

## Package Leaflet: Information for the User

### Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg diclofenac sodium/omeprazole

**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, please 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 Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg is and what it is used for
2. What you need to know before you take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg
3. How to take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg
4. Possible side effects
5. How to store Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg
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#### 1. What Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg is and what it is used for

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg contains two active ingredients in a single capsule. These active ingredients are diclofenac sodium (75 mg) and omeprazole (20 mg).

Diclofenac is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and is used to reduce pain and inflammation of joint disorders.

Omeprazole belongs to a group of medicines called 'proton pump inhibitors' which reduce the amount of acid that your stomach produces. Omeprazole reduces the risk of developing peptic ulcers (ulcers in your stomach or duodenum) caused by non-steroidal anti-inflammatory drugs (NSAIDs).

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg has been prescribed for you because you have symptoms caused by a joint disorder such as osteoarthritis, rheumatoid arthritis or ankylosing spondylitis. In addition, you may be at risk of developing peptic ulcers when taking (NSAIDs).

#### 2. What you need to know before you take Diclofenac / Omeprazole, 75 mg / 20 mg

##### Do not take the capsules

- if you are allergic to diclofenac, omeprazole or any of the other ingredients of this medicine (listed in section 6).
- if you have had an allergic reaction to ibuprofen, aspirin or other NSAIDs.
- if you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you have severe liver, kidney or heart failure
- if you are in the last three months of pregnancy
- if you are taking a medicine containing nelfinavir (used for HIV infection)
- if you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer or bowel perforation
- if you have now, or have even had, bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)

- 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)

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 think any of these apply to you, or you are unsure, do not take the capsules. Talk to your doctor first and follow the advice given.

### **Warnings and precautions**

Talk to your doctor before taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg if you are also taking other NSAIDs, as Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg should not be used at the same time as other NSAIDs.

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg may hide the symptoms of other diseases or make them worse. Therefore, if any of the following happen to you before you start taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg or while you are taking it, talk to your doctor straight away:

- You have asthma, hayfever or other allergies, polyps in your nose, difficulty breathing (COPD), long term respiratory infections.
- You suffer from Crohn's disease or ulcerative colitis.
- You have SLE (Systemic Lupus Erythematosus), an inflammation of the connective tissue.
- You have heart, kidney or liver problems (your doctor may want to carry out some tests while you are taking the capsules).
- You have high blood pressure.
- You have blood clotting problems.
- You lose a lot of weight for no reason or have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.

Tell your doctor if you are about to have major surgery.

Because Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg contains a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

Medicines such as Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg 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.

If you have heart problems, previously 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 take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Talk to your doctor before taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg if you have ever had a skin reaction after treatment with a medicine similar to Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg, or other medicine that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg. Remember to also mention any other ill-effects like pain in your joints.

Tell your doctor before taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg, if you are due to have a specific blood test (Chromogranin A).

**Other medicines and Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg can affect the way some medicines work and some medicines can have an effect on Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg.

Do not take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Other painkillers or anti-inflammatory drugs (NSAIDs), including aspirin, or any other medicines used to prevent platelet clumping
- Medicines to lower blood pressure (anti-hypertensives)
- Anti-diabetic tablets
- Certain antibiotics, such as ciprofloxacin
- Ciclosporin or tacrolimus (immunosuppressive medicines, used to dampen down the body's immune reactions)
- Corticosteroids
- Mifepristone (for early termination of pregnancy)
- Heart drugs, such as digoxin
- Medicines used to treat heart conditions or high blood pressure, for example betablockers or ACE inhibitors.
- Diuretics ("water tablets"), including the potassium-sparing type
- Lithium (a medicine used to treat mood swings and some types of depression)
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat some types of depression)
- Methotrexate (a medicine used to treat arthritis and some types of cancer)
- Zidovudine (used to treat HIV infection)
- Colestipol or cholestyramine (medicines used to lower cholesterol levels)
- Sulfinpyrazone (used to treat gout)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Diclofenac / Omeprazole modified-release capsules, hard 75 mg / 20 mg
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat transient pain or fatigue in the muscles of the lower leg)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer)
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Clarithromycin (a medicine used to treat bacterial infections)

**Children**

These capsules are not suitable for children.

