Approved Patient Information Leaflet

Read all of this leaflet carefully before you give this medicine to your child. It gives a summary of the information available on this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions or are not sure about anything, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child personally and you should not share their medicine with other people. It may harm them, even if their symptoms are the same as your child's.

Scheduling status: S4

Proprietary name and dosage form:

Klacid P125 Granules for Reconstitution

Klacid P250 Granules for Reconstitution

Clarithromycin

What Klacid P contains:

Each 5 ml spoonful of **Klacid P125** contains 125 mg clarithromycin (6-O-methyl erythromycin A) as the active ingredient.

Each 5 ml spoonful of **Klacid P250** contains 250 mg clarithromycin (6-O-methyl erythromycin A) as the active ingredient.

Other ingredients include: sucrose, carbopol 974P, povidone K90, hydroxypropyl methylcellulose phthalate, castor oil, silicon dioxide, xanthan gum, fruit punch flavour, potassium sorbate (preservative), citric acid, maltodextrin, titanium dioxide and water.

What Klacid P is used for:

Klacid P is an antibiotic belonging to a group called macrolides. Antibiotics stop the growth of bacteria (which cause infections). Its use is described below.

Klacid P is used to treat infections such as:

1. Throat and sinus infections
2. Chest infections, such as bronchitis and pneumonia
3. Skin and tissue infections
4. Ear infections particularly inflammation of the middle ear (acute otitis media)

Before giving Klacid P to your child:

Do not give Klacid P to your child:

- if you have been told that he or she is allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the medicine.

- Do not give your child ergotamine or dihydroergotamine tablets or let them use ergotamine inhalers for migraine while taking **Klacid P**. Consult your doctor, pharmacist or other health care professional for advice on alternative medicines.
- Do not give your child terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride or pimozide tablets while taking **Klacid P**, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor, pharmacist or other health care professional for advice on alternative medicines.
- Do not take colchicines (usually taken for gout), while receiving **Klacid P**, as this can also cause serious side effects.
- If your child has any liver or kidney problems, speak to your doctor before giving them this medicine.
- Safety and efficacy in infants less than 6 months of age have not been established.

Take special care with Klacid P:

- If your child has any liver or kidney problems, speak to your doctor before giving them this medicine.
- If your child develops severe or prolonged diarrhoea during or after receiving **Klacid P**, tell your doctor immediately.

Giving Klacid P with food and drink:

Klacid P can be given at mealtimes if this is most convenient.

Pregnancy and Breast-feeding:

If the patient is pregnant or breast feeding a baby, they should not take **Klacid P** without consulting your doctor, pharmacist or other health care professional for advice first, as the safety of **Klacid P** in pregnancy and breastfeeding is not known. **Klacid P** is excreted into the breast milk. As **Klacid P** may be given to girls of child-bearing age, you should speak to your doctor before giving this product if pregnancy is known or suspected.

Driving and using machinery: Not applicable

Important information about some of the ingredients of Klacid P: Not applicable

Giving other medicines with Klacid P:

If your child is taking medicines on a regular basis, using **Klacid P** at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice if they are taking any of the following drugs: digoxin (heart drug), warfarin (blood thinner), ergotamine or dihydroergotamine (for migraine), colchicine (for gout), carbamazepine, phenytoin or valproate

(drugs for epilepsy), theophylline (helps breathing), terfenadine or astemizole (for hay fever or allergy), alprazolam, triazolam or midazolam (sedatives), disopyramide or quinidine (heart drugs), simvastatin or lovastatin (for high cholesterol), cisapride or omeprazole (for stomach disorders), cyclosporin (drug taken following an organ transplant), pimozide, rifabutin, efavirenz, nevirapine, rifampicin, rifapentine, fluconazole, itraconazole (for treatment of some infections), ritonavir, atazanavir, saquinavir or zidovudine (for treatment of HIV infection), tacrolimus (for organ transplants), vinblastine (for certain cancers), sildenafil, tadalafil or vardenafil (for erection problems), methylprednisolone (cortisone) or cilostazol (poor circulation) or tolterodine (for bladder problems).

Klacid P does not interact with oral contraceptives.

Instructions on how to use Klacid P:

The usual doses of **Klacid P** are given below:

Dosage based on Body Weight

		Dosage in mls (spoonsful) twice daily	
Weight (kg)	Age (years)	**125 mg/5ml**	**250 mg/5ml**
8 - 11	1-2 *	2,5 ml (0,5)	--
12 - 19	2-4 *	5,0 ml (1)	2,5 ml (0,5)
20 - 29	4-8 *	7,5 ml (1½)	3,75 ml (0,75)
30 - 40	8-12 *	10,0 ml (2)	5,0 ml (1)

* Approximate ages.

Always give **Klacid P** exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure how the dose has been worked out for

your child. Doctors may sometimes prescribe higher or lower doses than these. If this applies to your child then you should discuss it with your doctor or pharmacist. If you have the impression that the effect of **Klacid P** is too strong or too weak, talk to your doctor or pharmacist.

