

Dominar® 250 mg film-coated tablets

Clarithromycin

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. Even if their signs or illness are similar to yours. They may have allergies or other conditions.
- 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.

- fidaxomicin (antibiotic).
 - simeprevir (a drug used in the treatment of hepatitis C).
 - rivotrigol (medicine used in certain pulmonary hypertension).
 - tamsulosin (a drug used to treat prostate enlargement).
- (see section "Warnings and precautions")
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Dominar 250 mg film-coated tablets with food and drinks

Not applicable.

Pregnancy and breast feeding

Pregnancy

If it is best not to use this medicine during pregnancy.

If you discover that you are pregnant during treatment, consult your doctor because only him can judge the need to continue.

Breastfeeding

Breastfeeding is usually possible but you should stop breastfeeding or the drug if the newborn has digestive disorders.

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

Driving and using machines

The risk of dizziness, vertigo, confusion and disorientation, which may occur with clarithromycin, should be considered before driving or operating machinery.

Dominar 250mg/500mg film-coated tablet contains

1. How to take Dominar 250 mg film-coated tablets

Always take this medicine exactly as your doctor has told you. Talk with your doctor or pharmacist if in doubt.

Dosage

As an indication, in adults, the usual posology is 500 mg/day to 2000 mg/day, twice daily. It depends on the indication, the location of the infection, the germ involved and the weight of the patient.

The posology can be adapted in case of renal or hepatic insufficiency. If you have the impression that the effect of Dominar 250 mg film-coated tablets is too strong or too weak, talk to your doctor or pharmacist.

Administration mode

Oral route

Swallow the tablets with a glass of water.

Duration of treatment

To be effective, this antibiotic should be used regularly at the prescribed doses, and as long as your doctor has advised you. The disappearance of fever or any other symptom, does not mean that you are completely healed.

The possible impression of fatigue is not due to the antibiotic treatment but to the infection itself. Reducing or suspending your treatment would favour relapse.

Special case: the treatment duration of certain cases of sore throat is 5 to 7 days.

2. How to take Dominar 250 mg film-coated tablets but you should

Immediately consult your doctor or pharmacist if:

• If you forget to take Dominar 250mg film-coated tablets

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

• If you stop taking Dominar 250mg/500mg film-coated tablets

Not applicable.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for more information.

3. POSSIBLE SIDE EFFECTS?

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

Common side effects (may affect more than 1 to 10 people in 100).

Gastro-intestinal

• Taste disorder (dysgeusia), headache,

• Diarrhea, vomiting, difficult digestion (dyspepsia), nausea, stomach pain,

• abnormal liver function tests,

• rash, excessive sweating (hyperhidrosis).

Uncommon side effects (may affect more than 1 to 10 people in 1000):

• Allergic reaction due to a microscopic fungus (candidiasis), vaginal infection,

• Insufficient amount of white blood cells in the blood (leukopenia),

• Decrease of certain white blood cells (neutrophils) in the blood (neutropenia),

• excessive amounts of certain white blood cells (eosinophils) in the blood (eosinophilia),

• Allergy,

• Loss (anorexia) or decreased appetite,

• Anxiety,

• Dizziness, drowsiness, trembling,

• Dizziness, impaired hearing, buzzing (tinnitus),

• QT prolongation to the electrocardiogram, palpitations

• Inflammation of the stomach (gastritis), inflammation of the mouth (stomatitis), inflammation of the tongue (glossitis),

• abnormal distension, constipation, dryness of the mouth, erection, gas (flatulence),

• Decrease of bile secretion (cholelithiasis), hepatitis, increased liver enzymes (ALT, ASAT, GGT),

• Itching, hives,

• Malaise, fatigue, chest pain, chills,

• Increased blood alkaline phosphatase, increased blood lactic dehydrogenase.

Adverse events of unknown frequency (cannot be estimated from the available data):

• Significant decrease in the number of certain white blood cells (granulocytosis), decreased platelets

(important blood elements in blood clotting) (thrombocytopenia),

• Allergic reaction, angioedema,

• Psychic disorder, confusion, loss of sense of reality (depersonalization), depression, disorientation, hallucination,

nightmares, manic syndrome,

• Oxygen, loss of taste (ageusia), olfactory disorder (parosmia), loss of smell (anosmia),

paresthesia (sensation of tingling),

• Deafness,

• Severe heart rhythm disorders (torsades de pointes), increased heart rate (ventricular tachycardia),

ventricular fibrillation,

• Haemorrhage,

• Acute pancreatitis (acute pancreatitis), tongue discoloration, staining of teeth,

• Failure of liver functions (liver failure), jaundice (hepatocellular jaundice),

• Skin detachment can rapidly spread very seriously to the whole body (Stevens-Johnson syndrome, Lyell syndrome),

• DRESS syndrome (excessive amount of certain white blood cells (eosinophils) associated with rash and multi-systemic (multi-organ) involvement),

• Immediately contact a doctor if you experience a severe skin reaction: red squamous rash with masses under the skin and blisters (exanthematous pustulosus),

• Acne,

• Photophy,

• Failure of kidney function (kidney failure), kidney inflammation (interstitial nephritis),

• Increased INR (International Standardized Ratio), increased prothrombin rate, abnormal staining of urine.

Reporting of side effects

If you get any new side effects, talk to your doctor or pharmacist. This also applies to any undesirable effect that is not mentioned in this leaflet. You can also report side effects directly through the national reporting system.

5. How to store Dominar 250 mg film-coated tablet?

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 carton after EXP. The expiry date refers to the last day of this month.

Store at a temperature not exceeding 25 °C

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 OUTER PACKAGING AND OTHER INFORMATION

What Dominar 250mg film-coated tablet contains:

Dominar 250 mg	
Active Ingredient :	250 mg
Clarithromycin	
Excipients :	

Microcrystalline Cellulose, Croscarmellose Sodium, Anhydrous Colloidal Silicon, Polyvidone PVP (K90), Stearic acid, Magnesium stearate, Talc, Pregelatinized Starch, Polysorbate, White Opadry (Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol/Macrogol, Talc).

What Dominar 250mg film-coated tablet looks like and contents of the outer packaging

film-coated tablet of white color.

Dominar 250 mg is available in packs of 14 tablets.

AMM N° 2923981

Conditions of prescription and dispensing :

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Marketing Authorisation Holder & Manufacturer :

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This is a Medicine

- A medicine is a product but not like any other product
- A medicine is a product that affects your health. If it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of your doctor and the use instruction prescribed, follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, don't increase the doses without your doctor's advice.

Keep the medicines out of reach of children



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