### **Elderly patients**

If you are elderly, your doctor may want to monitor you carefully while you are taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg.

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

Tell your doctor before taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg if you are pregnant or breast feeding. As with other non-steroidal anti-inflammatory drugs, Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg 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.

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg must not be taken during the last three months of pregnancy (see "Do not take the capsules" above). It is not usually recommended at other stages of pregnancy, but you may be able to take it if your doctor advises that it is necessary for you.

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg should be avoided if you are breast feeding, as small amounts of the medicine may pass into breast milk.

### **Driving and using machines**

These capsules can cause some people to feel dizzy or giddy, drowsy or sleepy, tired or have problems with their vision. If you are affected, do NOT drive or operate machinery.

## **3. How to take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg**

Always take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg daily. If your symptoms are not controlled by a once daily dosing, please talk to your doctor. Never take more than one capsule of Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg per day as this could increase the risk of side-effects.

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg must be swallowed whole with a drink of water (about half a glass). Do not chew or break open the capsules. The capsules are best taken with or after food. It may help you to remember to take your capsules if you take them at the same time every day, perhaps with breakfast or an evening meal.

Tell your doctor if you have any concerns about your treatment.

### **If you take more Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg than you should**

If you take more capsules than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

### **If you forget to take Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg**

Do not take a double dose to make up for a forgotten dose.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Taking this medicine for the shortest possible time will minimise side effects.

Some side effects can be serious. Stop taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg and tell your doctor immediately if you notice any of the following symptoms:

### **Symptoms caused by Diclofenac**

- Passing blood in your faeces (stools/motions)
- Bleeding from the stomach or intestines (e.g. passing black „tarry“ stools)

- Vomiting blood or dark particles that look like coffee grounds
- Stomach pains or other abnormal stomach symptoms
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg 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)
- Indigestion or heartburn
- Allergic reactions, which can include sudden wheeziness, difficulty in breathing, swelling of the face, lips, hand or fingers, skin rash, itching, bruising, painful red areas, peeling or blistering.

### Symptoms caused by Omeprazole

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with painful red areas, blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Your doctor may require you to have occasional check-ups while you are taking Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg.

Other side effects caused by Diclofenac include:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data.

Common side effects:

- Headache, dizziness and giddiness.
- Sickness, feeling sick, flatulence, diarrhoea, loss of appetite.
- Stomach pains or other abnormal stomach symptoms, indigestion or heartburn.
- Changes in blood tests that check how the liver is working.
- Rash.

Rare side effects:

- Allergic reactions, including sudden wheeziness, difficulty in breathing, swelling of the face, lips, tongue, hands or fingers, skin rash, itching, bruising, painful red areas, peeling or blistering. Problems swallowing.
- Tiredness, sleepiness.
- Blood in your faeces, bleeding from the stomach or intestines (e.g. passing black „tarry“ stools).
- Vomiting blood or dark particles that look like coffee grounds.
- Stomach ulcer or duodenal ulcer.
- Liver problems, jaundice (yellowing of the skin or whites of the eyes).
- Rashes and spots (urticaria).
- Perforation of the stomach or bowel (gastrointestinal perforation).

Very rare side effects:

- Anaemia.
- Depression, disorientation, insomnia, irritability, mood changes, nightmares.
- Memory problems, pins and needles.
- Stiff neck which could be a sign of meningitis.
- Confusion, hallucinations, feeling unwell.
- Changes in taste, tremor, fits, anxiety.
- Blurred vision, double vision.
- Impaired hearing, tinnitus (ringing in the ears).

- Worsening of Crohn’s disease or of ulcerative colitis.
- Constipation (including blockages).
- Oesophageal disorders.
- Inflammation of the pancreas.
- Sensitivity to light, skin rashes, blisters on the skin and sore mouth/eyes, flaky skin, eczema and unusual bruising, hair loss.
- Kidney problems, urinary problems (e.g. change in the usual amount or colour of the urine).
- Decrease in the number of white blood cells (leucopenia)
- Inflammation of the lung tissue (pneumonitis)

Other effects:

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

Other side effects reported in association with non-steroidal anti-inflammatory drugs include swelling caused by a build-up of fluid (known as oedema), high blood pressure, palpitations, chest pain and heart failure.

