Package leaflet

Package Leaflet: Information for the User

Ceclova 75 mg / 20 mg modified-release hard capsules
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 Ceclova 75 mg / 20 mg is and what it is used for

Ceclova has been prescribed for you to relieve the pain and swelling caused by rheumatoid arthritis, osteoarthritis or ankylosing spondylitis and it may help to protect against the risk of irritation or ulceration of the stomach or intestines.

Ceclova is indicated in adults who have already been treated with the combination of diclofenac and omeprazole as separate tablets with the same strength as Ceclova.

Ceclova contains two active substances in a single capsule, diclofenac sodium (75 mg) and omeprazole (20 mg):

- Diclofenac belongs to a group of medicinal products called Non-Steroidal Anti-Inflammatory drugs (NSAIDs) which are used to reduce pain and inflammation of joint disorders. Although diclofenac relieves the pain and inflammation, it can also reduce the amount of natural protective substances called prostaglandins in the stomach or duodenum (peptic ulcers).

- 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 caused by NSAIDs.

2. What you need to know before you take Ceclova

Do not take the capsules

- you think you may be allergic to diclofenac sodium, omeprazole, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Ceclova. (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 or kidney failure
- if you have severe heart failure
- if you are in the last three months of pregnancy (see section "Pregnancy, breast feeding and fertility")
- if you are taking a medicine containing nelfinavir (used for HIV infection)
- if you have now, or have a history of a recurrent stomach ulcer or duodenal ulcer, bleeding or perforation
- if you have a history of gastrointestinal bleeding or perforation related to previous use of painkillers (NSAIDs) (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)
- if you have an increased tendency to bleeding

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

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 or pharmacist before taking Ceclova if you are also taking other NSAIDs as Ceclova should not be used at the same time as other NSAIDs.

Ceclova may hide the symptoms of other diseases or make them worse. Therefore, if any of the following are applicable for you before you start taking Ceclova or while you are taking it, talk to your doctor straight away:

- You have asthma, hayfever or other allergies, polyps in your nose, pulmonary disease (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 will want to monitor you regularly to make sure that Ceclova is suitable for you).
- You have angina, blood clots or high blood pressure.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.
- You have ever had a skin reaction after treatment with a medicine similar to omeprazole that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).
- You have a disease called acute porphyria which may cause stomach problems and discolouration of the urine.

Make sure your doctor knows, before you are given Ceclova:
- If you smoke

- If you have diabetes
- If you have raised cholesterol or raised triglycerides

As with other anti-inflammatory agents, allergic reactions, including anaphylactic reactions can occur in rare cases with Ceclova without earlier exposure to the active ingredients.

Serious skin reactions have been reported very rarely in association with the use of NSAIDs. If you get a rash on your skin (especially in areas exposed to the sun) or any other sign of hypersensitivity reaction stop your treatment with Ceclova and tell your doctor as soon as possible. Remember to also mention any other ill-effects like pain in your joints.

Side effects may be minimised by using Ceclova for the shortest duration necessary.

If you get gastrointestinal problems, stop taking Ceclova and seek advice from a doctor.

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

Because Ceclova contains a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

Medicines such as Ceclova 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 need to take Ceclova on a long-term basis your doctor may need to keep you under regular surveillance and carry out blood tests to make sure that Ceclova is still suitable for you. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking medicines containing omeprazole, 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).

Elderly patients
Elderly persons should be aware of the greater risk of side effects that come with increasing age. If you are elderly, your doctor may want to monitor you carefully while you are taking Ceclova.

Children and adolescents
These capsules are not suitable for children and adolescents, 18 years or younger.

Other medicines and Ceclova
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 Ceclova can affect the way some medicines work and some medicines can have an effect on Ceclova.

Do not take Ceclova 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 acetylsalicylic acid, or any other medicines used to prevent platelet clumping
- Diuretics and other 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.
- 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 Ceclova
- 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 Ceclova
- 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)

Pregnancy, breast feeding and fertility
Tell your doctor before taking Ceclova if you are pregnant or breast feeding. As with other non-steroidal anti-inflammatory drugs, Ceclova 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.

Ceclova 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 absolutely necessary for you.

