SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Roxithromycin 150

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 150 mg of roxithromycin.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet
Yellow, round, convex film-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults: Roxithromycin is indicated for the treatment of the following types of mild to moderately severe infections in adults caused by or likely to be caused by susceptible microorganisms.

- Upper respiratory tract infection: acute pharyngitis, tonsillitis and sinusitis.
- Lower respiratory tract infection: acute bronchitis and acute exacerbations of chronic bronchitis; community acquired pneumonia.
- Skin and skin structure infections.
- Nongonococcal urethritis.

Children: Roxithromycin 150 mg tablets are indicated for the treatment of the following mild to moderately severe infections in children caused by or likely to be caused by susceptible microorganisms.

- Acute pharyngitis.
- Acute tonsillitis.
- Impetigo.

Appropriate culture and sensitivity tests should be performed when necessary to determine organism susceptibility and thus treatment suitability. Therapy with roxithromycin may be initiated before results of these tests are known; once results become available, appropriate therapy should be continued.

4.2 Posology and method of administration

Dosage
Adults
The recommended dosage is 300 mg per day, which may be taken according to one of the following dosage regimens.
Usual dosage: one tablet twice daily or two tablets once daily.
For atypical pneumonia, the recommended dosage is 150 mg twice daily.
The usual duration of treatment is five to ten days depending on the indication and clinical response. Streptococcal throat infections require at least ten days of therapy.
A small proportion of patients with nongonococcal genital infections may require 20 days for complete cure.

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Children
The recommended dose and duration of treatment should not be exceeded in children (see Section 4.4 Special warnings and precautions for use).
Roxithromycin is administered twice daily at a dose of 5 to 8 mg/kg/day.
Recommended dosage regimens are as follows.
40 kg and over: one Roxithromycin 150 mg tablet morning and evening. Roxithromycin is not recommended for children of under 40 kg.
The usual duration of treatment is five to ten days depending on the indication and clinical response. Streptococcal throat infections require ten days of therapy. The duration of treatment should not exceed ten days.

Method of administration
Roxithromycin should be taken at least 15 minutes before food or on an empty stomach (i.e. more than three hours after a meal).
Roxithromycin 150 mg film-coated tablets must be swallowed whole with a drink.

Dosage adjustment in:
- Renal impairment: one tablet twice daily or two tablets once daily.
- Elderly: one tablet twice daily or two tablets once daily.

4.3 Contraindications

- Hypersensitivity to roxithromycin, macrolides, including erythromycin or to any of the excipients.
- Severely impaired hepatic function (see Section 4.4 Special warnings and precautions for use).
- Concomitant therapy with vasoconstrictive ergot alkaloids (see Section 4.5 Interaction with other medicinal products and other forms of interaction).
- Coadministration with medicinal products with narrow therapeutic windows and which are substrates of CYP3A4 (e.g. astemizole, cisapride, pimozide and terfenadine) (see Section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use

Roxithromycin, like erythromycin, has been shown in vitro to elicit a concentration dependent lengthening in cardiac action potential duration. Such an effect is manifested only at supratherapeutic concentrations. Accordingly, the recommended doses should not be exceeded.
Prolonged or repeated use of antibiotics including roxithromycin may result in superinfection by resistant organisms. In the event of superinfection, roxithromycin should be discontinued and appropriate therapy instituted.
When indicated, incision, drainage or other appropriate surgical procedures should be performed in conjunction with antibiotic therapy.
Antibiotic associated pseudomembranous colitis has been reported with many antibiotics. A toxin produced by *Clostridium difficile* appears to be the primary cause.
If pseudomembranous colitis is suspected, roxithromycin must be stopped immediately.

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The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea particularly if severe, persistent and/or bloody, or colitis in association with antibiotic use (this may occur during treatment and up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases, appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement therapy should be provided when indicated.

