



09 March 2020

Smecta® (dioctahedral smectite or diosmectite): Restriction of treatment of acute diarrhoea to children above 2 years of age and adults, and recommendation against use in pregnant and breastfeeding women

Dear Healthcare Professional,

Emerging Pharma (S) Pte Ltd would like to inform you about changes to the use of Smecta® in children and in pregnant and breastfeeding women:

- Smecta® should be avoided in infants and children under 2 years of age for the treatment of acute diarrhoea, in line with the recommendations to use oral rehydration solutions (ORS) as the priority treatment for this age category.
- Chronic use of Smecta® in children of 2 years and older should be avoided.
- Smecta® is not recommended for use in pregnant and breastfeeding women due to insufficient data.

The patient information leaflet (PIL) for Smecta® has been updated to reflect these changes.

Background

The International Council for Harmonization (ICH) has set forth a guideline “ICH Q3D” on the levels of certain elements in medicines. This guideline seeks to limit exposure to these elements, given the population’s exposure to these elements from a broad range of sources over their life.

Elements such as lead occur naturally in soil and trace amounts of these elements can be found in food and water. Naturally occurring diosmectite – the clay from which Smecta® is produced – is no different and contains trace amounts of lead. Ipsen, the product owner of Smecta®, has always applied strict control criteria on the level of traces of lead.

In compliance with ICH Q3D guideline to the new international norm, Ipsen has conducted an in-depth review of the data related to Smecta® as well as a clinical study which did not find evidence of any actual risk related to lead in adult patients with chronic diarrhoea treated with Smecta® for 5 weeks. Other data developed by Ipsen confirmed the safety profile of Smecta® in the children population with treatment duration of up to 7 days.

As a precautionary measure and taking into consideration the lack of data in pregnancy and breastfeeding, Ipsen has decided to restrict the indication of Smecta® for treatment of acute diarrhoea to children 2 years of age and above and in adults, and to recommend against the use of Smecta® in pregnant and breastfeeding women. This is also in line with the treatment guidelines where ORS should be the first line treatment in this population to avoid dehydration.



Call for reporting

The Health Sciences Authority (HSA) has been notified of this issue. Healthcare professionals are encouraged to report any adverse events suspected to be associated with the use of Smecta® to Emerging Pharma (S) Pte Ltd at 6514 1368

Alternatively, such adverse events may be reported to the Vigilance and Compliance Branch, Health Product Regulation Group, HSA at Tel: 6866 1111, Fax: 6478 9069 or report online at http://www.hsa.gov.sg/ae_online

Company contact point

For more information on the product, please contact Emerging Pharma (S) Pte Ltd at 6514 1368.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Kong Meng Kian".

Kong Meng Kian
Regulatory Affairs Manager
EMERGING PHARMA (S) PTE LTD