

Package leaflet: Information for the patient

Easolief DUO 500 mg/150 mg film-coated tablets

Paracetamol and Ibuprofen

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 has 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 should not take this product for longer than 3 days.**
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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1. What Easolief DUO 500 mg/150 mg film-coated tablets are and what they are used for

Easolief DUO 500 mg/150mg film-coated tablets contain paracetamol and ibuprofen.

Paracetamol works to stop the pain messages from getting through to the brain.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness).

Easolief DUO 500 mg/150mg film-coated tablets are used for short-term symptomatic treatment of mild to moderate pain.

Ask your doctor or pharmacist if you have any questions about this medicine.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Easolief DUO 500 mg/150 mg film-coated tablets

Do not take Easolief DUO 500 mg/150 mg film-coated tablets:

- if you are allergic to the active substance(s) or any of the other ingredients of this medicine (listed in section 6);
- if you have a history with gastrointestinal bleeding or perforation, related to previous NSAIDs therapy;
- you have an active or recurrent peptic ulcer (i.e. stomach or duodenal ulcer), or bleeding (two or more distinct episodes of proven ulceration or bleeding);
- if you regularly drink large quantities of alcohol
- if you have severe heart failure, hepatic failure or renal failure
- if you have cerebrovascular or other active bleeding
- if you have blood-formation disturbances
- if you have asthma, urticaria or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs
- during the last three months of pregnancy
- if you are under the age of 18 years

Warnings and precautions

Talk to your doctor or pharmacist before taking Easolief DUO 500 mg/150mg film-coated tablets.

Talk to your doctor or pharmacist if you have an infection - please see heading "Infections" below.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Easolief DUO 500 mg/150mg film-coated tablets if you:

- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Skin reactions

Serious skin reactions have been reported in association with Easolief DUO 500 mg/150mg film-coated tablets treatment. You should stop taking Easolief DUO 500 mg/150mg film-coated tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Infections

Easolief DUO 500 mg/150mg film-coated tablets may hide signs of infections such as fever and pain. It is therefore possible that Easolief DUO 500 mg/150mg film-coated tablets may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Tell your doctor or pharmacist if:

- you have liver disease, hepatitis, kidney disease or difficulty urinating;
- you are a drug user;
- you are pregnant or intend to become pregnant;
- you are breast-feeding or plan to breast-feed;
- you currently have an infection;
- you plan to have surgery;
- you have or have had other medical conditions including:
 - heartburn, indigestion, stomach ulcer or any other stomach problems;
 - vomiting blood or bleeding from back passage;
 - asthma;
 - vision problems;
 - tendency to bleed or other blood problems;
 - bowel or intestinal problems such as ulcerative colitis or Crohn’s Disease;
 - swelling of ankles or feet;
 - diarrhoea;
 - inherited genetic or acquired disorder of certain enzymes that manifest with either neurological complications or skin problems or occasionally both i.e. porphyria;
 - smallpox;
 - autoimmune disease such as Lupus erythematosus or other connective tissue disorders.

In order to avoid the risk of overdose,

- check that other medicines do not contain paracetamol,
- observe the maximum recommended doses (see section 3).

Do not drink alcoholic beverages when taking this medication. Combining alcohol with Easolief DUO 500 mg/150mg film-coated tablets may lead to liver damage.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

The prolonged use of analgesics can result in headache which must not be treated by increasing the dose of the medicine.

Taking this medicine may interfere with the results from the urine analysis test for 5-hydroxyindoleacetic acid (5HIAA), causing false-positive results. To avoid false results do not take this medicine or other paracetamol containing products for several hours before or during the collection of the urine specimen.

Children and adolescents

This product is contraindicated in children under 18 years.

Other medicines and Easolief DUO 500 mg/150 mg film-coated tablets

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

Easolief DUO 500 mg/150mg film-coated tablets may affect or be affected by some other medicines. For example:

- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- probenecid, a medicine used to treat gout
- zidovudine, a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease)
- medicines used to treat tuberculosis such as isoniazid
- salicylates or other NSAID medicines
- diuretics, also called fluid tablets
- lithium, a medicine used to treat some types of depression
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- metoclopramide, propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- cholestyramine, a medicine used to reduce raised serum lipid levels
- tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant
- sulphonylureas, a medicine used to treat diabetes
- some antibiotics (such as quinolone antibiotics or co-trimoxazole)
- cardiac glycosides, medicines to strengthen the heart.
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

Some other medicines may also affect or be affected by the treatment of Easolief DUO 500 mg/150mg film-coated tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Easolief DUO 500 mg/150mg film-coated tablets with other medicines.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

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.

Do not take Easolief DUO 500 mg/150mg film-coated tablets 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 Easolief DUO 500 mg/150mg film-coated tablets 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, Easolief DUO 500 mg/150mg film-coated tablets 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. This product may impair female fertility and is not recommended in women attempting to conceive.

Driving and using machines

Be careful driving or operating machines until you know how Easolief DUO 500 mg/150mg film-coated tablets affect you.

Easolief DUO 500 mg/150 mg film-coated tablets contain lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Easolief DUO 500 mg/150mg film-coated tablets contain sodium:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Easolief DUO 500 mg/150 mg film-coated tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **Do not take for more than 3 days.**

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

The recommended dose is:

Adults: The usual dosage is one (500 mg paracetamol and 150 mg ibuprofen) to two (1000 mg paracetamol and 300 mg ibuprofen) tablets taken every six hours, as required up to a maximum of six in 24 hours.