Ceclova 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 Ceclova
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 capsule daily. If your symptoms are not controlled by a once daily dosing, please talk to your doctor. Never take more than 1 capsule per day as this leads to overexposure of the active substance omeprazole and increases the risk of side-effects.

The capsules must be swallowed whole with a drink of water (about half a glass). Do not chew or break open Ceclova. The capsules should preferably be taken with or just 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.

If you take more Ceclova 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 Ceclova
Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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 Ceclova and tell your doctor immediately if you notice any of the following symptoms:

Common (may affect up to 1 in 10 people):
- Stomach pains or other abnormal stomach symptoms, indigestion or heartburn.

Rare (may affect up to 1 in 1,000 people):
- Severe allergic reactions, which can include sudden wheeziness, difficulty in swallowing and breathing, swelling of the face, lips, tongue, throat, hand or fingers, skin rash, itching, bruising, painful red areas, peeling or blistering.
- Passing blood in your faeces (stools/motions), passing black "tarry" stools which may be signs of bleeding from the stomach or intestines
- Vomiting blood or dark particles that look like coffee grounds
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Very rare (may affect up to 1 in 10,000 people):
- 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'.
- Ceclova 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.

Not known (frequency cannot be estimated from the available data)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Your doctor may require you to have occasional check-ups while you are taking Ceclova.

<u>Other side effects:</u>

Common side effects (may affect up to 1 in 10 people):
- Headache, dizziness and giddiness.
- Being sick (vomiting), feeling sick (nausea), flatulence, diarrhoea, loss of appetite.
- Constipation, wind (flatulence).
- Changes in blood tests that check how the liver is working.

- Rash.
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people):
- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Skin rash, lumpy rash (hives) and itchy skin.
- Feeling unwell and lacking energy.
- Fracture of hip, wrist and spine.

Rare side effects (may affect up to 1 in 1,000 people):
- Tiredness.
- Stomach ulcer or duodenal ulcer.
- Rashes and spots (urticaria).
- Perforation of the stomach or bowel (gastrointestinal perforation).
- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- 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.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Increased sweating.
- Joint pains (arthralgia), muscle pains (myalgia)
- Severe kidney problems (intestinal nephritis)

Very rare side effects (may affect up to 1 in 10,000 people):
- Anaemia.
- Disorientation, irritability, mood changes, nightmares.
- Memory problems, pins and needles.
- Stiff neck which could be a sign of meningitis.
- Seeing, felling or hearing things that are not there (hallucinations).
- Tremor, fits, anxiety.
- 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.
- Urinary problems (e.g. change in the usual amount or colour of the urine).
- Decrease in the number of white blood cells (leucopenia) including agranulocytosis
- Inflammation of the lung tissue (pneumonitis)
- Aggression.

- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints
- If you are on Ceclova 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.

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.

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ceclova
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.

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 Ceclova contains
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, Colloidal anhydrous silica, Methacrylic acid ethyl acrylate copolymer (1:1), Type A, Propylene glycol, Ammonio methacrylate copolymer type A, Ammonio

methacrylate copolymer type B, Mannitol, Magnesium carbonate heavy, Hydroxypropylcellulose, Sodium laurilsulfate, Hypromellose, Polysorbate 80 Triethyl citrate, Talc,
Capsules shell:
Titanium dioxide E171, Iron oxide red E 172, Iron oxide yellow E 172, Gelatin

What Ceclova looks like and contents of the pack
Ceclova 75 mg / 20 mg are elongated 21.5 mm x 6.9 mm 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 hard capsules
Blister: 10, 20, 30, 50, 60, 100 modified-release hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Aenova IP GmbH
Temmlerstrasse 2
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Manufacturer
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Haupt Pharma Amareg GmbH
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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Napradiol 75 mg / 20 mg gélules à libération modifiée
Finland	Diotem 75 mg / 20 mg Säädellysti vapauttava kapseli, kova
Ireland	Ceclova 75 mg / 20 mg modified-release hard capsules
Luxembourg	Diotem 75 mg / 20 mg Hartkapseln mit veränderter Wirkstofffreisetzung
Sweden	Diotem 75 mg / 20 mg kapslar med modifierad frisättning, hård
United Kingdom	Napradiol 75 mg / 20 mg modified-release hard capsules

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