Drugs that delay peristalsis, e.g. opiates and diphenoxylate with atropine (e.g. Lomotil), may prolong and/or worsen the condition and should not be used.

In certain conditions, macrolides, including roxithromycin, have the potential to prolong the QT interval. Therefore, roxithromycin should be used with caution in patients with congenital prolongation of the QT interval, with ongoing proarrhythmic conditions (i.e. uncorrected hypokalemia or hypomagnesaemia, clinically significant bradycardia), and in patients receiving Class IA (e.g. quinidine, procainamide, disopyramide) and Class III (e.g. dofetilide, amiodarone) antiarrhythmic agents, citalopram, tricyclic antidepressants, methadone, some antipsychotics (e.g. phenothiazines), fluoroquinolones (e.g. moxifloxacin), some antifungals (e.g. fluconazole, pentamidine), and some antiviral drugs (e.g. telaprevir). (See Section 4.5 Interaction with other medicinal products and other forms of interaction).

As with other macrolides, roxithromycin may have the potential to aggravate myasthenia gravis.

Cases of severe bullous skin reactions such as Stevens Johnson Syndrome or Toxic Epidermal Necrosis have been reported with roxithromycin (see Section 4.8 Undesirable effects). If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present, roxithromycin treatment should be discontinued.

Severe vasoconstriction (“ergotism”) with possibly necrosis of the extremities has been reported when macrolides antibiotics have been associated with vasoconstrictive ergot alkaloids. Absence of treatment by these alkaloids must always be checked before prescribing roxithromycin.

Carefully consider the balance of benefits and risks before prescribing roxithromycin or other macrolides for any patients taking hydroxychloroquine or chloroquine, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality (see Section 4.5 Interaction with other medicinal products and other forms of interaction).

Monitoring of the liver and kidney function and the blood counts is recommended especially during long-term treatment.

<u>Use in hepatic impairment</u>

The safety of roxithromycin has not been demonstrated in patients with impaired hepatic function. Caution should be exercised if Roxithromycin is administered to patients with impaired hepatic function, in severe cases, use of roxithromycin is not recommended. If administered to patients with severely impaired hepatic function (e.g.

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hepatic cirrhosis with jaundice and/or ascites), consideration should be given to reducing the daily dosage to half the usual dosage.

Use in renal impairment

The safety of roxithromycin has not been demonstrated in patients with impaired renal function. Caution should be exercised if roxithromycin is administered to patients with impaired renal function.

Renal excretion of roxithromycin and its metabolites accounts for a small amount of an oral dose. The dosage should be kept unchanged in renal insufficiency.

Use in the elderly

No dosage adjustment is required in elderly patients.

Paediatric use

In young animal studies, high oral doses of roxithromycin were associated with bone growth plate abnormalities. However, no abnormalities were observed in the animals at doses resulting in unbound plasma roxithromycin concentrations that were 10 to 15 times higher than the unbound concentration measured in children receiving the therapeutic dose. The maintenance of such safety margins is primarily dependent on high affinity binding of roxithromycin to plasma alpha-1-acid glycoprotein and will be compromised by any circumstances attenuating the extent of this binding. It is recommended that the approved paediatric dosage regimen (i.e. 5 to 8 mg/kg/day for a maximum of ten days) be adhered to strictly.

Neutropenia was observed in children treated with roxithromycin. 31.6% of 402 children in clinical trials had a neutrophil count below the lower limit of the normal range (3,500/mm^3) at the conclusion of therapy with roxithromycin. Of these, 4% had a neutrophil count of less than 1,500/mm^3 and 1.2% had a count of less than 1,000/mm^3. It is not known whether this is an effect of the drug, or whether it reflects a normal fluctuation of the neutrophil count or a response to infection in children.

Effects on laboratory tests

No data available.