Use the lowest effective dose for the shortest time necessary to relieve symptoms. You should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

Do not take more than 6 tablets in a 24 hours period.

If your doctor prescribes a different dose, follow directions given by your doctor.

Take Easolief DUO 500 mg/150mg film-coated tablets with a full glass of water. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Use in children under 18 years

Easolief DUO 500 mg/150mg film-coated tablets are contraindicated in children under 18 years.

If you take more Easolief DUO 500 mg/150 mg film-coated tablets than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken more Easolief DUO 500 mg/150mg film-coated tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure

and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Easolief DUO 500 mg/150 mg film-coated tablets

If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally. Do not take a double dose to make up for a forgotten dose.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

If any of these serious side effects happen, stop taking Easolief DUO 500 mg/150mg film-coated tablets} and tell your doctor immediately or go to the emergency room at your nearest hospital:

Common:

- vomiting blood or material that looks like coffee grounds;
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea;
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing;

Very rare:

- asthma, wheezing, shortness of breath;
- sudden or severe itching, skin rash, hives;
- severe rash with blisters and bleeding in the lips, eyes, mouth, nose and genitals (Steven Johnson Syndrome). Very rare cases of serious skin reactions have been reported;
- worsening of existing severe skin infections (you may notice a rash, blistering and discolouration of the skin, fever, drowsiness, diarrhoea and sickness), or worsening of other infections including chicken pox or shingles or severe infection with destruction (necrosis) of subcutaneous tissue and muscle, blistering and peeling of the skin
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck.

Other possible side effects are:

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

- nausea or vomiting;
- loss of appetite;
- heartburn or pain the upper part of your stomach;
- cramps, wind, constipation or diarrhoea, slight gastrointestinal blood loss;
- skin rashes, itching of the skin;
- headache;
- dizziness;
- feeling of being nervous
- ringing or buzzing in the ears
- unusual weight gain, swelling and fluid retention, swelling of ankles or legs (oedema);

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

- decrease in red blood cells, nose bleed and heavier periods (menstrual bleeding);
- allergic reactions – skin rash, tiredness, joint pain (e.g. serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis, angioedema);
- enlargement of breast tissue in men; low blood sugar levels;
- sleeplessness;
- change in mood, for example depression, confusion, nervousness
- eye problems such as blurred vision (reversible), sore red eyes, itching;
- thickened mucus

- severe pain or tenderness in the stomach; peptic/gastrointestinal ulcer
- bowel inflammation and worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease) and complications of diverticula of the large bowel (perforation or fistula);
- inability to completely empty the bladder (urinary retention);
- abnormal laboratory test results (blood, liver and kidney enzyme test results);

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

- tingling of the hands and feet;
- abnormal dreams, seeing things (hallucinations);
- damage of the kidney tissue (particularly in long-term use);
- high level of uric acid in your blood (hyperuricemia)

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

- low potassium levels – weakness, fatigue, muscle cramps (hypokalaemia)
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale;
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin;
- severe or persistent headache;
- spinning sensation (vertigo);
- fast or irregular heartbeats, also called palpitations;
- increase in blood pressure and possible heart problems;
- inflammation of the oesophagus
- yellowing of the skin and /or eyes, also called jaundice;
- liver damage (particularly in long term use)
- loss of hair;
- increase in sweating;
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers.

Not known (frequency cannot be estimated from the available data):

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Easolief DUO 500 mg/150mg film-coated tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

The above list includes serious side effects that may require medical attention. Serious side effects are rare for low doses of this medicine and when used for a short period of 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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Easolief DUO 500 mg/150mg film-coated tablets

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

This medicinal product does not require any special temperature storage conditions. Store in the original blister package in order to protect from light.

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

Do not use this medicine if you notice packaging is torn or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. 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 Easolief DUO 500 mg/150mg film-coated tablets contain

The active substances are 500 mg paracetamol and 150 mg ibuprofen per tablet

The other ingredients for the tablet core are: maize starch, pregelatinised maize starch microcrystalline cellulose, croscarmellose sodium, magnesium stearate, talc and for the tablet coat: Opadry white (containing hypromellose (E464), lactose monohydrate (see section 2), titanium dioxide (E171), macrogol/PEG 4000 and, sodium citrate (E331)) and talc.

What Easolief DUO 500 mg/150mg film-coated tablets look like and contents of the pack

Easolief DUO 500 mg/150mg } film-coated tablets are white coloured, capsule shaped 19 mm in length film-coated tablets with break-line on one side and plain on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Each blister pack contains 8, 10, 16, 20, 24, 30 and 32, film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

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This medicine is authorised in the Member States of the European Economic Area under the following names:

AT: Combogesic 500 mg/150 mg Filmtabletten
CY: Duomax
DE: Paracetamol/Ibuprofen Acino 500 mg/150 mg Filmtabletten
EL: GOPAIN
HR: Combogesic 500 mg/150 mg filmom obložene tablete
IE: Easolief DUO 500 mg/150 mg film-coated tablets
LT: Adobil 500 mg/150 mg plėvele dengtos tabletės

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