

# **Class effect of Gonadotropin-releasing hormone agonists (buserelin, goserelin, histrelin, leuprorelin, nafarelin, triptorelin) on depression**

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

*Doc.Ref.: CMDh/PhVWP/049/2012  
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## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **4.4. Special warnings and precautions for use**

There is an increased risk of incident depression (which may be severe) in patients undergoing treatment with GnRH agonists, such as [Active substance]. Patients should be informed accordingly and treated as appropriate if symptoms occur.

### **4.8. Undesirable effects**

Psychiatric disorders: Mood changes, depression  
Frequency: Long term use: Common  
Short term use: Uncommon \*

*\*: a higher frequency may be appropriate for specific products and indications based on their own clinical trial data.*

## **PACKAGE LEAFLET**

### **2. Before you take [Medicinal Product]**

#### **Take special care with [Medicinal Product]**

There have been reports of depression in patients taking [Medicinal Product] which may be severe. If you are taking [Medicinal Product] and develop depressed mood, inform your doctor.

### **4. Possible side effects**

Frequency: Long term use: Common  
Short term use: Uncommon\*  
Mood changes, depression

*\*: a higher frequency may be appropriate for specific products and indications based on their own clinical trial data.*