Warning

1. Do not use in patients who are hypersensitivity to roxithromycin.
2. Use with caution in patients with liver disease.
3. Do not concomitant use with migraine medicines which contain ergotamine, because it may cause disability or death.
4. Use with caution in women who are pregnant.
5. Stop taking this medicine and contact your doctor or pharmacist immediately if any following symptoms occur such as skin rash, pustule, bullous, lymphadenopathy, or high fever that are not pre-existing symptoms, because it may cause severe cutaneous adverse drug reactions (SCARs).
6. Roxithromycin may have the potential to cause QT prolongation. Therefore, this medicine should be used with caution in patients with risk factors such as elderly patients, patients with heart disease, especially patients with cardiac arrhythmia, coronary artery disease, or hypokalemia.

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7. Use with caution in patients receiving the medicines that are metabolized by CYP3A4 (e.g. warfarin), heart disease medicines (e.g. digoxin), and HIV protease inhibitors (e.g. ritonavir) because plasma concentrations of these medicines may increase dangerously high. Moreover, roxithromycin should be used with caution in patients receiving lipid lowering medicines (e.g. simvastatin, atorvastatin) because it may increase risk of causing myopathy and rhabdomyolysis.

4.5 Interaction with other medicinal products and other forms of interaction

Roxithromycin has a much lower affinity for cytochrome P450 than erythromycin, and consequently has fewer interactions. Interactions may be observed, however, with drugs that bind to alpha-1-acid glycoprotein, e.g. disopyramide.

Roxithromycin does not appear to interact with oral contraceptives containing oestrogens and progestogens, prednisolone, carbamazepine, ranitidine or antacids.

Ergot alkaloids: Reactions of ergotism with possible peripheral necrosis have been reported after concomitant therapy of macrolides with vasoconstrictive ergot alkaloids, particularly ergotamine and dihydroergotamine. Because a clinical interaction with roxithromycin cannot be excluded, administration of roxithromycin to patients taking ergot alkaloids is contraindicated. Absence of treatment with these alkaloids must always be checked before prescribing roxithromycin.

Theophylline: A study in normal subjects, concurrently administered roxithromycin and theophylline, has shown some increase in the plasma concentration of the latter. While a change in dosage is usually not required, patients with high levels of theophylline at commencement of treatment should have levels monitored.

Disopyramide: An in vitro study has shown that roxithromycin can displace protein bound disopyramide; such an effect in vivo could result in increased serum levels of disopyramide. Consequently ECG and, if possible, disopyramide serum levels should be monitored.

Terfenadine: Some macrolide antibiotics (e.g. erythromycin) may increase serum levels of terfenadine. This can result in severe cardiovascular adverse events, including QT prolongation, torsades de pointes and other ventricular arrhythmias. Such a reaction has not been documented with roxithromycin, which has a much lower affinity for cytochrome P450 than erythromycin. However, in the absence of a systematic interaction study, concomitant administration of roxithromycin and terfenadine is not recommended.

Astemizole, cisapride, pimozide: Other drugs, such as astemizole, cisapride or pimozide, which are metabolized by the hepatic isozyme CYP3A4, have been associated with QT interval prolongation and/or cardiac arrhythmias (typically torsades de pointes) as a result of an increase in their serum level subsequent to interaction with significant inhibitors of this isozyme, including some macrolide antibacterials. Although roxithromycin has no or limited ability to complex CYP3A4 and therefore to inhibit the metabolism of other drugs processed by this isozyme, a potential for clinical interaction of roxithromycin with the above mentioned drugs cannot be either ascertained or ruled out in confidence; therefore, concomitant administration of roxithromycin and such drugs is not recommended.

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Roxithromycin, like other macrolides, should be used with caution in patients receiving Class IA and Class III antiarrhythmic agents (see Section 4.4 Special warnings and precautions for use).

Vitamin K antagonists: While no interaction was observed in volunteer studies, roxithromycin appears to interact with warfarin. Increases in prothrombin time (international normalized ratio (INR)) have been reported in patients treated concomitantly with roxithromycin and warfarin or the related vitamin K antagonist phenprocoumon, and severe bleeding episodes have occurred as a consequence. INR should be monitored during combined treatment with roxithromycin and Vitamin K antagonists.

