



**Strategy and Sustainability Division
MINISTRY FOR SOCIAL POLICY**

DH CIRCULAR No. 34/2010

DH 739/2010

15th February 2010

Attention all Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Co-amoxiclav and amoxicillin combination

SUMMARY:

Prescriptions for co-amoxiclav should ALWAYS be prescribed at a frequency of three times daily (tds) unless a reduced twice daily dosage is specifically needed for patients with liver and kidney problems.

Prescriptions for two co-amoxiclav 375mg tablets three times daily (tds) should be referred back to the prescribing physician due to the risk of irritant adverse effects such as diarrhoea.

Prescriptions for 625mg co-amoxiclav within the Government Health Services will be AUTOMATICALLY dispensed as a combination of one tablet amoxicillin 250mg together with another co-amoxiclav 375mg tablet.

In June 2009, the European Medicines Agency (EMA) issued a review report of Augmentin® (amoxicillin and clavulanic acid). The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonize prescribing information for co-amoxiclav oral formulations in the European Union, irrespective of brand.

The CHMP agreed that formulations containing amoxicillin and clavulanic acid as a 2:1 ratio (375mg tablets) should not be used in lower respiratory tract infections or in otitis media, because the total daily dose of amoxicillin is not sufficient to achieve effective bacterial kill. Multiples of this dosage should be avoided as they result in patients receiving too much clavulanic acid.

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For such infections, only a 4:1 ratio (625mg tablets; 156mg/5mL suspension) should be prescribed. Furthermore, whereas 625mg tablets and 156mg/5mL suspension used to be prescribed twice daily (bd), the CHMP agreed that such a twice-daily dosage is no longer appropriate as a standard dosage. The recommended dosage is now **three times daily**. The twice daily dosage should only be used for patients in whom a reduced dose is required, such as those with liver and kidney problems. If a dose higher than 625mg is required, only the amoxicillin content should be increased in order to avoid the patient taking too much clavulanic acid.

It is important that doctors specify the correct dose. Prescribers have sometimes incorrectly prescribed 2 tablets of co-amoxiclav 375mg three times daily (tds). This results in the patients being given excess amounts of clavulanic acid, leading to unacceptable irritant adverse effects such as diarrhoea. Such requests should be referred back to the prescribing physician.

A co-amoxiclav 625mg dose can be effectively obtained by a combination of amoxicillin 250mg and co-amoxiclav 375mg. Since co-amoxiclav tablet formulations within the Government Health Services are to date only available in the 375mg format, prescriptions for co-amoxiclav 625mg (three times daily) should be automatically dispensed as a combination, of amoxicillin 250mg PLUS co-amoxiclav 375mg. An example follows:

A prescription stating co-amoxiclav 625mg tds for 7 days will be dispensed as: 30 co-amoxiclav 375mg tablets (to be taken as 1-1-1) together with another 30 amoxicillin 250mg capsules (to be taken at the same time with the co-amoxiclav as 1-1-1) for 7 days

For your guidance.

Dr Natasha Azzopardi Muscat

Director General

References

EMA (European Medicines Agency). Questions and answers on the referral for Augmentin (amoxicillin and clavulanic acid). London: June 2009. EMA/CHMP/97898/2009. EMA/H/A-30/979.