediately with clear water and inform your doctor.**
- **Do NOT swallow.**
- Olfen Gel can be used at the same time as other Olfen formulations to support them.

Children

The use and safety of Olfen Gel in children and adolescents under 14 years of age has not been fully established.

For use in adolescents aged 14 years and over refer to the adult dosage above or the specific instructions prescribed by your doctor.

If Olfen Gel is needed for more than 7 days for pain relief in adolescents aged 14 years and over, or if the symptoms worsen, consult your doctor.

If you use more Olfen Gel than you should

In case you or a child accidentally swallows Olfen Gel, or in case you have accidentally used much more than recommended, contact your doctor immediately.

If you forget to use Olfen Gel

If you miss your application of Olfen Gel at the correct time, apply it when you remember and then carry on as normal. Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

If you experience any of the following, stop taking Olfen Gel at once and tell your doctor immediately:

- severe skin rash
- wheezing, shortness of breath
- swelling of the face, lips or mouth.

In decreasing order of frequency, side-effects can include:

- Common (may affect up to 1 in 10 people): rash; eczema; redness of the skin; inflammation of the skin; itchy skin.
- Rare (may affect up to 1 in 1,000 people): blisters on the skin.
- Very rare side effects (may affect up to 1 in 10,000 people): an allergic reaction (swelling of the lips, face or mouth leading to severe difficulty in breathing, skin rash or hives); rapid swelling of the skin; rash which occurs with lesions; asthma, shortness of breath; photosensitivity reactions, abnormal responses to sunlight or artificial light.

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.

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt.

5. How to store Olfen Gel

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

Do not use this medicine after the expiry date stated on the outer packaging after EXP.

Do not store above 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 Gel contains

- The active substance is diclofenac sodium. Each 1 g of gel contains 10 mg of diclofenac sodium.
- The other ingredients are: lactic acid, di-isopropyl adipate, Isopropyl alcohol, sodium metabisulphite (E223), hydroxyethylcellulose, hydroxypropylcellulose, purified water.

Contents of the pack

Aluminium tubes containing 20 g and 50 g of gel.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Mepha Lda
Lagoas Park
2740-298 Porto Salvo
Portugal

Manufacturer:

Pharma.MT Limited,
103, Stuart Street,
Gzira, GZR 1054,
Malta

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