Hydroxychloroquine or chloroquine: Observational data have shown that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events and cardiovascular mortality. Because of the potential for a similar risk with other macrolides when used in combination with hydroxychloroquine or chloroquine, careful consideration should be given to the balance of benefits and risks before prescribing roxithromycin for any patients taking hydroxychloroquine or chloroquine.

Digoxin and other cardiac glycosides: A study in healthy volunteers has shown that roxithromycin may increase the absorption of digoxin. This effect, common to other macrolides, may very rarely result in cardiac glycoside toxicity. This may be manifested by symptoms such as nausea, vomiting, diarrhoea, headache or dizziness; cardiac glycoside toxicity may also elicit heart conduction and/or rhythm disorders. Consequently, in patients treated with roxithromycin and digoxin or another cardiac glycoside, ECG and, if possible, the serum level of the cardiac glycoside should be monitored; this is mandatory if symptoms which may suggest cardiac glycoside overdosage occur.

HMG-CoA reductase inhibitors: When roxithromycin and an HMG-CoA reductase inhibitor (statin) are combined, there is a potential risk of muscle related adverse events, such as rhabdomyolysis due to a possible increase of the statin exposure.

Caution should be exercised when a statin is combined with roxithromycin and patients should be monitored for signs and symptoms of myopathy.

Midazolam: Roxithromycin, like other macrolides, may increase the area under the midazolam concentration-time curve and the midazolam half-life; therefore, the effects of midazolam may be enhanced and prolonged in patients treated with roxithromycin. There is no conclusive evidence for an interaction between roxithromycin and triazolam.

Bromocriptine: Roxithromycin may increase the AUC and plasma concentrations of bromocriptine, which could lead to an increased risk for adverse effects of the compound.

Rifabutin: Roxithromycin can increase the plasma concentration of rifabutin.

Theophylline and Cyclosporin: A slight increase in plasma concentrations of theophylline or cyclosporin A has been observed. This does not generally necessitate altering the usual dosage.

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CYP3A: Roxithromycin is a weak CYP3A inhibitor. The effect of roxithromycin on exposure to drugs predominantly cleared by CYP3A metabolism would be expected to be 2-fold or less. Caution should be exercised when roxithromycin is concomitantly prescribed with drugs metabolized by CYP3A (such as rifabutin and bromocriptine).

4.6 Fertility, pregnancy and lactation

Effects on fertility

There was no effect on the fertility of rats treated with roxithromycin at oral doses up to 180 mg/kg/day.

Use in pregnancy

Category B1

Reproductive studies in rats, mice and rabbits at doses of 100, 400 and 135 mg/kg/day, respectively, did not demonstrate evidence of developmental abnormalities. In rats, at doses above 180 mg/kg/day, there was evidence of embryotoxicity and maternotoxicity. The safety of roxithromycin for the human fetus has not been established.

Use in lactation

Small amounts of roxithromycin are excreted in the breast milk. Breastfeeding or treatment of the mother should be discontinued as necessary.

4.7 Effects on ability to drive and use machines

Attention should be drawn to the possibility of dizziness, visual impairment and blurred vision.

4.8 Undesirable effects

Roxithromycin is generally well tolerated. In clinical trials, treatment discontinuation due to adverse reactions occurred in only 1.2% of adult patients and 1.0% of children. The following side effects or serious adverse events possibly associated with roxithromycin have been reported.

Gastrointestinal: Nausea, vomiting, epigastric pain (dyspepsia), diarrhoea (sometimes containing blood), anorexia, flatulence, pseudomembranous colitis. In clinical studies, the incidence of gastrointestinal events was higher with the 300 mg once daily dosage regimen than with 150 mg twice daily. Symptoms of pancreatitis have been observed; most patients had received other drugs for which pancreatitis is a known adverse reaction.

