



# DRUG ALERT

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy Level**

Date: 27 February 2020

EL (20)A/12

Our Ref: MDR 188-01/20

Dear Healthcare Professional,

**G.L. Pharma GmbH**

**Oxylan 10 mg prolonged-release tablets**

**PL 21597/0062**

Batch Number	Expiry Date	Pack Size	First Distributed
9F115A	05/2024	56 tablets	16.01.2020
9F116A	05/2024	56 tablets	16.01.2020

**Oxylan 20 mg prolonged-release tablets**

**PL 21597/0063**

Batch Number	Expiry Date	Pack Size	First Distributed
9J114A	08/2024	56 tablets	16.01.2020

**Oxylan 40 mg prolonged-release tablets**

**PL 21597/0064**

Batch Number	Expiry Date	Pack Size	First Distributed
9F119A	05/2024	56 tablets	16.01.2020

**Oxylan 80 mg prolonged-release tablets**

**PL 21597/0065**

Batch Number	Expiry Date	Pack Size	First Distributed
9F120A	05/2024	56 tablets	16.01.2020

Active Pharmaceutical Ingredient: oxycodone hydrochloride



### **Brief description of the problem**

G.L. Pharma GmbH has informed us that the Patient Information Leaflet (PIL) within the packs for the above batches is missing important safety relevant text changes. The changes to the PIL include the addition of the following information:

- Warnings and precautions: If you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease
- Other medicines and Oxylan: The risk of side effects increases, if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Possible side effects, Frequency unknown: Long term use of Oxylan during pregnancy may cause life-threatening withdrawal symptoms in the new-born. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

It is important that any patients are provided with information on warnings, precautions and using other medicines whilst taking Oxylan. Additionally, patients who notice the symptoms/side effects should seek immediate medical advice.

### **Advice for healthcare professionals**

When dispensing this product, please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, ensure that patients are aware of any missing information.

The current PILs includes the special warning and precautions and should be issued when this product is dispensed. Click [here](#) for Oxylan PR Tablet PILs available from the [electronic medicines compendium](#) (emc).

### **Further Information**

For more information or medical information queries, please contact: GL Pharma GmbH on +43 3136 82577 or [office@gl-pharma.at](mailto:office@gl-pharma.at).

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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