Proposed Patient Information Leaflet

Read all of this leaflet carefully before you are given this medicine. 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 you personally and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.~~ (N/A)

Scheduling status: S4

Proprietary name and dosage form:

Klacid I.V. Lyophilised Powder for Injection

Clarithromycin

What Klacid I.V. contains:

Klacid I.V. is available in vials containing 500 mg clarithromycin (6-o-methyl erythromycin A) as the active ingredient. When made up with Water for Injection, each milliliter contains (ml) of solution contains 2 mg of clarithromycin.

Other ingredients include: Lactobionic acid, sodium hydroxide and nitrogen.

What Klacid I.V. is used for:

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

Klacid I.V. is used whenever an intravenous (injection into the vein) antibiotic is required to treat severe infections or alternatively, if a patient cannot swallow **KLACID** tablets. It is used to treat infections such as:

1. Chest infections, such as bronchitis and pneumonia
2. Throat and sinus infections
3. Skin and tissue infections

Before receiving Klacid I.V.:

You should not receive Klacid I.V.:

- if you know that you are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the medicine.
- Do not take ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine while receiving **Klacid I.V.** Consult your doctor, pharmacist or other health care professional for advice for advice on alternative medicines.

- Do not take terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride or pimozide tablets while receiving **Klacid I,V.**, as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor, pharmacist or other health care professional for advice for advice on alternative medicines.
- If you have any liver or kidney problems, consult your doctor before receiving **Klacid I.V.**

Take special care with Klacid I.V.:

- If you have any liver or kidney problems, speak to your doctor before receiving **Klacid I.V.**
- If you develop severe or prolonged diarrhoea during or after receiving **Klacid I.V.**, tell your doctor immediately.

Receiving Klacid I.V. with food and drink: (N/A)

Pregnancy and Breast-feeding:

If you are pregnant or breast feeding a baby, you should not receive **Klacid I.V.** without consulting your doctor, pharmacist or other health care professional for advice first, as the safety of **Klacid I.V.** in pregnancy and breastfeeding is not known.

Driving and using machinery: N/A

Important information about some of the ingredients of Klacid I.V.: N/A

Taking other medicines with Klacid I.V.:

If you are taking medicines on a regular basis, receiving **Klacid I.V.** at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice if you 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, zidovudine or rifabutin (for treatment of some infections), ritonavir (for treatment of HIV infection), tacrolimus (for organ transplants), vinblastine (for certain cancers), sildenafil (for erection problems), methylprednisolone (cortisone) or cilostazol (poor circulation).

Klacid I.V. does not interact with oral contraceptives.

Receiving Klacid I.V.:

Klacid I.V. is prepared by dissolving the powder in the vial in sterile water. The solution obtained is added to a larger volume of sterile liquid, and this is then infused (like being given a blood infusion) into one of your veins over at least an hour.

The usual dose of **Klacid I.V.** for adults and children over 12 years of age is 1,0 gram per day, in two doses, for 2 to 5 days and will be changed to oral clarithromycin therapy when appropriate. Your doctor will work out the correct dose for you. Children under 12 years of age should not be given **Klacid I.V**. Your doctor will prescribe another suitable medicine for your child.

~~**If you forget to take Klacid I.V.:**~~ N/A

Accidental overdosage of Klacid I.V.:

If a child accidentally swallows some of this medicine, seek medical advice urgently - in the event of overdosage, consult your doctor or pharmacist. An overdose of **Klacid I.V.** is likely to cause vomiting and stomach pains, and there is a possibility of allergic reactions.

~~**Effects when treatment with Klacid I.V. is stopped**~~**:** (Not applicable)

~~REMEMBER, this medicine is for YOU. DO NOT share medicines prescribed for you with any other person. The medicine may harm them, even if their symptoms are the same.~~ (N/A)

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 I.V. can sometimes cause inflammation, tenderness or pain at the point of injection. Other side-effects include stomach problems such as feeling sick, vomiting, stomach pain, indigestion or diarrhoea. You may also experience numbness or a feeling of 'pins and needles'. Headache, joint pain or muscle pain, or loss of muscle tissue have also been reported. If you develop severe or prolonged diarrhoea, which may have blood or mucous in it, during or after receiving **Klacid I.V.**, consult your doctor immediately.

If you have a blood test while taking **Klacid I.V.** it may show raised liver enzymes. These levels usually return to normal, and it is unlikely that you will show any symptoms. However, **Klacid I.V.** can rarely cause jaundice and other liver or gall bladder disorders, which can be severe or even fatal in extremely rare circumstances. If you feel generally unwell or develop 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 I.V.** 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).

Some people taking **Klacid** tablets notice a funny taste in their mouth, or a change in their sense of taste and smell. However, this has not been reported for **Klacid I.V.** 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 I.V.** causing the tongue to swell or darken, sore mouth or tongue and ‘thrush’ in the mouth.

There have also been some reports of dizziness, loss of bearings, ‘ringing’ in the ears, difficulty in sleeping, 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 hearing loss with **Klacid**, which is a temporary effect and is usually reversible on stopping treatment.

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

Storage and disposal information (how is Klacid I.V. stored?):

The powder in the vial will be stored at room temperature (below 30°C), protected from light, and kept out of reach of children. The reconstituted solution will be stored for either 48 hours at 5°C, or for 24 hours at 25°C.

The carton and vial are printed with the expiry date for the product. It should not be used after this date.

~~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.~~ (N/A)

Presentation:

Klacid I.V. Lyophilised Powder for Injection is supplied in clear glass vials with a capacity of 15 ml.

Identification of the medicine:

Klacid I.V. Lyophilised Powder for Injection: White to off-white caked, lyophilized powder which, on reconstitution with water for injection, produces a clear, colourless solution free of particulate matter.

Registration numbers of the medicine:

Klacid I.V. Lyophilised Powder for Injection: 28/20.1.1/0264

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

Abbott Laboratories SA (Pty) Ltd
Abbott Place
219 Golf Club Terrace
Constantia Kloof
South Africa
1709
Tel: +27 11 858-2000

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