Hypersensitivity: Urticaria, rash, pruritus, angioedema. Rarely, serious allergic reactions may occur, e.g. asthma, bronchospasm, anaphylactic like reactions, anaphylactic shock, purpura, glottic oedema, generalized oedema, erythema multiforme, exfoliative dermatitis, acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome and Toxic Epidermal Necrosis (TEN) (See Section 4.4 Special warnings and precautions for use).

Hepatic: Moderate increases in serum transaminases (AST and ALT) and/or alkaline phosphatase levels have been observed and are somewhat more likely to occur in the elderly (> 65 years). Acute cholestatic hepatitis and acute hepatocellular injury (sometimes with jaundice) are rarely reported.

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Infections and Infestations: superinfection (on prolonged use), Clostridium difficile colitis (pseudomembranous colitis)
Blood and lymphatic system disorders: eosinophilia, agranulocytosis, neutropenia, thrombocytopenia
Immune system disorders: anaphylactic shock
Cardiac disorders: QT interval prolongation, ventricular tachycardia, Torsade de pointes
Other: Eosinophilia, bronchospasm, hallucination, headache, dizziness, paraesthesia, tinnitus, malaise, moniliasis (candidiasis), pancreatitis, disorders of taste and/or smell, visual impairment, blurred vision, temporary deafness, hypoacusis and vertigo.
Prolonged use of antibiotics including roxithromycin may result in superinfection; overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. In the event of superinfection, appropriate measures should be taken.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC, Thai FDA

4.9 Overdose
Symptomatic treatment should be provided as required. There is no specific antidote.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Roxithromycin is a semisynthetic macrolide antibiotic.
Mechanism of action
Microbiology
Roxithromycin is bacteriostatic at low concentrations and bactericidal at high concentrations. It binds to the 50S subunit of the 70S ribosome, thereby disrupting bacterial protein synthesis.
A prolonged postantibiotic effect has been observed with roxithromycin. Whilst the clinical significance of this remains uncertain, it supports the rationale for once daily dosing. Although clinical data have demonstrated the efficacy and safety of once daily dosing in adults, these have not been demonstrated in children.
At plasma concentrations achieved with the recommended therapeutic doses, roxithromycin has been demonstrated to have in vitro and clinical activity against the following microorganisms:
Streptococcus pneumoniae, *Strep. pyogenes*, *Mycoplasma pneumoniae*, *Moraxella catarrhalis*, *Ureaplasma urealyticum* and *Chlamydia* sp.
Roxithromycin has been demonstrated to have clinical activity against the following microorganisms which are partially sensitive in vitro to roxithromycin:
Haemophilus influenzae and *Staphylococcus aureus*, except methicillin resistant *Staph. aureus* (MRSA).

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The following strains of microorganisms are resistant:
Multiresistant *Staph. aureus*, Enterobacteriaceae, *Pseudomonas* sp. and *Acinetobacter* sp.
Susceptibility Testing
Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognized and standardized method (e.g. NCCLS). Standardized susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.
A report of "Susceptible" indicates that a pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small-uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.
Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections. Using the National Committee for Clinical Laboratory Standard (NCCLS) method of susceptibility testing with a 15 mcg roxithromycin disc, susceptible organisms other than *Haemophilus influenzae* produce zones of inhibition 21 mm or greater. A zone size of 10 to 20 mm should be considered intermediate and a zone size of 9 mm or less indicates resistance. A bacterial isolate may be considered susceptible if the MIC value for roxithromycin is less than or equal to 1 mg/L. Organisms are considered resistant if the MIC value is greater than 8 mg/L.
For *Haemophilus influenzae*, zones of inhibition 10mm or greater indicate susceptibility when CO_2 incubation and the HTM agar is used with a 15 mcg roxithromycin disc. An isolate may be considered susceptible if the MIC value for roxithromycin is less than or equal to 8 mg/L.

