

Package leaflet: Information for the patient

Edolfen Dual Action 200 mg/500 mg film-coated tablets

ibuprofen / paracetamol

Read all of this leaflet carefully before you start taking this medicine 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 taking the medicine.
- **You should not take this medicine for longer than 3 days.**

What is in this leaflet

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

1. What Edolfen Dual Action is and what it is used for

The medicine is called Edolfen Dual Action.

Edolfen Dual Action contains two active substances (which make this medicine work). These are **ibuprofen and paracetamol**.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by reducing pain, reducing swelling and lowering high body temperatures. Paracetamol is an analgesic which, acting differently to ibuprofen, relieves pain and fever.

Edolfen Dual Action is used for the temporary relief of mild to moderate pain associated with migraine, headache, backache, menstrual pain, toothache, rheumatic pain, muscular pain, pain associated with mild forms of arthritis, cold and flu, sore throat or fever.

2. What you need to know before you take Edolfen Dual Action

Do not take Edolfen Dual Action

- if you are taking **any other product containing paracetamol**.

- if you are taking **any other painkillers**, such as **ibuprofen, high-dose acetylsalicylic acid** (above 75 mg daily) or other **non-steroidal anti-inflammatory drugs (NSAIDs)** including cyclooxygenase-2 (COX-2) inhibitors.
- if you are **allergic to ibuprofen, paracetamol** or any of the other ingredients of Edolfen Dual Action (listed in section 6).
- if you are **allergic to acetylsalicylic acid or other NSAIDs**.
- if you currently have or have had **ulceration or bleeding in the stomach or duodenum** (small intestine).
- if you have a **blood coagulation disorder**.
- if you have **heart, liver or kidney failure**.
- if you are in **the last 3 months of pregnancy**.
- if you are **below 18 years of age**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Edolfen Dual Action:

- if you are **elderly**.
- if you have **asthma** or a history of asthma.
- if you have **kidney, heart, liver or bowel problems**.
- if you have **Systemic Lupus Erythematosus (SLE)**, an autoimmune disease affecting the connective tissue, causing joint pain, skin lesions, and organ dysfunction; or other **mixed connective tissue disorders**.
- if you have **gastrointestinal disorder or chronic inflammatory bowel disease (e.g. ulcerative colitis, Crohn's disease)**.
- if you are in **the first 6 months of pregnancy** or are **breastfeeding**.
- if you are **planning to become pregnant**.

Taking anti-inflammatory/analgesic medicines such as ibuprofen may be associated with a small increase in the risk of heart attack or stroke, particularly when taken in high doses. Do not exceed the recommended dose and duration of treatment.

Before taking Edolfen Dual Action, you should discuss your treatment with your doctor or pharmacist if:

- you have heart problems such as heart failure, angina pectoris (chest pain), have had a heart attack, have had bypass surgery, have peripheral artery disease (poor blood circulation in the legs due to narrowing or blockage of the arteries), or have had any kind of stroke (including mini-stroke or transient ischemic attack - TIA).
- you have high blood pressure, diabetes, high cholesterol, a family history of heart disease or stroke, or if you are a smoker.

Other medicines and Edolfen Dual Action

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

Do not take Edolfen Dual Action:

- concomitantly with other **paracetamol containing** medicines.
- **with other NSAIDs**, such as aspirin or ibuprofen.

Special care is required as some medicines may interact with Edolfen Dual Action, such as:

- corticosteroid tablets.
- **antibiotics** (such as chloramphenicol or quinolones).
- **antiemetics** (such as metoclopramide, domperidone).
- **heart-stimulating medicines** (such as glycosides).
- medicine used in **patients with high cholesterol levels** (such as cholestyramine).
- **diuretics** (facilitating the excretion of excessive water).
- medicines that **suppress the immune response** (such as methotrexate, cyclosporine, tacrolimus).
- medicines used to treat **mania or depression** (such as lithium or SSRIs - selective serotonin reuptake inhibitors).
- **mifepristone** (a medicine that causes termination of pregnancy)
- medicine used to **treat HIV** (such as zidovudine).

Edolfen Dual Action may affect or be affected by the action of other medicines.

For example:

- anticoagulants (blood thinners/anti-clotting agents such as aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- medicines that lower blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol, angiotensin II receptor antagonists such as losartan).

Some other medicines may also affect or be affected by the treatment of Edolfen Dual Action. Therefore, always consult with your doctor or pharmacist before taking Edolfen Dual Action with other medicines.

Edolfen Dual Action with food, drink and alcohol

To reduce the risk of undesirable effects, Edolfen Dual Action should be taken with food.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Edolfen Dual Action in the last 3 months of pregnancy. Take special care in the first 6 months of pregnancy.

