Refer also to section "Taking other medicines".

Take special care with Ketek:
- if you have had certain heart problems such as coronary heart disease, ventricular arrhythmias, bradycardia or if you have had certain abnormal blood tests due to medical conditions such as hypokalaemia, hypomagnesaemia.
- if you develop severe or prolonged or bloody diarrhoea during or after taking Ketek tablets, consult your doctor immediately since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with antibiotics.
- ~~if you suffer from myasthenia gravis, a rare disease which causes muscle weakness.~~
- ~~if you experience any worsening of your symptoms of myasthenia gravis during treatment with Ketek, you should interrupt treatment with Ketek and immediately seek medical attention.~~
- if you have liver disease.
- if you experience visual disturbances (blurred vision, difficulty in focusing, double vision)
- if you experience transient loss of consciousness (fainting).
- Ketek tablets are not recommended for use in children and adolescents less than 12 years old.

Refer also to sections "Do not take Ketek"~~ and~~, "Taking other medicines" and "Driving and using machines".

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medecines, including medicines obtained without a prescription, as some of them could have an interaction with Ketek.

You should not use Ketek with medicines containing ergotamine or dihydroergotamine tablets or ergotamine inhalers for migraine, terfenadine or astemizole for allergic problems, cisapride for digestive problems and pimozide for psychiatric problems. You should not use Ketek if you are taking certain medicinal products to control the blood level of cholesterol or other lipids, like simvastatin. Refer also to section "Do not take Ketek".

It is particularly important for your doctor to know if you are taking medicines containing phenytoin, and carbamazepine (for epilepsy), rifampicin (antibiotic), phenobarbital or St John's wort, medicines like tacrolimus, cyclosporin and sirolimus (for organ transplantation), or metoprolol (against heart disorder) or the anti HIV medicine ritonavir.

Taking Ketek with food and drink
Ketek may be taken with or without food.

Pregnancy and Breast-feeding
If you are pregnant do not take Ketek tablets as the safety of Ketek in pregnancy is insufficiently established. If you are breast-feeding do not take Ketek tablets.

Driving and using machines
Limit driving or other hazardous activities while taking Ketek. If you have vision problems or faint while taking Ketek, do not drive, operate heavy machinery, or engage in dangerous activities.
Taking Ketek tablets may cause side effects such as visual disturbances, which may reduce the capacity to carry out certain tasks. Rare cases of transient loss of consciousness (fainting), which may be preceded by vagal symptoms (malaise, gastrointestinal distress), have been reported. These symptoms may appear as early as after the first dose of Ketek. ~~You should be aware of the potential effect of these symptoms on your ability to drive or operate machinery~~

3. HOW TO TAKE KETEK

Your doctor will tell you how many Ketek tablets to take, at what time and for how long.

The usual duration of treatment is 5 days for infections of the throat, infections of the sinuses, chest infections in patients with long standing breathing difficulties and 7 to 10 days for pneumonia.

The recommended dose of Ketek for adults and children of 12 years and older is two tablets of 400 mg once daily (800 mg once daily).
If you have severe renal insufficiency you should take alternating daily doses of 800 mg (two tablets of 400 mg) and 400 mg (one tablet of 400 mg), starting with the 800 mg dose.

Swallow the tablets whole with a glass of water.
It is best to take tablets at the same time each day. If possible take the tablets before going to bed, to reduce the potential impact of visual disturbances and loss of consciousness.

If you take more Ketek than you should
If you accidentally take one tablet too many, nothing is likely to happen. If you accidentally take several tablets too many, contact your doctor or pharmacist. If possible, take your tablets or the box with you to show the doctor or pharmacist.

If you forget to take Ketek
If you forget to take a dose, take it as soon as possible. However, if it is nearly time for your next dose *skip the missed dose and take the next tablet at the usual time.*

If you stop taking Ketek
Take the complete course of tablets prescribed by your doctor, even if you begin to feel better before you have finished them all. If you stop taking the tablets too soon, the infection may return, or your condition may get worse.
If you stop taking the tablets too soon you may also create a bacterial resistance to the medicine.
If you feel you are suffering from a side effect, tell a doctor immediately to get advice before taking the next dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Ketek can cause side effects, although not everybody gets them. Most of them are mild and transient, but very rare cases of serious adverse liver reactions and liver failure, including fatal cases, have been reported. So, if any of the following happens, stop taking Ketek and tell your doctor immediately:

- Allergic or skin reactions such as face swelling, general allergic reactions including allergic shock, or serious skin conditions associated with red spots, blisters.
- Severe, persistent or bloody diarrhoea associated with abdominal pain or fever, which can be a sign of serious bowel inflammation which may occur very rarely following treatment with antibiotics.
- Signs and symptoms of hepatitis (liver disease) such as yellowing of skin and eyes, dark urine, itching, loss of appetite or abdominal pain.
- Worsening of a condition called myasthenia gravis, a rare disease which causes muscle weakness. ~~Reports have included death and life threatening breathing trouble that happens fast in myasthenia gravis patients~~.

