

PACKAGE LEAFLET: INFORMATION FOR THE USER

Difene® 75mg Dual Release Capsules  
(diclofenac sodium)

Your medicine is imported from Austria under the name of ‘Deflamat’, but is marketed as ‘Difene’ in Ireland.

Read all of this leaflet carefully before you start using 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. 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.

In this leaflet:

- What Difene is and what it is used for
- What you need to know before you take Difene
- How to take Difene
- Possible side effects
- How to store Difene
- Contents of the pack and other information

1. What Difene is and what it is used for

Difene contains diclofenac sodium as the active ingredient which is a non-steroidal anti-inflammatory drug (NSAID). This means that it is a “painkilling” medicine which reduces inflammation and swelling, but it does not contain any steroid medicine. Difene is used to relieve pain and inflammation. It is used to relieve painful conditions associated with your bones and joints and to reduce swelling and inflammation (e.g. arthritis) and for sprains, strains and bruising of tendons and ligaments, acute gout and for period pain. It can also be used to reduce pain or inflammation after surgery.

2. What you need to know before you take Difene

Do not take Difene if you:

- are allergic (hypersensitive) to diclofenac or to any of the other ingredients of Difene. Please refer to section 6 of the leaflet for a full list of ingredients of Difene.
- have ever had an allergic reaction (difficulty in breathing, skin rash and runny nose) to aspirin (acetylsalicylic acid) or any other NSAID such as ibuprofen.
- have or have ever suffered from a stomach ulcer or bleeding from the stomach.
- have had any gastrointestinal problems after taking any other NSAID e.g. vomiting blood or passing black, tarry stools.
- have severe heart failure.
- have severe kidney failure or liver failure.
- Difene should not be used in the last three months of pregnancy - please see section on ‘Pregnancy and breast-feeding’.

Warnings and Precautions

Speak to your doctor before taking Difene if you:

- if you have experienced asthma, allergic inflammation of the nasal airways
- if any skin rash develops such as hives or itchy skin
- if you have experienced symptoms of chronic obstructive pulmonary diseases (COPD), shortness of breath, persistent cough
- have high blood pressure
- have heart problems
- have mild to moderate heart failure
- have liver or kidney problems
- have severe liver or kidney disease
- suffer from porphyria
- suffer from any bowel problems such as ulcerative colitis or Crohn’s disease
- suffer from an upset stomach or irritation of the gut
- have suffered from any blood or bleeding disorder such as haemophilia
- are pregnant or think you may become pregnant
- are breast-feeding
- are elderly
- have peripheral arterial disease (signs and symptoms of this may be pain and numbness in the arms and legs)
- have cerebrovascular disease, this is a condition that develops as a result of problems with blood vessels in the brain. If you have a history of strokes or mini-strokes please speak to your doctor
- are taking Difene long-term or if you are a patient with severe liver impairment as you will need to undergo monitoring while taking Difene.

- if you have heart problems, previous strokes or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- have recently had major surgery

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

You may also be prescribed a medicine to protect the lining of stomach while taking diclofenac. Non-steroidal anti -inflammatory drug (NSAIDs) can cover the signs and symptoms of an infection.

It is advised to use the lowest dose for the shortest time to reduce the likelihood of side-effects.

If you have asthma, hayfever (seasonal allergic rhinitis), swelling of the nasal mucosa (nasal polyps), narrowing of the airways (due to a condition known as chronic obstructive pulmonary disease) or chronic infections of the respiratory tract (e.g. chest infections and especially allergic symptoms affecting the nose) you are more likely to experience reactions to NSAIDs (e.g. diclofenac). These reactions could include worsening of asthma (often referred to as intolerance to analgesics/analgesics asthma), development of hives on the skin and swelling of the eyes and lips and mucous membranes. You may be at greater risk of developing these reactions to NSAIDs if you are already allergic to, and have had reactions to, other substances. A doctor’s supervision and extreme precaution is advised with the use of NSAIDs if you have any allergic condition as described here that could predispose you to an allergic reaction.

