**ABBOTIC**
**Clarithromycin**

## 1. NAME OF THE MEDICINAL PRODUCT
Abbotic 125 mg/5 ml, Granules for Oral Suspension (Pediatric Suspension)
Abbotic 250 mg/5 ml, Granules for Oral Suspension (Pediatric Suspension)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Clarithromycin 125 mg/5 ml, Granules for Oral Suspension (Pediatric Suspension):
Each 5 ml of the granules for suspension contains 125 mg of clarithromycin.
Excipient: Sucrose 2,6793 mg/ 5 ml

Clarithromycin 250 mg/5 ml, Granules for Oral Suspension (Pediatric Suspension):
Each 5 ml of the granules for suspension contains 250 mg of clarithromycin.
Excipient: Sucrose 2276,2 mg/ 5 ml

For the full list of excipients, see section List of Excipients.

## 3. PHARMACEUTICAL FORM
White to off-white granules for suspension

## 4. CLINICAL PARTICULARS
### 4.1 Therapeutic indications
Abbotic® Granules 125 mg or 250 mg/5 ml is indicated for treatment of infections due to susceptible organisms, in the following conditions:
1) Upper respiratory infections (e.g., streptococcal pharyngitis)
2) Lower respiratory infections (e.g., bronchitis, pneumonia)
3) Acute otitis media
4) Skin and skin structure infections (e.g., impetigo, folliculitis, cellulitis, abscesses)

### 4.2 Posology and method of administration
The recommended daily dosage of ABBOTIC® GRANULES (125 mg/5 ml or 250 mg/5 ml) in children is 7.5 mg/kg b.i.d. up to a maximum dose of 500 mg b.i.d. for severe infections. The usual duration of treatment is for 5 to 10 days depending on the pathogen involved and the severity of the condition.
Treatment for Streptococcal pharyngitis should be at least 10 days. The prepared suspension can be taken with or without meals and can be taken with milk.

The following table is a suggested guide for determining dosage:

| **DOSAGE GUIDELINES FOR PEDIATRIC PATIENTS Based on Body Weight** | | |
|---|---|---|
| **Weight *** | **Dosage in Standard 5 mL Teaspoonful given twice daily** | |
| **Kg** | **125 mg/5 mL** | **250 mg/5 mL** |
| 8 - 11 | 0.5 | -- |

| | | |
|---|---|---|
| 12 - 19 | 1 | 0.5 |
| 20 - 29 | 1.5 | 0.75 |
| 30 - 40 | 2 | 1 |
| * Children < 8 kg should be dosed on a per kg basis (approx. 7.5 mg/kg b.i.d.) | | |

**4.3 Contraindications**

Clarithromycin is contraindicated in patients with known hypersensitivity to macrolide antibiotic drugs. Clarithromycin is contraindicated in patients receiving terfenadine therapy who have preexisting cardiac abnormalities (arrhythmia, bradycardia, QT interval prolongation, ischemic heart disease, congestive heart failure, etc.) or electrolyte disturbances (hypokalemia or hypomagnesaemia, due to risk of prolongation of QT- interval).
Concomitant administration of clarithromycin and lomitapide is contraindicated (see section 4.5).

**4.4 Special warnings and precautions for use**

Clarithromycin is principally metabolized by the liver. Therefore, caution should be exercised in administering the antibiotic to patients with impaired hepatic function. Caution should also be exercised when administering clarithromycin to patients with moderate to severe renal failure.

Attention should also be paid to the possibility of cross resistance between clarithromycin and other macrolide drugs, as well as lincomycin and clindamycin.
Prolonged or repeated use of Clarithromycin may result in an overgrowth of non-susceptible bacteria or fungi. If superinfection occurs, clarithromycin should be discontinued, and appropriate therapy instituted.

If Abbotic Granules 125 mg or 250 mg/5 ml is considered for patients of post-pubertal age, the physician should carefully weigh the benefits against the risk when pregnancy is either suspected or confirmed.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including macrolides, and may range in severity from mild to life-threatening.

Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of bacterial agents. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of Clostridioides difficile is a primary cause of “Antibiotic associated colitis”. After the diagnosis of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug effective against Clostridioides difficile.

