

Package leaflet: Information for the user
Difene® 25 mg Capsules
Difene® 50 mg Capsules
(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. 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 Difene is and what it is used for
2. What you need to know before you take Difene
3. How to take Difene
4. Possible side effects
5. How to store Difene
6. 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, and in acute gout. 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 listed in section 6.
- if you have ever had an allergic reaction (skin reaction, difficulty in breathing or runny nose) to aspirin (acetylsalicylic acid) or any other NSAID such as ibuprofen.
- if you suffer from an upset stomach or irritation of the gut, if you have or have ever suffered from a stomach ulcer or bleeding from the stomach.
- if you have been told that you have bleeding in the brain or other bleeding elsewhere.
- if you have a history of gastro-intestinal bleeding related to previous NSAID use e.g. any other gastrointestinal problems, e.g. vomiting blood or passing black, tarry stools.
- if you have severe heart 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 or bypass blockages
- if you have or have had problems with your blood circulation (peripheral arterial disease)
- if you have severe kidney or liver failure.
- this medicine must not be used by women who are in the last three months of pregnancy.

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you.

Warnings and precautions

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

Talk to your doctor

- if you think you may be allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Difene. (These are listed at the end of the leaflet.) Signs of a hypersensitivity reaction include swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic type reaction
- 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 ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Difene or other pain medications
- if you have experienced symptoms of chronic obstructive pulmonary diseases (COPD), shortness of breath, persistent cough
- have mild to moderate heart failure
- have liver or kidney problems
- have severe liver or kidney disease
- if you have porphyria (a disorder of your metabolism)
- if you are pregnant or think you may become pregnant
- if you are breast feeding
- if you have peripheral arterial disease, signs and symptoms of this are pain and numbness in the arms and legs
- if you 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 stroke or mini stroke please speak to your doctor
- if you recently had major surgery
- if you are elderly
- if you are taking Difene long-term or if you have severe liver impairment as you will need to undergo monitoring while taking Difene
- if you have heart problems, previously have had a stroke 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
- if you suffer from any bowel disorders, e.g. ulcerative colitis or Crohn’s disease
- if you suffer from any blood or bleeding disorder such as haemophilia

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you.

Make sure your doctor knows, before you are given diclofenac

- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- If you recently had or you are going to have a surgery of the stomach or intestinal, as Difene can sometimes worsen wound healing in your gut after surgery.

You may also be prescribed a medicine to protect the lining of the stomach while taking diclofenac.

This medicine should be used in great caution with elderly patients.

Non-steroidal anti-inflammatory drug (NSAIDs) such as diclofenac can cover the signs and symptoms of an infection. If you experience the onset or worsening of signs of infection, contact your doctor as you may require antibiotic therapy.

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.

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

Other medicines and Difene

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
- drugs for the treatment of gout (probenecid)
- drugs 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 (sulfapyrazone)
- antifungal medication (voriconazole)

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

Difene with food, drink and alcohol

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.

If you are not sure about using Difene then talk to your doctor or pharmacist.

Taking Difene at the same time as alcohol can increase the risk and severity of side effects, especially those relating to the gut.

Pregnancy, breast-feeding and fertility

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.

Do not take Difene if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Difene during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Difene can cause kidney problems in your unborn baby, that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Do not use Difene if you are breast-feeding. This is because small amounts may pass into the mother's milk.

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.

Important information about some of the ingredients of Difene

This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This product contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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.

It is important that you use the lowest dose that controls your pain and you should not use Difene for longer than necessary.

Difene capsules should be swallowed whole not chewed or crushed, with or after food with a glass of water or milk.

Adults:

The usual total daily dose is 100 mg in divided doses. This may be increased to 150 mg daily.

Elderly:

The dosage should be kept as low as possible.

Use in children:

Children aged 9 years (min. 35 kg BW) or over and adolescents should be given up to 2 mg/kg body weight per day in 3 divided doses, depending on the severity of the disorder.

If you take more Difene than you should

If you take too many Difene 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 take a double dose to make up for a forgotten dose. Then go on as before. Do not take more than 150 mg 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 you experience any of the following side effects, stop taking your capsules and either tell your doctor immediately or go to your nearest hospital. You may be experiencing an allergic or other type of reaction to Difene:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives)
- a serious allergic skin reaction which may include large widespread red and/or dark patches, swelling of the skin, blisters, and itching (Generalised bullous fixed drug eruption)
- 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.
- mild cramping and tenderness of the abdomen, starting shortly after the start of treatment with Difene and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of the abdominal pain (frequency not known, cannot be estimated from the available data)
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

The frequency of the side effects listed below is defined using the following convention:

Very common ($\geq 1/10$);

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very Rare ($< 1/10,000$)

Not Known (cannot be estimated from available data).

Common:

- Headache, dizziness, agitation
- 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
- Inflammation of the lining of the stomach
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels
- 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:

- Blood disorders such as low red blood cell count (anaemia), low white blood cell count or low platelet count. Signs of a blood disorder could include fever, sore throat, blisters in the mouth, flu-like symptoms, severe exhaustion, nosebleeds or bleeding into the skin
- 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
- Inflammation 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 or 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 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 the urine and cloudy urine

Not known:

- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again

Gastrointestinal bleeding associated with this product can be fatal.

Medicines such as Difene may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment.

If you have a rare disease called systemic lupus erythematosus, you might be at increased risk of some of the side effects of Difene, such as skin reactions, allergic reactions, damage to the liver and aseptic meningitis.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Difene

Do not store above 25°C.

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

Do not use Difene Capsules after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Difene contains

- The active substance is diclofenac sodium

- Each capsule contains 25 mg or 50 mg of diclofenac sodium
- The other ingredients are sucrose, microcrystalline cellulose, gelatin, maize starch, methacrylic acid copolymer, talc, povidone, propylene glycol, colloidal anhydrous silica, titanium dioxide E171, sodium hydroxide, indigotine E132, erythrosin E127, shellac and sodium lauryl sulphate.

What Difene looks like and contents of the pack

Difene Capsules are gastro-resistant hard gelatin capsules with dark blue opaque caps and a colourless transparent body printed with "D25" or "D50" in white, containing white to cream pellets. Each capsule contains diclofenac sodium 25 mg or 50 mg in an enteric coated formulation. Difene Capsules are available in packs of 20, 50 and 56 capsules on prescription from your doctor. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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Manufacturer:

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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