PACKAGE LEAFLET: INFORMATION FOR THE USER

BREVIL® 200 mg prolonged release capsules
(CLARITHROMYCIN)

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

BREVIL® 200 mg prolonged release capsules
Clarithromycin

In this leaflet:

1. WHAT BREVIL® IS AND WHAT IT IS USED FOR

BREVIL® belongs to a group of antibiotics called macrolides. Antibiotics stop the growth of bacteria that cause infections.

These antibiotics are used to treat the following infections:
- Streptococcal pharyngitis (sore throat).

2. BEFORE YOU TAKE BREVIL®

Do not take BREVIL®
- if you are allergic (hypersensitive) to clarithromycin or other macrolide antibiotics, such as erythromycin or azithromycin.
- if you take ergotamine or dihydroergotamine tablets or use ergotamine nasal sprays (for migraine), when you are taking BREVIL® capsules.
- if you take terfenadine or astemizole (a common medication for hay fever or allergies) or cisapride or pimozide tablets, when you are taking BREVIL®. The simultaneous use of these medications may cause severe cardiac arrhythmias. Consult your doctor for alternative medicines.
- if you take simvastatin or lovastatin. Treatment with these agents should be interrupted during clarithromycin treatment

- if you suffer from severe hepatic failure in combination with renal impairment
- if you take colchicine (usually taken for gout) whist taking BREVIL® as this can also cause serious side effects

Take special care with BREVIL®

- If you have liver or kidney disorders, contact your doctor before taking these capsules.
- If you experience severe or prolonged diarrhea during or after the use of BREVIL® capsules, contact your doctor immediately.

Taking other medicines

The following medicines are not recommended for use simultaneously with BREVIL®, because their action may be affected or because the co-administration of the medicines may cause severe side effects.

Tell your doctor, if you are taking any of the following medicines:

- Lincomycin, clindomycin or other antibiotics
- digoxin, disopyramide (heart medicines);
- warfarine (anticoagulant);
- ergotamine or dihydroergotamine (for migraine);
- carbamazepine or phenytoin (antiepileptics);
- theophylline (assists breathing);
- terfenadine or astemizole (for hay fever or allergy);
- triazolam or midazolam (sedatives);
- disopyramide (heart medicine);
- simvastatine, lovastatine, atorvastatine or other statins (medicine that lowers blood cholesterol levels);
- cisapride (for stomach disorders);
- ciclosporine, tacrolimus, sirolimus (medicines preventing organ rejection reactions)
- zidovudine, ritanovir (HIV medicines)
- fluconazole (antifungal agent)
- methyl prednisolone or other cortisone
- Hypericum perforatum (a health product)
- Insulin and other anti-diabetic medicines
- colchicine (medicine taken for gout)

BREVIL® has no interaction with oral contraceptives.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, do not take BREVIL® capsules without consulting your doctor. The safety of BREVIL® capsules during pregnancy or breast-feeding has not been established.

Ask your doctor for advice before taking any medicine.

Driving and using machines
When performing these activities, the possibility of adverse effects, such as dizziness, vertigo, confusion and disorientation should be taken into account.

3. HOW TO TAKE BREVIL®

Always take BREVIL® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

A starting pack of two BREVIL® capsules may be given to you. These two capsules do not form the entire treatment course. Your doctor will give you a prescription for the full course.

BREVIL® should be taken with food. The capsules should be swallowed whole without chewing. BREVIL® capsules may be opened carefully to empty the granules onto a spoon. The spoon with granules should be placed in the patient's mouth. Then the patient should drink a glass of water to rinse the mouth so that all granules are swallowed. The granules should not be chewed or crushed.

The usual BREVIL® dose in adults and children over 15 years of age is two 200 mg capsules once daily. The usual duration of treatment is between 5 and 10 days.

These capsules are not suitable for children under 15 years of age. The doctor will prescribe a suitable alternative medicine for the child.

If you take more BREVIL® than you should
If you inadvertently take more than two BREVIL® capsules per day or if a child inadvertently swallows some capsules, consult a doctor immediately. An overdose of BREVIL® capsules is likely to cause vomiting and stomach pain. In addition, allergic reactions are possible.

If you forget to take BREVIL®
If you forget to take a BREVIL® capsule, take the capsule as soon as you remember. Do not take more capsules per day than prescribed by your doctor.

If you stop taking BREVIL®
Do not stop taking BREVIL® capsules even if you feel better. It is important for you to continue taking the capsules for as long as prescribed by your doctor, else the problem may recur.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, BREVIL® can cause side effects, although not everybody gets them.