<u>Cardiovascular Events</u>

Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and *torsades de pointes*, have been seen in treatment with macrolides including clarithromycin (see section 4.8). Therefore, as the following situations may lead to an increased

risk for ventricular arrhythmias (including *torsades de pointes*), clarithromycin should be used with caution in the following patients;

- Patients with coronary artery disease, severe cardiac insufficiency, conduction disturbances or clinically relevant bradycardia
- Clarithromycin must not be given to patients with hypokalaemia or hypomagnesaemia (see section 4.3).
- Patients concomitantly taking other medicinal products associated with QT prolongation (see section 4.5).
- Concomitant administration of clarithromycin with astemizole, cisapride, pimozide and terfenadine is contraindicated (see section 4.3).
- Clarithromycin must not be used in patients with congenital or documented acquired QT prolongation or history of ventricular arrhythmia (see section 4.3).

Carefully consider the balance of benefits and risks before prescribing clarithromycin 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).

Epidemiological studies investigating the risk of adverse cardiovascular outcomes with macrolides have shown variable results. Some observational studies have identified a rare short-term risk of arrhythmia, myocardial infarction and cardiovascular mortality associated with macrolides including clarithromycin. Consideration of these findings should be balanced with treatment benefits when prescribing clarithromycin.

Oral Anticoagulants

There is a risk of serious hemorrhage and significant elevations in INR and prothrombin time when clarithromycin is co-administered with warfarin. INR and prothrombin times should be frequently monitored while patients are receiving clarithromycin and oral anticoagulants concurrently.

Caution should be exercised when clarithromycin is co-administered with direct acting oral anticoagulants such as dabigatran, rivaroxaban and apixaban, particularly to patients at high risk of bleeding (see section 4.5).

**4.5 Interaction with other medicinal products and other forms of interaction**

Results of clinical studies indicate that there was a modest but statistically significant ($p \leq 0.05$) increase of circulating theophylline or carbamazepine levels when either of these drugs are administered concomitantly with clarithromycin. As with other macrolide antibiotics the use of clarithromycin in patients concurrently taking drugs metabolized by the cytochrome P-450 system (e.g. Digoxin, Warfarin) may be associated with elevations in serum levels of these other drugs.

Macrolides have been reported to alter the metabolism of Terfenadine resulting in increased levels of Terfenadine which has occasionally been associated with cardiac arrhythmias. In one study in 14 healthy volunteers, the concomitant administration of clarithromycin and Terfenadine resulted in a 2-3 fold increases in the serum level of the acid metabolites of Terfenadine and in prolongation of the QT-interval which did not lead to any clinically detectable effect.

Lomitapide
Concomitant administration of clarithromycin with lomitapide is contraindicated due the potential for markedly increased transaminases (see section 4.3).

**Effects of Other Medicinal Products on Clarithromycin**
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 <clarithromycin/erythromycin> for any patients taking hydroxychloroquine or chloroquine.

**Effect of Clarithromycin on Other Medicinal Products**

Direct acting oral anticoagulants (DOACs)
The DOAC dabigatran is a substrate for the efflux transporter P-gp. Rivaroxaban and apixaban are metabolised via CYP3A4 and are also substrates for P-gp. Caution should be exercised when clarithromycin is co-administered with these agents particularly to patients at high risk of bleeding (see section 4.4).

**4.6 Fertility, Pregnancy, and lactation**

Pregnancy
The safety of clarithromycin for use in pregnancy has not been established. Based on variable results obtained from animal studies and experience in humans, the possibility of adverse effects on embryofetal development cannot be excluded. Some observational studies evaluating exposure to clarithromycin during the first and second trimester have reported an increased risk of miscarriage compared to no antibiotic use or other antibiotic use during the same period. The available epidemiological studies on the risk of major congenital malformations with use of macrolides including clarithromycin during pregnancy provide conflicting results. Therefore, use during pregnancy is not advised without carefully weighing the benefits against risk.

Breastfeeding
Clarithromycin is excreted into human breast milk in small amounts. It has been estimated that an exclusively breastfed infant would receive about 1.7% of the maternal weight-adjusted dose of clarithromycin. The safety of clarithromycin use during breast-feeding of infants has not been established.

Fertility
In the rat, fertility studies have not shown any evidence of harmful effects.

**4.7 Effects on ability to drive and use machines**

There are no data on the effect of clarithromycin on the ability to drive or use machines. The potential for dizziness, vertigo, confusion and disorientation, which may occur with the medication, should be taken into account before patients drive or use machines.