Medicines such as diclofenac may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

Taking other medicines

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

If you are taking other medicines make sure your doctor is aware of them before you take Difene, particularly if they are any of the following:

- other anti-inflammatory or “painkilling” medicines (NSAIDs)
- water tablets (diuretics)
- steroids which are used as the main treatment for certain inflammatory conditions (corticosteroids)
- medicines used to thin blood, such as warfarin (anticoagulants)
- aspirin (anti-platelet agents)
- mood stabilising drugs such as lithium
- immunosuppressive agents, which are drugs that inhibit or prevent activity of the immune system (ciclosporine)
- medicines which may be used to treat cancer (methotrexate)
- medicines for heart conditions or high blood pressure (beta blockers, ACE inhibitors, digoxin)
- quinolone antibiotics (ciprofloxacin, ofloxacin)
- aminoglycosides antibiotics used in serious infections (streptomycin)
- tablets to treat diabetes
- medicines for the treatment of gout (probenecid)
- medicines for the treatment of depression (selective serotonin re-uptake inhibitors)
- an anticoagulant such as heparin
- treatment of hypertension and congestive heart failure (angiotensin-receptor blockers)
- if taking tablets to relieve the symptoms of inflammation and pain (COX inhibitors)
- medicine for epilepsy (phenytoin)
- cholesterol medication (colestipol)
- medicine used to reduce bile acid (cholestyramine)
- medicine used for gout (sulfinpyrazone)
- antifungal medication (voriconazole)

If you are presently taking any of these medicines and are unsure talk to your doctor or pharmacist.

Taking Difene with food and drink

As with other anti-inflammatory medicines, Difene may cause stomach upset. To reduce this effect swallow your Difene capsules whole with a glass of water or milk, either with or after a meal.

Pregnancy, breast-feeding and fertility

Do not take Difene if you are pregnant or breast-feeding unless it is considered essential by your physician.

Difene 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.

This medicine must not be used by women who are in the last three months of pregnancy.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Taking Difene should not affect your ability to drive or operate machinery. If in the unlikely event that you have dizziness or blurred vision do not drive or operate machinery.

3. How to take Difene

Always take Difene exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Difene should be swallowed whole not chewed or crushed
- Take Difene capsules with or after food with a glass of water or milk
- It is important that you use the lowest dose that controls your pain and you should not use Difene for longer than necessary
- If two capsules are taken in one day, the dose should be divided (e.g., one in the morning and one in the evening). Never take two Difene 75mg capsules in a single dose.

Adults:

The usual dose is one to two capsules daily. The dose should not exceed 150mg daily.

Elderly:

The dosage should be kept as low as possible.

Children:

Not recommended in children.

If you take more Difene than you should

If you take too many Difene capsules, tell your doctor or hospital emergency department at once. Take your medicine with you.

If you forget to take Difene

If you forget to take a dose, take one as soon as you remember. Do not double up on the next dose to make up for the one missed. Do not take more than 150mg in 24 hours.

If you stop taking Difene

Your doctor will decide how long you will take this medicine. Your doctor has carefully chosen the correct dosage for you taking into account the severity of your condition, your age and any other reasons special to you, therefore you should always take the dose prescribed. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Difene can cause side effects, although not everybody gets them. These may occur in the initial stages of treatment and may be more serious if they occur in the elderly.

If the following happens at any time during your treatment, stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives)
- passing blood in your faeces (stools/motions)
- passing black tarry stools
- vomiting any blood or dark particles that look like coffee grounds
- a serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Very common (≥1/10);

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to < 1/100)

Rare ( ≥ 1/10,000 to <1/1,000)

Very Rare (<1/10,000)

Not Known (cannot be estimated from available data).