The above serious side effects are uncommon (1 out of 1000 to less than 1 out of 100), rare (1 out of 10,000 to less than 1 out of 1000 patients) or very rare (less than 1/10,000 patients including isolated report), but may require urgent medical attention.

The other side effects listed below are given with an estimation of the frequency with which they may occur.

The most common side effect (10 or more out of 100 patients) which may occur with Ketek is diarrhoea, usually mild and temporary.

Other side effects which may commonly (1 to 10 out of 100 patients) occur with Ketek are:
Nausea, vomiting, abdominal pain, flatulence (excess wind), dizziness, headaches, disturbance of taste, vaginal *Candida* infection (fungal infection associated with local itching, burning and white discharge), increase in liver enzymes (detected by blood test).

Uncommon or rare side effects (1 out of 10,000 to less than 1 out of 100 patients) which may occur with Ketek are:
Constipation, anorexia (loss of appetite), stomatitis (inflammation in themouth), oral *Candida* infection (fungal infection), hepatitis, rash, urticaria (hives), pruritus (itching), eczema, somnolence, insomnia, nervousness, vertigo, paraesthesia (tingling of the hands or feet), , visual disturbances (blurred vision, difficulty in focusing, double vision), , flushes, transient loss of consciousness (fainting), arrhythmia, bradycardia or palpitations (changes in heart rate or in ECG), hypotension (low blood pressure), eosinophilia (increase of certain white blood cells, detected by blood test).
Very rare side effects(less than 1 out of 10,000 patients) which may occur with Ketek are :
Disturbance of smell, muscle cramps.

Additional side effects which may occur with Ketek are:
abnormality of electrocardiogram (ECG) called prolongation of QT interval and inflamed pancreas (pancreatitis).
During post-marketing experience, liver failure has been reported (frequency unknown).

If any of these undesirable effects are troublesome, severe, or do not wear off as treatment goes on, tell your doctor.

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.

5. HOW TO STORE KETEK

Keep out of the reach and sight of children.

Do not use Ketek after the expiry date which is stated on the pack.

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 Ketek contains

- The active substance is telithromycin
- The other ingredients are microcrystalline cellulose, povidone K25, croscarmellose sodium, magnesium stearate in the tablet core as well as talc, macrogol 8000 , hypromellose 6 cp, titanium dioxide E171, yellow iron oxide E172, red iron oxide E172 in the film-coating.

What Ketek looks like and contents of the pack

Ketek 400 mg tablets are light orange, oblong, biconvex, film-coated tablet imprinted with "H3647" on one side and "400" on the other.

Ketek tablets are presented in blister packs. Two tablets are contained in each blister cavity.
They are available in packs of 10, 5x2, 14, 20 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder of Ketek is:
Aventis Pharma S.A.
20 Avenue Raymond Aron
F-92160 ANTONY
France

The manufacturer of Ketek is:
Aventis Pharma S.p.A.
Strada Statale No 17, km 22
I-67019 Scoppito (L'Aquila), Italy

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Belgique/België/Belgien
sanofi-aventis Belgium
Tél/Tel: +32 (0)2 710 54 00
България
sanofi-aventis Bulgaria EOOD
Тел: +359 (0)2 970 53 00
Česká republika
sanofi-aventis, s.r.o.
Tel: +420 233 086 111
Danmark
sanofi-aventis Denmark A/S
Tlf: +45 45 16 70 00
Deutschland
Sanofi-Aventis Deutschland GmbH
Tel: +49 (0)180 2 222010
Eesti
sanofi-aventis Estonia OÜ
Tel: +372 627 34 88
Ελλάδα
sanofi-aventis AEBE
Τηλ.: +30 210 900 16 00
España
sanofi-aventis, S.A.U.
Tel: +34 93 485 94 00
France
sanofi-aventis france
Tél : 0 800 222 555
Appel depuis l'étranger : +33 1 57 63 23 23
Ireland
sanofi-aventis Ltd.
Tel: +353 (0) 1 403 56 00