**4.8 Undesirable effects**

The safety profile of pediatric formulation is similar to that of the 250 mg tablet in adult patients. The majority of adverse events reported were of the gastrointestinal system, e.g., diarrhea, vomiting, abdominal pain, dyspepsia, and nausea. Other adverse events included headache, altered taste, and transient elevations of liver enzymes.

Allergic reactions ranging from urticaria and mild skin eruptions to anaphylaxis have occurred with orally administered clarithromycin. There have been reports with oral clarithromycin of transient central nervous system side effects including anxiety dizziness, insomnia, hallucinations, bad dreams and confusion, however, a cause and effect relationship has not been established.

Taste perversion may occur, and glossitis and stomatitis have been reported.

**4.9 Overdose**

Reports indicate that the ingestion of large amounts of clarithromycin can be expected to produce gastrointestinal symptoms. One patient who had a history of bipolar disorder ingested eight grams of clarithromycin and showed altered mental status, paranoid behavior, hypokalemia, and hypoxemia. Allergic reactions accompanying overdosage should be treated by the prompt elimination of unabsorbed drug and supportive measures. As with other macrolides, clarithromycin plasma levels are not expected to be appreciably affected by hemodialysis or peritoneal dialysis.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Abbotic® Granules 125 mg or 250 mg/5 ml (Clarithromycin Pediatric Suspension), is an oral dosage form of clarithromycin for use primarily in children. When reconstituted each 5 ml contains 125 mg or 250 mg clarithromycin with potassium sorbate 0.4% w/w as preservative.

Clarithromycin exerts its antibacterial action by binding to the 50S ribosomal subunits of susceptible bacteria and suppresses protein synthesis.

The in vitro antibacterial spectrum of clarithromycin is as follows:

USUALLY SENSITIVE BACTERIA

Streptococcus viridans
PasteureIla multocida
Streptococcus pyogenes
Mycoplasma pneumoniae
Listeria monocytogenes
Campylobacter jejuni
Helicobacter pylori
Chlamydia trachomatis
Streptococcus pneumoniae
Chlamydia pneumoniae
Mycobacterium avium

Moraxella catarrhalis
Mycobacterium leprae
Bordetella pertussis
Neisseria gonorrhoeae
Borrelia burgdorferi
Propionibacterium acnes
Staphylococcus aureus
Streptococcus agalactiae
Clostridium perfringens
Haemophilus influenzae
Peptococcus niger
Haemophilus parainfluenzae
Bacteroides melaninogenicus
Legionella pneumophila
Mycobacterium kansasii

NON-SENSITIVE BACTERIA
Enterobacteriaceae
Pseudomonas species

The principal metabolite of clarithromycin in man and other primates is a microbiologically-active metabolite, 14-OH-Clarithromycin. This metabolite is as active or 1- to 2-fold less active than the parent compound for most organisms, except for H. influenzae against which it is twice as active. In vitro studies showed that the protein binding of clarithromycin in human plasma averaged about 70 % at concentrations of 0.45-4.5 µg/ml. A decrease in binding to 41 % at 45.0 µg/ml suggested that the binding sites might become saturated, but this only occurred at concentrations far in excess of the therapeutic drug level.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Clarithromycin 125 mg/5 ml Granules for Oral Suspension (Pediatric Suspension)
Clarithromycin 250 mg/5 ml Granules for Oral Suspension (Pediatric Suspension)

Sucrose
Xanthan gum
Silicon dioxide
Potassium sorbate
Citric acid
Maltodextrin
Titanium dioxide
Fruit punch flavor

### 6.2 Special precautions for disposal and other handling

Preparation for Use
An appropriate amount of water should be added to the granules in the bottle and shaken until all of the particles are suspended. Avoid vigorous and/or lengthy shaking. Shake prior to each

subsequent use to ensure resuspension. The concentration of clarithromycin in the reconstituted suspension is either 125 mg/5 ml or 250 mg/5 ml.

Administration

Several devices can be used to dose and administer Clarithromycin Pediatric Suspension.

Conservation

Abbotic granules 125 mg/ 5 ml or 250 mg/ 5 ml:
After reconstitution, store at temperature not exceed 30°C and use within 14 days.