Clinical trials
No data available.

5.2 Pharmacokinetic properties

Absorption
Roxithromycin is absorbed after oral administration with an absolute bioavailability of approximately 50%. Peak plasma concentrations following administration of 150 mg film-coated tablets are achieved in young and elderly adult patients approximately one to two hours post-dose.
As food intake delays absorption, Roxithromycin should be administered at least 15 minutes before food or, alternatively, on an empty stomach (i.e. more than three hours after a meal).

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Absorption is not linear; with increasing doses in the range 150 to 300 mg, peak plasma levels and area under the curve (AUC) do not increase in proportion to the dose.
After repeated administration of 2.5 mg/kg every 12 hours to children, the average peak plasma concentration at steady state was 9 mg/L and the AUC was 61 mg.h/L.
Following administration of a single oral dose of Roxithromycin 150 mg to healthy young adults, the mean peak plasma concentration was 6.6 mg/L and the AUC was 69 mg.h/L. At steady state following doses of 150 mg twice daily, the mean peak plasma concentration was 9.3 mg/L and the AUC was 71 mg.h/L.
In elderly patients, the mean peak plasma concentration following a single 150 mg dose was 9.1 mg/L and the AUC was 148 mg.h/L. At steady state, a dosage regimen of 150 mg twice daily produced a mean peak plasma concentration of 11.3 mg/L and an AUC of 83 mg.h/L.

Distribution

Roxithromycin is 92 to 96% bound to plasma proteins (principally alpha-1-acid glycoprotein, but also albumin) at concentrations less than 4.2 mg/L. The binding is saturable; in subjects with normal plasma levels of alpha-1-acid glycoprotein, the extent of binding decreases when plasma concentrations of roxithromycin exceed 4.2 mg/L. At a plasma concentration of 8.4 mg/L approximately 87% of the drug is protein bound. Roxithromycin is highly concentrated in polymorphonuclear leucocytes and macrophages, where levels 30 times those in serum have been reported.

Metabolism

Roxithromycin undergoes limited metabolism in the body, presumably in the liver. The major metabolite is descladinose roxithromycin. Two minor metabolites have also been identified. Plasma levels of roxithromycin are approximately twice those of all metabolites; a similar ratio is seen in the urine and faeces.
Approximately 7% of a dose is excreted in the urine and 13% is eliminated via the lungs. Faecal excretion, which represents the unabsorbed fraction and the small proportion excreted by the liver, accounts for approximately 53% of the dose. The fate of the remainder is unknown.
When roxithromycin plasma levels are above 4.2 mg/L, renal clearance increases because reduced plasma protein binding (see Distribution) causes increased levels of unbound roxithromycin, which may be excreted by the kidneys.

Excretion

The mean half-life of roxithromycin is approximately 12 hours in young adults and 20 hours in children. The apparently longer half-life in children does not cause excessive accumulation; minimum concentration (C_{min}) and AUC values are comparable for adults and children.
The half-life is prolonged to 25 hours in patients with impaired hepatic function and 18 hours in patients with renal insufficiency.
The mean half-life in elderly patients is approximately 27 hours.

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5.3 Preclinical safety data

Genotoxicity

Roxithromycin has shown no mutagenic potential in standard laboratory tests for gene mutation and chromosomal damage.

Carcinogenicity

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of roxithromycin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Ludipress
Croscarmellose sodium
Colloidal silicon dioxide
Magnesium stearate
Opadry
Tartrazine lake
Polyethylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at temperature below 30º C, Protect from light.

6.5 Nature and contents of container

Aluminium strip containing 10 tablets, 10 strips per paper box.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pharmasant Laboratories Co., Ltd.
96/3 Moo 6, Bangbuathong-Suphanburi Road, Rajniyom, Sainoi, Nonthaburi, Thailand
Tel. +66-2985-5855 Fax. +66-2985-5866

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1A 948/42

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29/12/1999

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