Common:

- Headache, dizziness
- Vertigo
- Nausea, vomiting, diarrhoea, indigestion, flatulence, abdominal pain, loss of appetite
- Skin rash
- Increased levels of serum glutamic oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGTP), enzymes that are normally present in liver and heart cells, SGOT and SGTP are released into blood when the liver or heart are damaged

Rare:

- Allergic reactions (e.g. difficulties in breathing, wheezing or low blood pressure)
- Drowsiness, tiredness
- Asthma, shortness of breath
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels
- Inflammation of the lining of the stomach
- Gastro-intestinal ulcers with or without bleeding
- Yellowing of your skin or the whites of your eyes (hepatitis or liver function disorders)
- Hives
- Fluid retention

Very Rare:

- Decrease of platelets in the blood, signs of this can be bleeding inside the body or bleeding from the skin
- Decrease of white blood cells in the blood
- Anaemia, abnormal bleeding
- Rapid swelling , including swelling of the face
- Disorientation, depression, insomnia, nightmares, irritability, psychotic disorder
- Sensation of tingling, pricking, or numbness of skin
- Impaired memory
- Convulsions, tremors
- Anxiety
- Symptoms of aseptic meningitis with neck stiffness, headaches, nausea, vomiting or clouding of consciousness
- Impaired sense of taste
- Loss of appetite
- Lesions in the food pipe
- Stroke
- Visual disturbances (blurred and double vision)
- Hearing loss, tinnitus (ringing in the ears)
- Palpitations, chest pain
  - Cardiac failure
  - Heart attack
- High blood pressure
- Inflammatory destruction of blood vessels, symptoms of which can be fever and weight loss
- Inflammation of lung tissue
- Swelling of the large intestine
- Crohn’s disease
- Inflammation of the pancreas
- Constipation
- Constipation of the mucous lining in the mouth
- Swollen tongue and colour change of the tongue
- Reflux, heartburn
- Fulminant hepatitis
- Liver failure
- Eczema
- Reddening of the skin
- Skin diseases known as Steven Johnson syndrome and Lyell’s, which are the detachment of top layers of skin from bottom layers.
- Inflammation of scaling of skin
- Loss of hair
- Photosensitivity reactions, abnormal responses to sunlight or artificial light
- Purpura, the appearance of red or purple discolouration on the skin
- Allergic reaction of unknown origin causing red patches on the skin
- Kidney failure, signs and symptoms of this are bloody stools, fatigue, bruising easily and fluid retention
- Blood in the urine
- Excess protein in your urine which can cause your urine to become foamy
- Nephrotic syndrome, which is a disorder in which the kidneys can become damaged the most common signs of this are weight gain due to excess fluid retention, swelling and foamy urine
- Interstitial nephritis, which is a kidney disorder in which the spaces between the kidney tubules become swollen (inflamed). Some symptoms of this condition may be blood in urine, fever, nausea and vomiting
- Renal papillary necrosis, which is a disorder of the kidneys, symptoms of this may be back pain blood in urine, cloudy urine

Gastrointestinal bleeding associated with this product can be fatal.

**If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.**

5. How to store Difene

- Do not store above 25°C.
- Store in the original package.
- Check the expiry date printed on the label and outer carton. Do not use the medicine if the expiry date has passed.
- Always keep your medicine in a safe place out of the sight and reach of children.
- We suggest that you return any unused medicine to your pharmacist.
- If your tablets appear to be discoloured, damaged, or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Difene contains

Each capsule contains 75mg diclofenac sodium (25mg as gastro-resistant pellets and 50mg as prolonged-release pellets).

The capsules also contain: microcrystalline cellulose, povidone, methacrylic acid ethyl acrylate copolymer, talc, ammonio methacrylate copolymer type A + B, colloidal silicon dioxide, propylene glycol, triethyl citrate, sodium laurilsulfate, gelatin, indigo carmine (E132), titanium dioxide (E171).  
Printing Ink: shellac, lecithin soya, antifoam and titanium dioxide (E171).

What Difene looks like and contents of the pack

Difene 75mg Dual Release Capsules are modified release hard gelatin capsules with light blue opaque caps and colourless transparent bodies, containing white to cream-coloured spherical pellets. The capsules are printed "D75M" in white.

Difene 75mg Dual Release Capsules are available in packs of 60.

Manufacturer:

Manufactured by: Temmler Werke GmbH,  
Weihenstephaner Strasse 28, 81673 München, Germany.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

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