

The PL includes alternative texts for different legal status in different countries as follows:  
-Grey-shaded texts are only applicable for OTC versions.  
-Boxed texts are only applicable for prescription versions.

### Package leaflet: Information for the user

**Dicuno 25 mg film-coated tablets**

**Dicuno 50 mg film-coated tablets**

diclofenac potassium

*OTC only:*

**Read all of this leaflet carefully because it contains important information for you.**

***Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.***

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days for migraine headache or 5 days for other pain conditions.

*POM only:*

**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. 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:**

1. What Dicuno is and what it is used for
2. What you need to know before you take Dicuno
3. How to take Dicuno
4. Possible side effects
5. How to store Dicuno
6. Contents of the pack and other information

#### **1. What Dicuno is and what it is used for**

Dicuno belongs to the group of medicines known as non-steroidal anti-inflammatory drugs (NSAID). It has antiinflammatory, analgesic and fever-reducing effect.

Dicuno is used for symptomatic treatment of acute mild and moderate pain including acute migraine headaches.

#### **2. What you need to know before you take Dicuno**

##### **Do not take Dicuno**

- if you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6)

- if you have or have a history of a stomach ulcer or duodenal ulcer
- if you have a history of gastrointestinal bleeding/perforation related to previous use of painkillers (NSAIDs)
- if you have an increased tendency to bleeding
- if you have severely reduced liver function
- if you suffer from porphyria (metabolic disease)
- 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 disease
- during the final three months of pregnancy
- if you think you may be allergic to diclofenac potassium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Dicuno. (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.

### **Warnings and precautions**

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary. Higher doses than the recommended dose are generally associated with an increased risk of side effects. This also means that the combination of several NSAID products at the same administration time should be avoided.

Talk to your doctor before treatment if you have or have had any of the following diseases:

- inflammatory bowel disease (ulcerative colitis, Chron's disease)
- asthma, heart disease, liver disease or kidney disease
- chronic obstructive pulmonary disease or chronic airway inflammation (diseases that lead to narrowed airways and limitation of the airflow causing shortness of breath)
- inflammation of the nasal mucous membranes
- SLE (connective tissue disease)
- hives or angioedema (local swelling that appears periodically)
- diseases that result in an increased tendency to bleed
- hepatic porphyria (metabolic disease)

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

Elderly persons should be aware of the greater risk of side effects that comes with increasing age.

Serious skin reactions have been reported very rarely in association with the use of NSAIDs. Stop using Dicuno if you get any skin rash or mucous membrane lesions and contact a doctor. During varicella it is advisable to avoid use of this drug.

Stop taking Dicuno and contact a doctor immediately if you develop any of the following symptoms (angioedema): swelling of the face, tongue or throat, difficulties in swallowing, hives and difficulties in breathing.

Medicines like Dicuno may entail an increased risk of heart attack or stroke. This increased risk is more likely when using high doses and in long-term treatment. Do not exceed the recommended dose or treatment time.

Stomach bleeding can occur at any time during treatment with or without warning symptoms. This generally has more serious consequences in elderly patients. If you get gastrointestinal problems or

notice signs of bleeding in the gastrointestinal tract such as blood in stool, black tarry stool or vomiting blood, discontinue to take Dicuno and seek advice from a doctor.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Dicuno, as Dicuno can sometimes worsen wound healing in your gut after surgery.

Prolonged use of any type of painkiller for headaches can make the headache worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued.

Like other anti-inflammatory agents, Dicuno can mask the signs or symptoms of infection.

Dicuno may cause a reduction in the number of white blood cells and your resistance to infection may be decreased. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about your medicine.

### **Other medicines and Dicuno**

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

Certain medicines may be affected by treatment with Dicuno, for example:

- medicines against blood clots (warfarin, ticlopidine, acetylsalicylic acid, heparin etc.)
- methotrexate (medicine used against tumours and disturbances of the immune system)
- medicines for treating diabetes, except for insulin
- lithium (used for manic depression)
- SSRIs (used for depression)
- digoxin (used for heart problems)
- tacrolimus (used in transplantations and eczema)
- cyclosporin (used during transplantations, for severe psoriasis and for rheumatism)
- certain medicines for high blood pressure (beta-blockers, angiotensin II receptor antagonists and ACE inhibitors)
- diuretics (agents to stimulate urine production, and used against high blood pressure)
- quinolone antibiotics (used for urinary tract infection)
- zidovudine (used in the treatment of HIV infection)
- corticosteroids (used to treat inflammatory diseases)
- colestipol or cholestyramine (used to treat high levels of blood fat). These medicines can be used together with Dicuno if they are taken several hours apart.
- fluconazole (used for fungal infections)
- rifampicin (an antibiotic used for tuberculosis)
- carbamazepine (used for epilepsy)
- barbiturates (sleeping agents)
- diazepam (a sedative)
- pentoxifylline (an agent to dilate blood vessels)
- phenytoin (used for epilepsy)

Never take several different pain-relief medicines at the same time without first consulting your doctor or pharmacist.

### **Pregnancy, breast-feeding and fertility**

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

Do not take Dicuno 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 Dicuno 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, Dicuno 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.

#### Breast-feeding

Diclofenac passes into the breast milk. Therefore, Dicuno should not be administered during breast-feeding in order to avoid undesirable effects in the infant.

#### Fertility

Diclofenac 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 to become pregnant.

#### **Driving and using machines**

If you experience dizziness, drowsiness, fatigue or visual disturbances while taking Dicuno, you should refrain from driving or operating machinery.

