Package Leaflet: information for the user

Dicloduo Combi capsules modified release, 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, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg is and what it is used for

Dicloduo Combi capsules modified release, 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).

Dicloduo Combi capsules modified release, 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, modified-release capsules, hard, 75 mg / 20 mg

Do not take the capsules

- if you think you may be allergic or if you are allergic to diclofenac sodium, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Dicloduo Combi capsules modified release, 75 mg / 20 mg (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 are allergic to medicines containing other proton pump inhibitors (e.g. 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.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before taking Dicloduo Combi capsules modified release, 75 mg / 20 mg, as Dicloduo Combi capsules modified release, 75 mg / 20 mg can sometimes worsen wound healing in your gut after surgery.

Warnings and precautions
Talk to your doctor before taking Dicloduo Combi capsules modified release, 75 mg / 20 mg if you are also taking other NSAIDs, as Dicloduo Combi capsules modified release, 75 mg / 20 mg should not be used at the same time as other NSAIDs.

Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg or while you are taking it, talk to your doctor straight away:

- you have asthma, hay fever 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg contains a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

Medicines such as Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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).

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Talk to your doctor before taking Dicloduo Combi capsules modified release, 75 mg / 20 mg if you have ever had a skin reaction after treatment with a medicine similar to Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg. Remember to also mention any other ill-effects like pain in your joints.

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

Other medicines and Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg can affect the way some medicines work and some medicines can have an effect on Dicloduo Combi capsules modified release, 75 mg / 20 mg.

Do not take Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg.

Pregnancy, breast feeding and fertility
Tell your doctor before taking Dicloduo Combi capsules modified release, 75 mg / 20 mg if you are pregnant or breast feeding. As with other non-steroidal anti-inflammatory drugs, Dicloduo Combi capsules modified release, 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.

Do not take Dicloduo Combi capsules modified release, 75 mg / 20 mg 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg 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, Dicloduo Combi capsules modified release, 75 mg / 20 mg 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.
Dicloduo Combi capsules modified release, 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.

The product contains propylene glycol and sodium The product contains 1.0 mg propylene glycol per capsule.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Dicloduo Combi capsules modified release, 75 mg / 20 mg

Always take Dicloduo Combi capsules modified release, 75 mg / 20 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one capsule of Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg per day as this could increase the risk of side-effects.

Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg and tell your doctor immediately if you notice any of the following symptoms:

Symptoms caused by Diclofenac

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- 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 Dicloduo Combi capsules modified release, 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 kips, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal .
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 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 Dicloduo Combi capsules modified release, 75 mg / 20 mg looks like and contents of the pack
Dicloduo Combi capsules modified release, 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:

Bausch Health Ireland Limited,
3013 Lake Drive,
Citywest Business Campus, Dublin, Ireland

Manufacturer:

HDPE bottles:
Haupt Pharma Amareg GmbH
Donaustauf Straße 378
93055 Regensburg
Germany

Blister:
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
Slovakia	DIOMPRAZ 75 mg /20 mg tvrdé kapsuly s riadeným uvoľňovaním

This leaflet was last revised in December 2024.