Read all of this leaflet carefully before you take these tablets. 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.

Scheduling status: S4

Proprietary name and dosage form:

Clacee 250 mg Tablets

Clacee 500 mg Tablets

Clarithromycin

What Clacee contains:

Each **Clacee 250 mg** tablet contains 250 mg clarithromycin (6-o-methyl erythromycin A) as the active ingredient.

Each **Clacee 500 mg** tablet contains 500 mg clarithromycin (6-O-methyl erythromycin A) as the active ingredient.

Other ingredients include: Yellow colour E104, croscarmellose sodium, starch *, microcrystalline cellulose, silica gel, povidone, stearic acid, magnesium stearate, talc, hypromellose, propylene glycol, sorbitan monoleate, hydroxypropyl cellulose, titanium dioxide, vanillin and sorbic acid.

(*250 mg tablet only)

What Clacee is used for:

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

Clacee 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
4. *Helicobacter pylori* infection associated with duodenal ulcer.

Before taking Clacee tablets:

Do not take Clacee tablets:

- if you have know that you are allergic to clarithromycin, other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients in the tablets.

- Do not take ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine while taking **Clacee**. 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 taking **Clacee**, 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 taking these tablets.

Take special care with Clacee:

- If you have any liver or kidney problems, speak to your doctor before taking these tablets.
- If you develop severe or prolonged diarrhoea during or after receiving **Clacee**, tell your doctor immediately.

Taking Clacee with food and drink:

Clacee can be taken at mealtimes if this is most convenient, as it may be taken either with or without food.

Pregnancy and Breast-feeding:

If you are pregnant or breast feeding a baby, do not take **Clacee** tablets without consulting your doctor, pharmacist or other health care professional for advice first, as the safety of **Clacee** tablets in pregnancy and breastfeeding is not known.

Driving and using machinery:

Not applicable.

Important information about some of the ingredients of Clacee:

Not applicable.

Taking other medicines with Clacee:

If you are taking medicines on a regular basis, using **Clacee** 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).

Clacee does not interact with oral contraceptives.

Instructions on how to use Clacee:

Take **Clacee** with at least half a glass of water.

For chest infections, throat or sinus infections and skin and soft tissue infections:

The usual dose of **Clacee** for adults and children over 12 years of age is 250 mg twice daily for seven days, eg. one 250 mg tablet in the morning and one in the early evening. Your doctor may increase the dose to 500 mg twice daily in severe infections. These tablets are not suitable for children under 12 years of age as liquid medicines are generally preferable – your doctor will prescribe another suitable medicine for your child.

For the treatment of *Helicobacter pylori* infection associated with duodenal ulcers:

There are a number of effective treatment combinations available to treat *Helicobacter pylori* in which **Clacee** tablets are taken together with one or two other drugs. These combinations include the following:

- One **Clacee 500 mg** tablet taken twice a day together with amoxycillin 1000 mg taken twice a day plus omeprazole 20 mg taken once a day for 7 - 10 days.

The treatment combination you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor, pharmacist or other health care professional for advice.

Do not stop taking **Clacee** tablets because you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

If you forget to take Clacee:

If you forget to take a **Clacee** tablet, take one as soon as you remember and then continue dosing as normal. Do not take more tablets in one day than your doctor has told you to. If you are concerned about having missed one or more doses of medicine, consult your doctor or pharmacist.

If you take more Clacee than you should:

If you accidentally take more **Clacee** tablets in one day than your doctor has told you to, or if a child accidentally swallows some tablets, seek medical advice urgently - in the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. An overdose of **Clacee** tablets is likely to cause vomiting and stomach pains, and there is a possibility of allergic reactions.

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.

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.

Clacee can sometimes cause 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 taking **Clacee** tablets, consult your doctor immediately.

If you have a blood test while taking **Clacee** it may show raised liver enzymes. These levels usually return to normal, and it is unlikely that you will show any symptoms. However, **Clacee** 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 **Clacee**. 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 **Clacee** notice a funny taste in their mouth, or a change in their sense of taste and smell. However, these are only temporary effects and you should not stop taking the tablets 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 **Clacee** 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 **Clacee**, 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 should Clacee be stored?):

Do not use these tablets after their 'use-by' (expiry) date, which is printed on the box and indented on the blister strip. If the tablets are out of date, return them to your pharmacist and, if necessary, get a new prescription from your doctor.

Store at room temperature (below 25°C) in a dry place, protected from light. 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.

If your doctor decides to stop your treatment with **Clacee**, return any remaining tablets to a pharmacist.

Presentation:

Clacee 250 mg Tablets are supplied in packs of 10 tablets.

Clacee 500 mg Tablets are supplied in packs of 10 and 14 tablets.

Identification of the medicine:

Clacee 250 mg Tablets: Yellow, ovaloid tablets.

Clacee 500 mg Tablets: Pale yellow, ovaloid tablets.

Registration numbers of the medicines:

Clacee 250 mg Tablets: X/20.1.1/229

Clacee 500 mg Tablets: 29/20.1.1/0163

Name, Business Address and Telephone Number of the Holder of the

Certificate of Registration:

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