In the evaluation of side effects the following frequency conventions are taken as the basis:

Very common:	***more than 1 in 10 treated patients***
Common:	***fewer than 1 in 10 but more than 1 in 100 treated patients***
Uncommon:	***fewer than 1 in 100 but more than 1 in 1000 treated patients***
Rare:	***fewer than 1 in 1000 but more than 1 in 10,000 treated patients***
Very rare:	***fewer than 1 in 10,000 treated patients including isolated cases***

Common:
Yeast infection of oral mucosa (or other infection caused by a clarithromycin resistant microbe), headache, changes in the sense of smell, nausea, diarrhea, vomiting, stomach pains,
indigestion, infection of the mouth or tongue, reversible tongue or tooth discolouration,
disorders of the sense of taste and elevated blood urea levels.

Uncommon
Decreased white blood cell count, allergic reactions such as urticaria, rash and anaphylaxis (hypersensitivity reaction with severe, rapidly developing general symptoms), usually short-term and
transient liver dysfunction, hepatitis and cholestasis, which may be associated with jaundice,
joint pain, muscle pain, delayed blood coagulation, elevated blood creatinine levels and elevated liver values.

Rare
Tinnitus.

Very rare
Reduced red blood cell levels, anxiety, insomnia, hallucinations, mental disorder, obscured sense of time and place, personality disorders, nightmares, confusion, dizziness, vertigo, tactile hallucinations, convulsions, reversible hearing loss, cardiac arrhythmias, pancreatitis, ulcerative inflammation of the small and large intestines (pseudomembranous colitis), severe liver dysfunction, Stevens-Johnson syndrome (severe skin disease), toxic epidermal necrolysis (Lyell's syndrome), kidney infection, kidney dysfunction and decreased blood sugar levels.

If prolonged and possibly bloody diarrhea occurs during the treatment or soon after its completion, please consult your doctor without delay, because this could be an indication of pseudomembranous colitis, which requires treatment.

You should also consult your doctor, if you experience cardiac arrhythmias during or soon after the treatment.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. Some side effects may require treatment.

5. HOW TO STORE BREVIL®

Keep out of the reach and sight of children.

Do not use BREVIL® capsules after the expiry date which is stated on the label of carton and blister.
The expiry date refers to the last day of that month

Do not store above 25 °C.

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. FURTHER INFORMATION

What BREVIL® contains

The active substance is clarithromycin
Each prolonged release capsule contains 200 mg clarithromycin
The other ingredients are:

Capsule content

- cellulose microcrystalline
- povidone,
- citric acid anhydrous
- stearic acid

Pellet coating

- hypromellose
- polysorbate 80,
- talc
- titanium dioxide (E171)
- polyacrylate dispersion 30%
- Antifoam C Emulsion:
  -Dimethicone
  -Methylated silica
  -Octamethyl cyclotetrasiloxane
  -Methylcellulose
  -Sorbic acid
  -Benzoic acid

Capsule shell

- titanium dioxide (E171)
- quinoline yellow (E104)
- erythrosine (E127)
- gelatin.

What BREVIL® looks like and contents of the pack

- BREVIL® 200 mg prolonged release capsules are yellow hard capsules.

PVC-Aclar/ALU blister
2, 5, 7 10 or 14 capsules/blister
The capsules have been packed in blister packs and will be supplied in cartons containing 2*, 4, 6, 7, 10, 14, 20, 22, 24, 28, 50, 100 or 120 capsules.

* The pack containing two capsules is a starting pack not intended as part of the treatment course.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Meditrina Pharmaceuticals Ltd.,
Irakleitou 117, 15238 Chalandri,
Athens, Greece

Manufacturer:
SMB Technology, S.A.,
39 rue du Parc Industriel,
B-6900 Marche-en-Famenne, Belgium

This medicinal product is authorised in the Member States under the following names:

BELGIUM	MONOCLARIUM 200 mg gélule à libération prolongée
FINLAND	CLARIUM 200 mg depotkapseli, kova
GERMANY	UNOKLAR 200 mg Hartkapseln, retardiert
GREECE	BREVIL OD 200 mg Καφάκιο παρατεταμένης αποδέσμευσης, σκληρό
LUXEMBOURG	CLARIUM 200 mg gélule à libération prolongée
POLAND	CLARIUM 200 mg kapsulka o przedluzonym uwalnianiu, twarda

This leaflet was last approved in