**HOW SUPPLIED**

Abbotic granules 250 mg/ 5 ml: bottle of 50 ml and 70 ml
Reg. No.: DKL0800202238B1
Abbotic granules 125 mg/ 5 ml: bottle of 30 ml and 60 ml
Reg. No.: DKL9400202238A1

Store at temperature not exceed 30°C

**ON MEDICAL PRESCRIPTION ONLY**
**HARUS DENGAN RESEP DOKTER**

Manufactured by:
**PT. Abbott Indonesia**
Jl. Raya Jakarta Bogor Km. 37
Depok 16415, Indonesia

Under license:
**Abbott Laboratories, ILL, USA**

Refer to RDCCDS000046/10 v10
Date of Revision: 12 April 2022
L005/04/22

**INFORMASI UNTUK PASIEN**
**SIRUP KERING ABBOTIC 125mg/5ml & 250mg/5ml**
**(*Clarithromycin*)**

**Baca seluruh isi brosur ini secara seksama sebelum Anda mulai minum obat ini karena brosur ini berisi informasi penting bagi Anda.**
- Simpan brosur ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Obat ini hanya diresepkan untuk Anda. Jangan memberikannya kepada orang lain. Hal ini dapat membahayakan mereka, bahkan jika gejalanya sama dengan Anda.
- Jika Anda mengalami efek samping, sampaikan kepada dokter atau apoteker Anda. Termasuk kemungkinan efek samping yang tidak tercantum di dalam brosur ini. Lihat bagian 4.

**Apa yang ada di dalam brosur ini:**

1. Apa yang dimaksud dengan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dan apa kegunaannya?
2. Apa yang perlu Anda ketahui sebelum Anda minum Sirup Kering Abbotic 125mg/5ml & 250mg/5ml?
3. Bagaimana cara minum Sirup Kering Abbotic 125mg/5ml & 250mg/5ml?
4. Kemungkinan efek samping
5. Bagaimana cara menyimpan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml?
6. Isi kemasan dan informasi lainnya


## 1. Apa yang dimaksud dengan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dan apa kegunaannya?

Setiap satu sendok 5ml Sirup Kering Abbotic 125mg/5ml mengandung 125 mg bahan aktif *clarithromycin*.

Setiap satu sendok 5ml Sirup Kering Abbotic 250mg/5ml mengandung 250 mg bahan aktif *clarithromycin*.

Abbotic termasuk dalam kelompok obat yang disebut antibiotik makrolida (*macrolide antibiotic*). Antibiotik menghentikan pertumbuhan bakteri yang menyebabkan infeksi.

Sirup kering Abbotic digunakan untuk mengobati infeksi seperti:
1. Infeksi pernafasan, seperti bronkitis dan pneumonia
2. Infeksi tenggorokan dan sinus
3. Infeksi kulit dan jaringan
4. Infeksi telinga khususnya radang telinga tengah (otitis media akut).

## 2. Apa yang perlu Anda ketahui sebelum memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml?

**Jangan memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml kepada anak Anda jika mereka;**
- mengetahui bahwa Anda **alergi** terhadap *clarithromycin*, antibiotik makrolida lainnya seperti erythromycin atau azithromycin, atau bahan lainnya di dalam Sirup Kering Abbotic 125mg/5ml & 250mg/5ml.

- sedang mengonsumsi *terfenadine* karena dapat menyebabkan gangguan serius pada irama jantung. Konsultasikan dengan dokter Anda untuk mendapat saran tentang obat-obatan alternatif.
- sedang mengonsumsi obat lain yang diketahui menyebabkan gangguan serius pada irama jantung.
- sedang minum obat yang mengandung *lomitapide.*
- memiliki kadar kalium atau magnesium yang sangat rendah di dalam darah Anda (hipokalemia atau hipomagnesemia).
- sedang mengonsumsi obat jantung (untuk mengatasi aritmia, bradikardia, perpanjangan interval QT, penyakit jantung iskemik, atau gagal jantung kongestif).
- sedang mengonsumsi obat untuk gangguan elektrolit (hipokalemia atau hipomagnesemia).