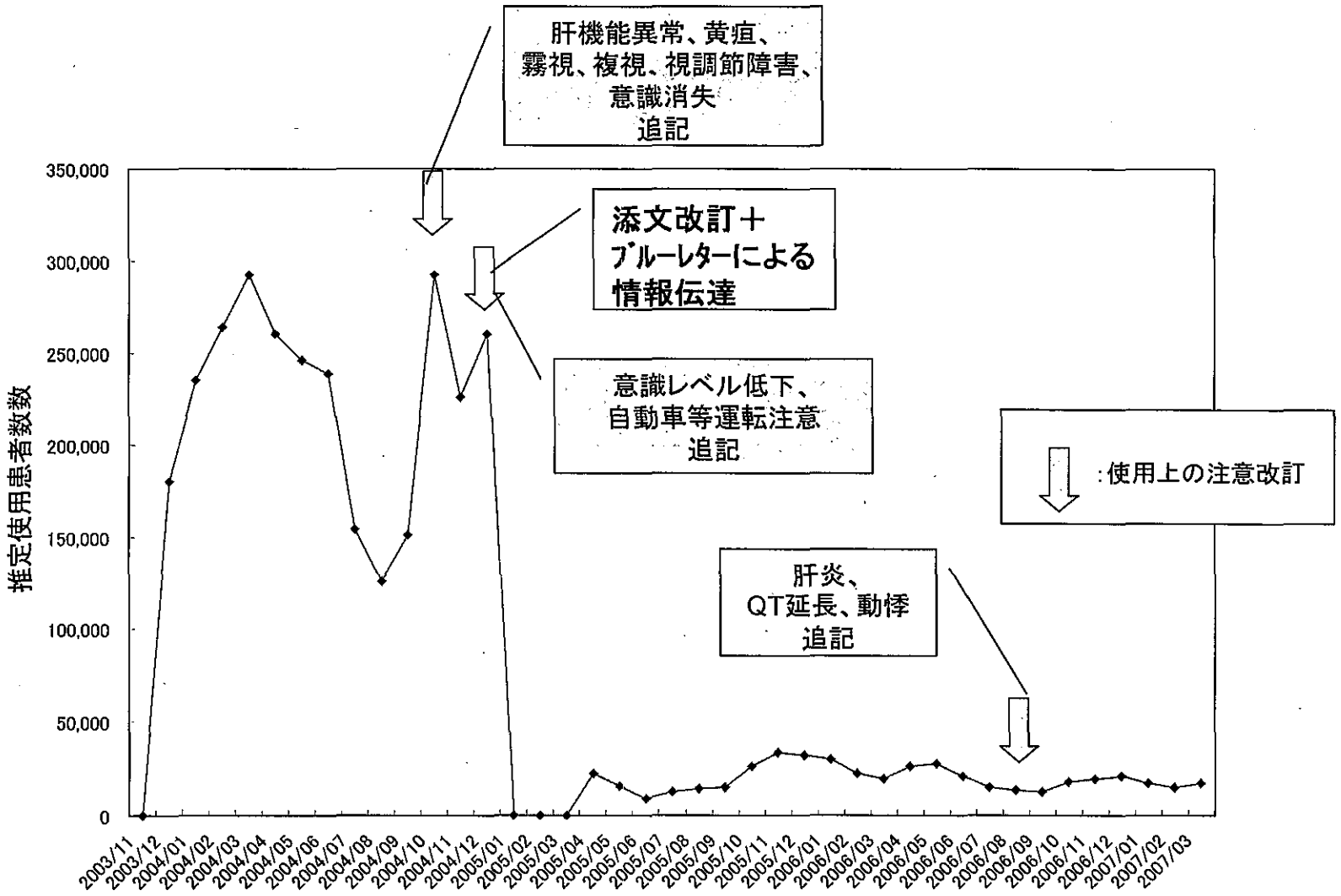
Luxembourg/Luxemburg
sanofi-aventis Belgium
Tél/Tel: +32 (0)2 710 54 00 (Belgique/Belgien)
Magyarország
sanofi-aventis zrt., Magyarország
Tel: +36 1 505 0050
Malta
sanofi-aventis Malta Ltd.
Tel: +356 21493022
Nederland
sanofi-aventis Netherlands B.V.
Tel: +31 (0)182 557 755
Norge
Aventis Pharma AS
Tlf: +47 67 10 71 00
Österreich
sanofi-aventis GmbH
Tel: +43 1 80 185 – 0
Polska
sanofi-aventis Sp. z o.o.
Tel: +48 22 541 46 00
Portugal
sanofi-aventis - Produtos Farmacêuticos, S.A.
Tel: +351 21 35 89 400
România
sanofi-aventis România S.R.L.
Tel: +40 (0)21 317 31 36

Slovenija
sanofi-aventis d.o.o.
Tel: +386 1 560 48 00

Ísland
Vistor hf.
Sími: +354 535 7000
Italia
sanofi-aventis S.p.A.
Tel. +39 02 393 91
Κύπρος
sanofi-aventis Cyprus Ltd.
Τηλ.: +357 22 871600
Latvija
sanofi-aventis Latvia SIA
Tel.: +371 7 33 24 51
Lietuva
UAB sanofi-aventis Lietuva
Tel: +370 5 2755224

This leaflet was last approved in

Slovenská republika
sanofi-aventis Pharma Slovakia s.r.o.
Tel: +421 2 57 103 777
Suomi/Finland
sanofi-aventis Oy
Puh/Tel: +358 (0) 201 200 300
Sverige
sanofi-aventis AB
Tel: +46 (0)8 634 50 00
United Kingdom
sanofi-aventis
Tel: +44 (0) 1483 505 515



ケテック®錠300mg 推定使用患者数

サノフィ･アベンティス株式会社