#### **Dicuno contains Ponceau 4R aluminium lake (E 124)**

Dicuno 50 mg tablets contain colouring agent Ponceau 4R aluminium lake (E 124) that may cause allergic reactions.

### **3. How to take Dicuno**

#### *OTC only:*

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

#### *POM only:*

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

#### *Mild and moderate pain conditions*

Adults (18 years and older): the usual dose is 25-50 mg up to 3 times daily. The maximum recommended daily dose is 150 mg.

#### *Migraine headache*

Adults (18 years and older): 50 mg should be taken at the first signs of migraine headache. In cases where relief 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4-6 hours, not exceeding a total dose of 150 mg per day.

The tablets are to be taken with fluid. The tablets should not be taken with a meal or directly after a meal. The tablets can be divided into equal doses.

Dicuno should not be given to children and adolescents under 18 years of age.

#### **If you take more Dicuno than you should**

If you have taken more Dicuno than you should, or if children have been taking medicine by accident, please contact your doctor or the hospital to get an opinion of the risk and advice on action to be taken.

Overdose symptoms include nausea, vomiting, epigastric pain, gastrointestinal haemorrhage, diarrhoea, dizziness, somnolence, headache, tinnitus, anxiety, hallucinations, convulsions (in children also myoclonic seizures), unconsciousness effects in the kidneys and in the liver, possibly also body producing too much acid (metabolic acidosis), and tendency to swellings. Further, low blood pressure, depression of breathing, and blue skin and lips might occur.

**If you forget to take Dicuno**

Do not take 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.

**Some side effects can be serious**

Stop taking Dicuno and seek immediate medical help if you suffer from any of the following

- Agranulocytosis (symptoms: fever, sore throat, painful mouth ulcers, anal ulcers, reduced immune response, prone to bacterial infections).
- Stevens-Johnson syndrome and toxic epidermal necrolysis (Life-threatening skin diseases that cause rash, skin peeling, and sores on the mucous membranes).
- Hypersensitivity reactions (narrowing and obstruction of the respiratory airway, hives, allergic shock reaction with a fall in blood pressure).
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- You should stop taking Dicuno and see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx, difficulty to swallow, hives, and difficulties to breathe.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Dicuno 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 side effects that may occur**

Common (may affect up to 1 in 10 people):

- abdominal pain
- nausea
- vomiting
- diarrhoea
- digestive problems
- reduced appetite
- excessive gas
- headache
- dizziness
- vertigo
- rash
- raised liver values

Rare (may affect up to 1 in 1,000 people):

- tiredness
- asthma (with shortness of breath, breathlessness)
- gastritis, bleeding or ulcers in the gastrointestinal tract (which may include blood in feces or vomit)
- liver function disorders (including liver inflammation with or without yellowing of the skin)
- eczema, redness of the skin
- swelling of the body as a result of fluid retention

Very rare (may affect up to 1 in 10,000 people):

- bullous skin reactions reduction of certain blood cells (red blood cells, platelets and neutrophils)
- disorientation, depression, insomnia, nightmares, irritability, disturbed sense of reality
- sensation of burning or pricking of the skin with no apparent physical cause (paresthesia), memory impairment, convulsion, anxiety, uncontrolled muscle movements (tremor), taste disturbances, cerebrovascular accident
- effects on vision (blurred vision, double vision) and hearing (reduced hearing, tinnitus)
- effects on the heart and blood vessels (such as palpitations, chest pain, cardiac failure, myocardial infarction)
- high blood pressure
- inflammation of the blood vessels
- inflammation of the lungs
- problems with the large intestine, constipation, inflammation of the tongue, mouth or gullet
- inflammation of pancreas
- inflammation of the brain membrane (meningitis)
- acute liver failure
- hair loss
- hypersensitivity to light
- acute kidney failure
- effects on the kidneys (which may lead to reduction or stoppage in urine production and blood in the urine)

Exceptional serious infections of the skin in case of varicella.

### **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 via **the national reporting system** listed in [Appendix V](#).<sup>\*</sup> By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store dicuno**

Store below 25°C.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

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 further information**

### **What Dicuno contains**

The active substance is 25 mg or 50 mg diclofenac potassium.

The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate dihydrate, pregelatinized starch (maize), croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, polyvinyl alcohol, macrogol, talc, titanium dioxide (E 171), red iron oxide (E 172) and yellow iron oxide (E 172).

Dicuno 25 mg contains also black iron oxide (E 172).

Dicuno 50 mg contains also ponceau 4R aluminium lake (E 124).

### **What Dicuno looks like and contents of the pack**

What Dicuno tablets look like:

Dicuno 25 mg: Tablets are light red, round and convex with a score on one side. Diameter is 8 mm.  
Dicuno 50 mg: Tablets are reddish-brown, round and convex with a score line on one side. Diameter is 10 mm.

Pack sizes:

Dicuno 25 mg: 10, 20, 30, 50 and 100 tablets.

Dicuno 50 mg: 30, 50 and 100 tablets.

**Marketing Authorisation Holder and Manufacturer**

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

Dicuno 25 mg (CZ, DK, EE, FI, LT, LV, NO, SE, SI, SK)

Diclotin 25 mg (DE)

Diclomax 25 mg (PL)

Dicuno 50 mg (CZ, DK, EE, FI, LT, LV, NO, PL, SE, SI, SK)

Diclotin 50 mg (DE)

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