**Peringatan dan tindakan keselamatan**
Bicarakan dengan dokter atau apoteker Anda sebelum memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml:
- jika anak Anda memiliki masalah jantung (misalnya penyakit jantung, gagal jantung, detak jantung sangat lambat)
- jika anak Anda memiliki masalah hati atau ginjal
- jika anak Anda memiliki, atau rentan terhadap, infeksi jamur (misalnya sariawan)

**Obat-obatan lain dan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml**
Anak Anda tidak boleh diberi Sirup Kering Abbotic 125mg/5ml & 250mg/5ml jika mereka sedang mengonsumsi salah satu obat yang tercantum di bagian "Jangan memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml kepada anak Anda jika mereka" di atas;

Beritahu dokter Anda jika anak Anda sedang mengonsumsi obat-obatan berikut ini karena dosisnya mungkin perlu diubah atau mereka mungkin perlu melakukan tes rutin:
- *digoxin* (untuk masalah jantung)
- *warfarin*, atau antikoagulan lainnya, misalnya, *dabigatran*, *rivaroxaban*, *apixaban* (untuk pengencer darah)
- *carbamazepine* (untuk epilepsi)
- *theophylline* (digunakan pada pasien dengan kesulitan bernapas, misalnya asma)
- *triazolam* atau *midazolam* (obat penenang)
- obat makrolida lainnya, seperti *lincomycin* dan *clindamycin*
- *hydroxychloroquine* atau *chloroquine* (digunakan untuk mengobati kondisi-kondisi termasuk *rheumatoid arthritis*, atau untuk mengobati atau mencegah malaria). Mengonsumsi obat-obatan ini pada saat bersamaan dengan *clarithromycin* dapat meningkatkan peluang Anda mengalami efek samping yang mempengaruhi jantung Anda
- *astemizole*
- *lomitapide*

**Kehamilan dan menyusui**
Keamanan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml pada kehamilan dan menyusui belum diketahui. Karena Sirup Kering Abbotic 125mg/5ml & 250mg/5ml mungkin diberikan kepada anak perempuan usia subur, Anda harus berbicara dengan dokter Anda sebelum memberikan obat ini jika diketahui atau dicurigai sedang hamil.

**Mengemudi dan Mengoperasikan Mesin:**
Sirup Kering Abbotic dapat membuat Anda merasa pusing atau mengantuk. Jika hal ini memengaruhi Anda atau anak Anda, jangan mengemudi, mengoperasikan mesin, atau melakukan hal apapun yang mengharuskan Anda untuk waspada.

**Sirup Kering Abbotic 125mg/5ml & 250mg/5ml mengandung sukrosa**
Obat ini mengandung sukrosa, yakni sejenis gula. Jika anak Anda telah diberitahu bahwa mereka memiliki intoleransi terhadap gula, hubungi dokter Anda sebelum anak Anda minum obat ini.

**3. Bagaimana cara pemberian Sirup Kering Abbotic 125mg/5ml & 250mg/5ml?**
Selalu berikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml persis seperti yang diberitahukan oleh dokter Anda kepada Anda. Tanyakan kepada dokter atau apoteker Anda jika Anda tidak yakin dengan dosis yang tepat untuk anak Anda.

Dosis yang dianjurkan untuk Sirup Kering Abbotic 125mg/5ml & 250mg/5ml diberikan di bawah ini:

**Dosis berdasarkan berat badan**

| **PEDOMAN DOSIS UNTUK PASIEN ANAK<br>Berdasarkan Berat Badan** | | |
|---|---|---|
| **Berat Badan*** | **Dosis dalam Standar Sendok Teh 5 mL<br>diberikan dua kali sehari** | |
| **Kg** | **125 mg/5 mL** | **250 mg/5 mL** |
| 8 - 11 | 0.5 | -- |
| 12 - 19 | 1 | 0.5 |
| 20 - 29 | 1.5 | 0.75 |
| 30 - 40 | 2 | 1 |
| * Anak-anak <8 kg harus diberi dosis berdasarkan per kg (sekitar 7,5 mg/kg b.i.d.) | | |

Dokter terkadang meresepkan dosis yang lebih tinggi atau lebih rendah dari pedoman dosis ini. Sirup Kering Abbotic 125mg/5ml & 250mg/5ml harus diberikan dua kali sehari, sekali di pagi hari dan sekali di sore hari. Dapat diberikan pada waktu makan jika lebih nyaman dan dapat diminum dengan susu.

Anda harus mengocok botol sampai merata sebelum digunakan dan menutupnya rapat-rapat setelah digunakan. Sirup Kering Abbotic 125mg/5ml & 250mg/5ml biasanya diberikan selama 5 sampai 10 hari tergantung pada tingkat keparahan kondisinya.

**Jika Anda memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml lebih banyak dari yang seharusnya**

Jika Anda secara tidak sengaja memberi anak Anda Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dalam satu hari lebih banyak daripada yang diberitahukan oleh dokter kepada Anda, atau jika anak Anda secara tidak sengaja menelan obat tambahan, segera hubungi dokter Anda atau unit gawat darurat rumah sakit terdekat. Overdosis Sirup Kering Abbotic 125mg/5ml & 250mg/5ml kemungkinan dapat menyebabkan muntah dan sakit perut.

