

## **Oral Methotrexate – Review on potential fatal overdose due to medication errors**

**Final SmPC and PL wording agreed by the PhVWP in December 2011**

*Doc.Ref.: CMDh/PhVWP/043/2012  
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### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### SmPC Section 4.2:

- This medicine should be taken once a week.
- The prescriber may specify the day of intake on the prescription.

#### SmPC Section 4.4:

- The prescriber may specify the day of intake on the prescription.
- Patients should be aware of importance of adhering to the once weekly intakes.

#### SmPC Section 4.9:

- Cases of overdose, sometimes fatal, due to erroneous daily intake instead of weekly intake of oral methotrexate have been reported. In these cases, symptoms that have been commonly reported are haematological and gastrointestinal reactions.

### **PACKAGE LEAFLET**

- Take *<product>* once a week.

#### Packaging and container's label/cap:

- **Take the prescribed dose once a week** for products with an indication in rheumatology and/or dermatology only.