Other side effects caused by Omeprazole include:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data.

Common side effects:

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach.

Uncommon side effects:

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.
- Abnormal liver blood tests.
- Fracture of hip, wrist or spine.

Rare side effects:

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.

- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects:

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.

Not known

- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.
- If you are on Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Other effects:

Omeprazole may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

### **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 [to be completed nationally].

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

### **5. How to store Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg**

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

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

HDPE Bottle/Blister: Do not store above 30 °C.

HDPE Bottle:

Shelf life after first opening: 1 month

Store in the original package. Keep the bottle tightly closed in order to protect from moisture.

Blister:

Store this blister in the original package in order to protect from moisture.

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 Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg contain**

The active substances are diclofenac sodium and omeprazole.

Each modified-release capsule, hard contains 75 mg diclofenac sodium and 20 mg omeprazole.

The other ingredients are:

Capsules content:

Microcrystalline cellulose, Povidone K 25, Colloidal anhydrous silica, Methacrylic acid ethyl acrylate copolymer (1:1), Type A, neutralized with (6 mol%) sodium hydroxide, Propylene glycol, Ammonio methacrylate copolymer type A, Ammonio methacrylate copolymer type B, Mannitol, Magnesium carbonate heavy, Hydroxypropylcellulose (75-150 mPas/5% sol.), Sodium laurilsulfate, Hypromellose (6mPas), Methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30% (dry substance), Polysorbate 80 Triethyl citrate, Talc,

Capsules shell:

Titanium dioxide (E171), Iron oxide red E 172, Iron oxide yellow E 172, Gelatin

### **What Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg looks like and contents of the pack**

Diclofenac / Omeprazole modified-release capsules, hard, 75 mg / 20 mg are elongated hard gelatin capsules with pink opaque cap and yellow opaque body, filled with white to light yellow pellets.

### **Pack sizes**

HDPE bottles: 30 modified-release capsules, hard

Blister: 10, 20, 30, 50, 60, 100 modified-release capsules, hard

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Pharmaswiss Česká republika s.r.o.  
Jankovcova 1569/2c  
170 00 Praha 7  
Czech Republic

#### **Manufacturer:**

C.P.M. ContractPharma GmbH & Co. KG  
Frühlingstr. 7  
83620 Feldkirchen-Westerham  
Germany

Haupt Pharma Amareg GmbH  
Donaustauf Straße 378  
93055 Regensburg  
Germany

Swiss Caps GmbH  
Grassingerstrasse 9  
83043 Bad Aibling  
Germany

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

Bulgaria	ДИКЛОПРАМ 75 mg / 20 mg твърди капсули с изменено освобождаване
Cyprus	DICLODUO COMBI 75 mg / 20 mg, καψάκιο ελεγχόμενης αποδέσμευσης σκληρό
Estonia	DICLOPRAM

Greece	DICLODUO COMBI 75 mg / 20 mg, καψάκιο ελεγχόμενης αποδέσμευσης σκληρό
Hungary	DICLOPRAM 75 mg / 20 mg módosított hatóanyagleadású kemény kapszula
Latvia	DIOMPRAZ 75 mg / 20 mg ilgstošās darbības cietās kapsulas
Lithuania	DIOMPRAZ 75/20 mg modifikuoto atpalaidavimo kietosios kapsulės
Malta	DICLODUO COMBI 75 mg / 20 mg, modified-release hard capsules
Poland	DICLODUO COMBI
Romania	DICLOPRAM 75 mg / 20 mg capsule cu eliberare modificată
Slovakia	DIOMPRAZ 75 mg /20 mg tvrdé kapsuly s riadeným uvoľňovaním
Slovenia	Diklofenak/omeprazol PharmaSwiss 75 mg/20 mg trde kapsule s prirejenim sproščanjem
United Kingdom	DICLOPRAM 75 mg / 20 mg modified-release hard capsules

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