**Jika Anda lupa memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml**

Jika Anda lupa memberikan dosis obat kepada anak Anda, berikan satu dosis segera setelah Anda ingat. Jangan memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dalam satu hari lebih banyak dari yang disarankan oleh dokter Anda.

**Jika Anda berhenti memberikan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml**

Jangan berhenti memberikan obat ini meskipun anak Anda sudah merasa sehat. Penting untuk memberikan obat selama yang telah diberitahukan oleh dokter kepada Anda, jika tidak maka masalahnya mungkin akan kembali.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

**4. Kemungkinan Efek Samping**

Seperti halnya semua obat, Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dapat menyebabkan efek samping meskipun tidak semua orang mengalaminya.

Jika anak Anda menderita salah satu dari hal berikut ini selama pengobatan mereka HENTIKAN pemberian obat dan segera hubungi dokter Anda:

- ruam
- reaksi alergi mulai dari urtikaria dan erupsi kulit ringan hingga anafilaksis, Sindrom Stevens-Johnsons telah terjadi dengan klaritromisin yang diberikan secara oral.
- Perubahan warna lidah, infeksi jamur pada mulut, mual, *dyspepsia*, sakit perut, muntah, diare, *stomatitis*, *glossitis*, sakit kepala, perubahan rasa, peningkatan sementara enzim hati, reaksi alergi, gangguan kecemasan, mengantuk, insomnia, halusinasi, mimpi buruk, kebingungan, kehilangan arah.
- elevasi SGOT dan SGPT
- pembengkakan, kemerahan atau gatal pada kulit
- radang lambung dan usus
- vertigo
- gangguan pendengaran
- kembung, sembelit, masuk angin, bersendawa
- mulut kering
- merasa lemah, lelah dan tidak bertenaga

**Pelaporan efek samping**

Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker Anda. Ini mencakup kemungkinan efek samping yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping secara langsung ke: pv.indonesia@abbott.com

Dengan melaporkan efek samping Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

**5. Cara menyimpan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml**

**Jauhkan obat ini dari penglihatan dan jangkauan anak-anak**

Jangan menggunakan obat ini setelah tanggal kedaluwarsanya (exp.) yang tercetak di label.
Simpan pada temperatur yang tidak melebihi 30°C

Sirup Kering Abbotic 125mg/5ml dan 250mg/5ml harus digunakan dalam waktu 14 hari setelah Anda menerima botol dari apoteker.

Jangan membuang obat melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker Anda bagaimana cara membuang obat yang tidak Anda gunakan lagi. Langkah-langkah ini akan membantu melindungi lingkungan.

**6. Isi kemasan dan Informasi lainnya**

**Apa yang terkandung di dalam Sirup Kering Abbotic 125mg/5ml & 250mg/5ml**

Setiap satu sendok 5ml Sirup Kering Abbotic 125mg/5ml mengandung 125 mg bahan aktif *clarithromycin*.

Setiap satu sendok 5ml Sirup Kering Abbotic 250mg/5ml mengandung 250 mg bahan aktif *clarithromycin*.

Bahan lainnya adalah: Sukrosa, Xanthan gum, Silikon dioksida, Kalium sorbat, Asam sitrat Maltodekstrin, Titanium dioksida, Perisa buah.

**Seperti apa penampakan Sirup Kering Abbotic 125mg/5ml & 250mg/5ml dan isi kemasan**
Sirup Kering Abbotic 125mg/5ml adalah butiran berwarna putih hingga putih pucat untuk dilarutkan dengan air (suspensi) dan tersedia dalam kemasan botol 30ml dan 60ml.
Reg. No.: DKL9400202238A1

Sirup Kering Abbotic 250mg/5ml adalah butiran berwarna putih hingga putih pucat untuk dilarutkan dengan air (suspensi) dan tersedia dalam kemasan botol 50ml dan 70ml.
Reg. No.: DKL0800202238B1

HARUS DENGAN RESEP DOKTER

**Diproduksi oleh:**
PT Abbott Indonesia
Jl. Raya Jakarta Bogor Km. 37
Depok, Indonesia

**Atas lisensi dari:**
Abbott Laboratories, ILL, USA