Expert peer review on application for adding Calcium Carbonate (500mg elemental)

1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓  No  (if no, please provide reference and information)

   b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      The risk of pre-eclampsia was reduced by more than half in those with low and high risk of hypertensive disorders. There was reduction in high blood pressure especially among those with high risk.

   c. Please provide any additional relevant information with reference


2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes ✓  No  (if no, please provide reference and information)

   b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      There was significant increase in the risk of developing HELLP (hemolysis, elevated liver enzymes, low platelet count) as noted in two studies among women receiving supplementation.

   C. Please provide any additional relevant information with reference

3. Assessment of cost and availability
   a. Have all relevant data on cost been provided
      Yes ✓  No  (if no, please provide reference and information)

   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

      Calcium Carbonate is more cost effective than Calcium Lactate.

   c. Please provide any additional relevant information with reference
d. Is the product available in several low and middle income countries? Yes

4. Assessment of public health need
a. Please provide the public health need for this product (1-2 sentences)

Hypertensive disorders in pregnancy are common causes of maternal morbidity and mortality worldwide. In the studies done, calcium supplementation has reduced the risk of gestational hypertensive disorders and pre-term deliveries.

b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable

1. WHO recommendation for prevention and treatment of pre-eclampsia and eclampsia.

5. Are there special requirements for use or training needed for safe/effective use?
If yes, please provide details in 1-2 sentences

No

6. Is the proposed product registered by a stringent regulatory authority?

Yes No

7. Any other comments?

No

8. What is your recommendation to the committee (please provide the rationale)

In developing countries low intake of calcium among pregnant women puts them at increased risk of gestational hypertension, pre-eclampsia or poor pregnancy outcomes. As calcium supplementation has been shown to reduce these risks I strongly recommend that it should be included in the EML.