Klacid P should be given twice a day, once in the morning and again in the early evening. It can be given at mealtimes if this is most convenient. You should shake the bottle well before using and close it tightly afterwards. **Klacid P** is usually given for 5 to 10 days.

Do not stop giving this medicine because your child feels better. It is important to give the medicine for as long as the doctor has told you to, otherwise the problem might come back.

If you forget to give Klacid P:

If you forget to give your child a dose of medicine, give this missed dose as soon as you remember and then continue dosing as normal. Do not give more **Klacid P** in one day than your doctor tells you to. If you are concerned about having missed one or more doses of medicine, consult your doctor or pharmacist.

If you give more Klacid P than you should:

If you accidentally give your child more **Klacid P** in one day than your doctor has told you to, or if your child accidentally swallows some extra medicine, seek medical advice urgently - in the event of over dosage, consult your doctor or

pharmacist. If neither is available, contact the nearest hospital or poison control centre. An overdose of **Klacid P** is likely to cause vomiting and stomach pains, and there is a possibility of allergic reactions.

Effects when treatment with Klacid P is stopped: Not applicable

REMEMBER, this medicine is for YOUR child. DO NOT share medicines prescribed for you with any other person. The medicine may harm them, even if their symptoms are the same.

Possible Side-Effects:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Klacid P can sometimes cause stomach problems such as vomiting, stomach pain or diarrhoea. If your child develops severe or prolonged diarrhoea, which may have blood or mucous in it, during or after receiving **Klacid P**, consult your doctor immediately.

Your child may complain of having a funny taste in their mouth, or a change in their sense of taste and smell, while taking **Klacid P**. However, these are only temporary effects and they should not stop taking the medicine because of them. Very rarely, the teeth become discoloured, but in most cases this can be removed by professional dental cleaning. There have also been reports of **Klacid**

P causing the tongue to swell or darken, sore mouth or tongue and ‘thrush’ in the mouth.

If your child has a blood test whilst taking **Klacid P** he/she may be found to have raised liver enzymes. These levels usually return to normal, and your child is unlikely to show any symptoms. However, **Klacid P** can rarely cause jaundice and other liver or gall bladder disorders, which can be severe or even fatal in extremely rare circumstances. If your child is generally unwell or develops yellow skin and/or eyes, or pale stools with dark urine, consult you doctor immediately. Kidney problems, including raised levels of protein normally excreted by the kidneys and rarely kidney failure, have also been reported. Occasionally, a blood test may also show low levels of white blood cells.

Allergic reactions including rashes have been reported with **Klacid P**. In very rare cases, difficulty in breathing, fainting and swelling of the face and throat can occur which may need emergency treatment. Allergic rashes may range in severity from mild, itchy skin eruptions to a rarer, more serious condition called Stevens-Johnson syndrome (which causes severe illness with ulceration of the mouth, lips and skin) or toxic epidermal necrolysis (which causes severe illness and sloughing of the skin).

There have been a few reports of dizziness, loss of bearings, ‘ringing’ in the ears, difficulty in sleeping, depression, hallucinations (seeing things), bad dreams,

confusion, change in sense of reality and panicking. These effects are usually short-lived and soon disappear. Very rarely, fainting due to low blood sugar, and mood and behavioural disorders have been reported, which in severe cases have required hospitalisation. Very rarely, some patients may experience unexpected bruising and their blood may take longer to clot after a cut to the skin. Changes in heart rhythm, inflammation of the pancreas and convulsions have also been reported rarely.

There have been rare reports of loss of sense of smell and of hearing with **Klacid P**, which is a temporary effect and is usually reversible on stopping treatment.

Consult your doctor if your child develops any of these problems or has any other unexpected or unusual symptoms.

Storage and disposal information (how should Klacid P be stored?):

Do not use this medicine after its ‘use-by’ (expiry) date, which is printed on the label. If the suspension is out of date, return it to your pharmacist and, if necessary, get a new prescription from your doctor.

Store at room temperature (below 25°C). Store in the original package. Store all medicines out of reach of children – keep this medicine in a safe place where children cannot reach it.

After reconstitution, **Klacid P** must be used within 14 days of you receiving the bottle from the pharmacist.

If your doctor decides to stop your child's treatment with **Klacid P**, return any remaining suspension to a pharmacist.

Presentation:

Klacid P125 and **Klacid P250** Granules for Reconstitution are supplied in 50 ml and 100 ml bottles.

Identification of the medicine:

Klacid P125 and **Klacid P250:** White to off-white granules, which when reconstituted, become a white to off-white opaque suspension containing white suspended particles, with a fruity aroma.

Registration numbers of the medicines:

Klacid P125: 28/20.1.1/0035

Klacid P250: 29/20.1.1/0190

Name, Business Address and Telephone Number of the Holder of the Certificate of Registration:

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If you have any questions about your child's treatment, which are not answered by this leaflet, ask your doctor or pharmacist.