Edolfen Dual Action may cause difficulties in becoming pregnant. Ibuprofen belongs to a group of medicines that may adversely affect fertility in women. This effect is reversible after discontinuation of the medicine. Tell your doctor if you are planning to become pregnant or if you are experiencing problems becoming pregnant.

3. How to take Edolfen Dual Action

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.

This medicine is for oral use and is intended for short-term use only.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. **Do not use Edolfen Dual Action for more than 3 days.** If your symptoms worsen or do not resolve, contact your doctor.

Adults: take 1 tablet **with food or drink**, up to 3 times daily.

Wait at least **6 hours between successive doses.**

If the symptoms do not resolve after taking one tablet, you can take a maximum of 2 tablets up to 3 times a day.

Do not take more than six tablets in 24 hours (the equivalent of 3,000 mg paracetamol and 1,200 mg ibuprofen in 24 hours).

Not for use by children under 18 years of age.

If you take more Edolfen Dual Action than you should

If you have taken more than the recommended dose of Edolfen Dual Action, or if your child has accidentally taken the medicine, you should always contact your doctor or go to the nearest hospital for an opinion on the possible health risks and advice on action to be taken.

The symptoms may include nausea, stomach pain, vomiting (traces of blood may be present), headache, ringing in the ears, confusion and nystagmus. Drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in the urine, feeling cold and breathing problems have occurred after a high dose.

If you forget to take Edolfen Dual Action

Do not use a double dose to make up for a missed dose. If you forget to take a dose, take it as soon as you remember it and then take the next dose at least 6 hours later.

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.

Stop taking the medicine and contact your doctor if you experience any of the following:

- **heartburn, indigestion.**
- **symptoms of gastrointestinal bleeding** (acute abdominal pain, vomit with blood or vomit containing dark-colored particles that resemble coffee grounds, blood in the stools, black tarry stools).
- **symptoms of meningitis** such as stiff neck, headache, malaise, fever, or a feeling of confusion.
- **symptoms of severe allergic reaction** (swelling of the face, tongue or throat, breathing difficulties, worsening of asthma).
- **severe skin reactions** known as DRESS syndrome (frequency unknown). Symptoms of DRESS syndrome include skin rash, fever, swollen lymph nodes and increased numbers of eosinophils (a type of white blood cell).

Other possible undesirable effects

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

- abdominal pain or malaise, nausea or vomiting, diarrhea.
- increased liver enzymes (in blood tests).

Uncommon (may affect up to 1 in 100 people):

- headache and dizziness, gas and constipation, rash, facial swelling.
- decreased number of red blood cells or increased number of platelets (blood cells involved in blood clotting).

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

- decreased blood cell count (manifested by sore throat, mouth ulceration, flu-like symptoms, severe fatigue, unexplained bleeding, bruising and nose bleeds).
- visual disturbances, tinnitus, confusion.
- confusion, depression, hallucinations.
- fatigue and bad mood.
- severe skin reactions including blistering.
- high blood pressure, water retention.
- liver problems (manifested by yellowing of the skin and whites of the eyes).
- kidney problems (with increased or decreased urination, swelling of the legs).
- heart problems (manifested by shortness of breath, swelling).

Medicines such as Edolfen Dual Action may be associated with a small increase in the risk of heart attack (“myocardial infarction”) or stroke (see section 2).

If any of the undesirable effects gets serious, or if you notice any undesirable effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Cyprus

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

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Fax: +357 22608669

Website: www.moh.gov.cy/phs

5. How to store Edolfen Dual Action

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

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

This medicine does not require any special temperature storage conditions. Keep the blisters in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Edolfen Dual Action contains

- The active substances are ibuprofen and paracetamol. Each film-coated tablet contains 200 mg ibuprofen and 500 mg paracetamol.

- The other ingredients are:

Tablet core: maize starch, crospovidone (E1202), silica colloidal anhydrous (E551), povidone (E1201), starch pregelatinised, talc (E553b), stearic acid.

Film-coating: poly(vinyl alcohol) (E1203), talc (E553b), macrogol 3350 (E1521), titanium dioxide (E171).

What Edolfen Dual Action looks like and contents of the pack

Edolfen Dual Action 200 mg/500 mg film-coated tablets are white to off-white, oval shaped, film-coated tablets with dimensions of 19.7 mm x 9.2 mm.

Pack sizes:

Cardboard box containing perforated Aluminium-PVC/PVDC blisters of 10 film-coated tablets.

Pack sizes of 10 or 20 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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